Building a global cluster of advanced pharmaceutical manufacturing and R&D in Richmond/Petersburg

VCU College of Engineering

Final Report to GO Virginia under

Enhanced Capacity Building Grant Contract 20-GOVA-04A

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EXECUTIVE SUMMARY

Purpose of the Enhanced Capacity Grant

At the direction of Dean Barbara Boyan, the VCU College of Engineering sought and received a GO Virginia Enhanced Capacity grant to conduct a strategic analysis and prepare a plan for harnessing the breakthrough technologies developed at VCU's Medicines for All Institute (M4ALL) to develop a world class advanced pharmaceutical manufacturing cluster that can drive job growth and economic development in the Richmond-Petersburg region. The emerging cluster's focus is development and use of advanced manufacturing platforms, including continuous processing, for approved, in-market, small-molecule active pharmaceutical ingredients. This focus is narrow enough to reflect the region's competitive advantages, yet broad enough to support remarkable development and growth.

Method

VCU convened a wide range of stakeholders and leaders in relevant business, local, regional and state economic development organizations, and higher education to examine the potential of the cluster, to identify key determinants of success, to address major obstacles to its development, and to make action-oriented recommendations that would help the cluster fulfill its great promise. Work groups formed in the process addressed the following key issues: infrastructure, workforce, communications/branding, and a set of leadership issues (organization/coordination of the cluster, government relations and inter-university and university-industry collaborations).

Key Work Group Findings

Infrastructure

The work group noted that the collaboration led by Richmond-based startup Phlow Corp. with M4ALL, Petersburg-based AMPAC Fine Chemicals and Civica Rx to lead a multiyear effort to create a supply and national stockpile of active pharmaceutical ingredients for essential medicines and to create new continuous processing manufacturing capability gives the cluster a competitive advantage and genuine jumpstart. The work group noted that continued attention to utility issues and site readiness in the manufacturing footprint and expanding lab and pilot space throughout the region are essential to the cluster's success, as well as the importance of exploring the potential for developing a signature pilot and scale up "development park".

Workforce

The work group noted that workforce issues are increasingly a key determinant of economic development success and site decisions of businesses considering relocation or expansion. The advanced pharmaceutical manufacturing cluster can take advantage of the pioneering undergraduate and advanced degree programs at the VCU College of Engineering, and science and engineering programs at Virginia State University and at other universities around the Commonwealth. In addition, the unique nature of the venture and its societal implications can attract advanced degree holders nationally and internationally. Programs led by the Virginia Economic Development Partnership, the Community College Workforce Alliance, and Commonwealth Center for Advanced Manufacturing position the region to meet manufacturing production needs. At the same time, the national and regional challenge in recruiting and retaining an experienced and highly skilled manufacturing workforce remains a challenge. The cluster holds great promise to produce a wide array of high paying jobs across the region.

Communications/Branding

The work group noted that the emergence of this advanced pharmaceutical manufacturing cluster is an extraordinary story because it uniquely addresses a confluence of urgent national interests such as the reshoring of U.S. manufacturing, and critical unmet social needs such as assuring a reliable, safe and affordable supply of essential medicines to hospitals and patients in the U.S. and around the world. The work group identified a set of “internal” audiences in the region and the state from whom the cluster will need participation and support, including its businesses, innovators and policy leaders. The work group also addressed the importance of collaboration among regional and state economic development agencies in marketing and recruitment efforts directed toward companies and talent that can gain from and strengthen the cluster in R&D, manufacturing and completing the supply chain the new industry will require.

Leadership

The leadership work group addressed the future organization and coordination of the cluster, government relations needs, and inter-university and university-industry collaborations. The work group noted that studies of cluster development initiatives point to the difficulty of sustaining early momentum and emphasize the imperative of establishing a coordinating entity dedicated to its formation and buildout. It noted the unique regional footprint of the emerging cluster, spanning

Richmond to Petersburg. The leadership work group also identified immediate government relations opportunities because of the federal government's current interest in making investments in infrastructure, reshoring manufacturing, securing the nation's supply of medicine and other interests served by the cluster. The work group detailed how VCU can become a model for university-industry collaboration and the potential for VCU partnering with VSU, local community colleges and colleges/universities across the Commonwealth.

Recommendations

The report contains 16 major recommendations across 8 categories. The report highlights the importance of establishing an Advanced Pharmaceutical Manufacturing Council with broad stakeholder representation as an action group that can implement both the short-term and longer-term initiatives required for the buildout of the cluster.

Specific recommendations address the issues and challenges that the individual work groups identified. These include the call to develop a process for addressing lab space needs across the region; addressing workforce and talent needs by coordinating with the best-in-class programs offered by VEDP, community colleges, and regional organizations; and a communications campaign with set objectives. In addition, the recommendations provide guidance for building out the ecosystem and supply chain for an advanced pharmaceutical manufacturing cluster and pursuing federal support for the transformational opportunities.

As a whole the recommendations convey a tone of urgency and importance, reflecting the momentum of impressive recent accomplishments and the unusual confluence of important and unifying goals and interests which this emerging cluster brings to the region. Continued partnership with GO Virginia will be vital in sustaining the enthusiasm and momentum that has been built by this planning process and realizing this enormous opportunity.

FINAL REPORT

The vision is deceptively simple. But the implications are powerful and far reaching.

Reduce the cost of manufacturing pharmaceuticals by employing novel chemical and engineering innovations to intensify the production process. Use the streamlined processes to develop essential, high quality generic medicines more quickly and less expensively, with significantly lower environmental impact. Establish companies in the Richmond-Petersburg region that will become national and global leaders in developing these processes and manufacturing these medicines, reshoring U.S. pharmaceutical manufacturing, and replenishing and securing the nation's supply of essential drugs. Build upon the success of these companies to create the first cluster of the new industry in Richmond-Petersburg that will create thousands of high paying jobs, become a magnet for talent and investment in the region, and provide it with a globally recognized industry identity.

This is the vision at the heart of the Enhanced Capacity Building Grant that that the Medicines for All (M4ALL) initiative at the VCU College of Engineering received from GO Virginia. The promise is grounded in three crucial insights.

The economic incentives in the pharmaceutical industry have disincentivized innovation and efficiency in manufacturing.

The cost structure of medicines is unusual: innovation and efficiency in the manufacturing process are simply not prioritized in either the development of a new drug or in the production of generics

Consider the development of a new drug. Companies that focus on drug development incur enormous research and development costs. The process of discovery, optimization, pre-clinical trials, clinical trials, FDA review and approval, and sales/marketing is time consuming, multifaceted, and expensive. The cost of Active Pharmaceutical Ingredients (APIs) makes up only between 5% to 10% of the total cost of a new patented drug product. Thus, there is little incentive to make efficiencies and improvements in API manufacturing processes. Before clinical trials start, the API process is locked down and companies focus on getting the drug to market as quickly as possible before the patent runs out.

When an innovator drug reaches the end of its patent life, FDA receives abbreviated new drug applications (ANDA) from other drug companies for permission to make and market a generic version of

the drug. Their measure of success is to prove equivalency to the original drug. Again, time is of the essence to bring the first generic on the market. Thus, generic companies are disincentivized from making changes to the process for fear that FDA approval would be delayed or denied. It is better to stick as closely as possible to how the drug was originally made.

The result? A process developed 20 years ago to synthesize a complex molecule with no incentive to reduce costs is perpetuated beyond the entire branded life of the drug and its generic life cycle as well. This often carries on for decades for as long as the generic is made and sold.

Remarkably, this occurs even though in generic manufacturing, the cost of active pharmaceutical ingredients constitutes 50% to 70% of the overall manufacturing expense. To the extent that cost reduction is the focus of generic drug production, the emphasis has been placed on labor costs and other savings associated with outsourcing and moving manufacturing overseas. A very large proportion of our medicines are sourced overseas. But offshoring has brought its own set of problems: repeated shortages of essential drugs; overreliance on political adversaries; and quality issues that can impact therapeutic outcomes.

The combination of novel chemistry with cutting edge engineering techniques makes it possible to manufacture small molecule drugs more efficiently and less expensively than ever before.

The VCU Medicines for All initiative, (M4All) under the leadership of Dr. Frank Gupton, recognized that the pharmaceutical industry was lagging other industries in the application of leading-edge science to its manufacturing processes. M4All focuses on “small molecule” medicines. These comprise all generic drugs, all branded generic drugs, and approximately 2 out 3 drugs that the FDA currently approves.

In small molecule medicines, the API is constructed step-by-step with synthetic chemistry. By applying “process intensification” to the construction of active pharmaceutical ingredients, M4ALL synthesizes molecules in a manner that results in fewer operations, higher yields, less impurities, less waste, less time, and less expense. It does so at the intersection of chemistry and chemical engineering, drawing upon new scientific discoveries, innovative equipment, waste minimization and catalysis. M4ALL has had great success in creating more efficient and more effective processes in manufacturing drugs critical to global health issues such as HIV/AIDS. For example, after M4All’s reinvented chemistry for the HIV/AIDS drug nevirapine was employed in global commercial production the global price was reduced by 15%.

The process intensification for drug manufacturing at M4ALL has an additional benefit. The elegance of the chemistry enables the use of an alternative advanced manufacturing platform. Continuous processing, the emerging platform, offers significant advantages over the traditional method of batch processing in time, cost, environmental impact, supply chain resiliency and transparency for the FDA and other regulatory bodies. While continuous processing is relatively mature in chemical manufacturing, it is in its infancy in the sophisticated and highly regulated field of pharmaceutical manufacturing. The research conducted at VCU will be vital to the advancement of the continuous flow platform and helps ground the industry cluster in the Richmond-Petersburg region.

The process intensification for small molecule pharmaceuticals developed through VCU's Medicines for All initiative is catalyzing a transformative high-wage, high growth industry cluster in the Richmond-Petersburg region

Drug discovery and development is a famously, indeed infamously, risky business. It offers enormous rewards for companies that succeed in developing an efficacious therapeutic for a disease that is prevalent in the general population. But drug discovery and development are also accompanied by extraordinary risk. The drug might not result in the intended therapeutic outcome; side effects could prevent regulatory approval; or a competitor might develop a more effective therapeutic.

M4ALL is not attempting to enter this part of the pharmaceutical industry. Its work is at the other end of the risk scale. *The technology is not focused on discovering and developing new drug therapies. Instead, M4ALL focuses on improving the manufacture of already approved and widely used drugs, whose safety, clinical efficacy, and market adoption is well established.*

M4ALL is filling a crucial gap in pharmaceutical manufacturing. There is growing recognition of the practical implications of its innovative science by health care philanthropies, federal agencies, and private sector companies.

- Dr. Gupton and the College of Engineering have received multiple grants and contracts to apply its process intensification technology to drugs that treat the world's major infectious diseases such as HIV/AIDS, malaria, tuberculosis and, recently, COVID-19.
- In collaboration with MIT, researchers at VCU have been funded by the Defense Advanced Research Projects Agency to create a technology that will supply needed battlefield medicines on demand and on site.

- M4All also is working in a long-term collaboration with the U.S. Agency for International Development (USAID) to create highly automated, self-contained manufacturing facilities for third world countries to own and use, so they can independently supply their own (or their region's) essential medicines, and reduce dependence on the global generic drug market, with its uncertainties and chronic issues of quality and supply chain security.

The implications of M4ALL for the economy in the Richmond-Petersburg region have become evident in the past few years by a striking series of developments. In 2020, the federal government launched a major initiative to address the problems associated with the outsourcing of pharmaceutical manufacturing to secure the nation's supply of essential medicines. The U.S. Department of Health and Human Services announced an historic effort to secure the supply of essential medicines in the U.S. The U.S. Biomedical Advanced Research and Development Authority (BARDA) awarded a contract to Richmond based Phlow Corp. to lead a multiyear effort with its partners to: (i) create and supply a national Strategic API Reserve (SAPIR) for essential medicines at risk of shortage, including medicines required for response to the global pandemic; (ii) create the capability to manufacture API using innovative continuous process advanced manufacturing technologies; (iii) provide a direct supply of essential medicines at risk of shortage to the nation's hospitals; and (iv) ultimately, manufacture essential medications end-to-end, from key starting materials (KSMs) to finished formulations with advanced pharmaceutical manufacturing methods. The contract included a four-year base award of $354 million and $458 million more in potential options long term for a total value of $812 million. To accomplish the work of the contract, AMPAC Fine Chemicals, a leading U.S.-based custom manufacturer of API, drug substances and registered intermediaries, has launched a major expansion of its manufacturing facilities in Petersburg. Phlow has initiated planning and construction of scale up and manufacturing facilities adjacent to AMPAC Fine Chemicals. In collaboration, Phlow and AMPAC Fine Chemicals will produce API used in the manufacture of essential medicines, incorporating M4ALL breakthrough chemistry and technologies. Moreover, Civica Rx is building a manufacturing facility adjacent to AMPAC Fine Chemicals and Phlow where it will use API manufactured on site by Phlow and AMPAC Fine Chemicals to produce finished formulations of essential medicines at risk of shortage and distribute them directly to the nation's major hospitals systems. Civica Rx is a nonprofit consortium formed by the nation's leading hospitals to great acclaim and with an extraordinary mission: create a direct and secure supply of essential medicines at risk of shortage for the nation's hospital using any feasible means. To this point Civica Rx has used innovative purchasing arrangements with an array of

suppliers and manufacturers. In Petersburg for the first time Civica Rx will manufacture by itself and supply directly to its member hospitals medicines which are essential for them to serve their patients. Taken together, this will be the nation's most advanced manufacturing complex dedicated to the manufacture of API for essential medicines and incorporating continuous flow process advanced manufacturing and it will feature one of nation's most striking structural innovations in the supply chain of essential medicines.

The foundation for an advanced pharmaceutical manufacturing cluster in Richmond-Petersburg is strong. The combination of innovative university-based science, its validation by leading national and global health care organizations, the unique opportunity posed by the practical shortcomings of outsourcing the supply chain for essential medicines, and the formation of companies in the area to address the challenge is extraordinarily promising. But it will not grow and reach its full potential without a genuine regional and statewide effort to develop further collaboration and to address the real challenges that could inhibit the fulfillment of its promise.

THE 6 TRAITS OF HIGHLY SUCCESSFUL CLUSTERS

Supporting cluster development has been a founding principle of the GO Virginia initiative. But actual cluster specialization (and re-specialization) is a significant challenge for most regions, not only in the Commonwealth but across the country. Recent studies have indicated that very few regions have the resources and the capacities to create and maintain genuine clusters and successfully readapt when these clusters become outdated or competitively disadvantaged. Regions can take steps to be more successful by enhancing their workforce and capitalize on locational advantages but constructing a nationally and globally competitive industry is a heavy lift. Most regional economic development efforts are characterized by "episodic success but systematic failure." In thinking about the Richmond-Petersburg region, the potential for developing a true advanced pharmaceutical manufacturing cluster is an opportunity that emerges once in a generation.

The Brookings Institution has focused more attention on clusters and on the factors that support metropolitan growth than perhaps any other institution in the country over the past decade. It has produced a series of reports describing best practices in regional economic development and the

principal obstacles to success. Adapting a phrase from Stephen Covey, the Brookings studies have identified 6 traits of highly successful clusters.

- *University-fueled, industry driven, and government funded.* Universities provide innovation and talent, private sector firms work collaboratively to enhance the cluster, and governments at every level make early investments.
- *Placing a collective big bet on a unique opportunity.* The most successful initiatives are in regions that are willing to place strategic bets in distinct cluster opportunities.
- *Championed by passionate, leaders and dedicated organizations*. Individual leaders have proven invaluable in championing successful cluster initiatives. They are thought leaders who have recognized a unique opportunity, have crafted a compelling narrative, and are willing to dedicate the time to launch and sustain a bold cluster initiative. Successful clusters develop strong collaborative organizations to implement the founding vision over a sustained period.
- *Smart Civics.* Lack of attention to the civic nature of transformative change explain why so many economic development plans fail. "As Nobel Laureate Michael Spence noted, 'the economics of economic growth is only part of the story. Sustaining growth has more to do with leadership, governance, institutions..., and the interaction of these processes and institutions with economic outcomes."
- *Focus on establishing a robust ecosystem, not just quick job gains*. Cluster initiatives must focus on generating a robust ecosystem that produces the innovation, talent and economic opportunities that will enable the cluster to thrive, and not simply on job growth.
- *Anchored by a physical center.* Successful cluster initiatives often create a physical center that provides a space to facilitate knowledge spillover between firms, academic researchers, and related enterprises. While companies may be scattered throughout the region, these centers tie them together.

The planning process for the Enhanced Capacity Grant was singularly focused on the organization, the ecosystem, and the infrastructure that are required to fulfill the promise of creating a genuine pharmaceutical cluster in Richmond-Petersburg.

PLANNING FOR THE EMERGING CLUSTER

The College of Engineering brought together a wide range of relevant stakeholders in the Richmond-Petersburg area to assist in developing a strategic plan for the development of the cluster. Scientific and

operational leaders at VCU and the region's pharmaceutical manufacturing firms were centrally involved. Dr. Gupton, William DuBay Vice President of Research and Development at AMPAC Fine Chemicals, and Eric Edwards, Co-founder and CEO of Phlow all took leadership roles and devoted all the time that was required. The leadership of the Greater Richmond and Crater District regional economic development and entrepreneurial innovation organizations volunteered to lead critical elements of the planning process. Community college leaders and other organizations that focus on workforce development such as the Community College Workforce Alliance, the Commonwealth Center for Advanced Manufacturing and the Commonwealth Center for Advanced Logistics Systems addressed the wide spectrum of workforce needs- from jobs that require a Ph.D. to those that call for special training but not a 4-year degree. The Commonwealth's principal agency for promoting economic development, the Virginia Economic Development Partnership, has validated the region's belief in the potential development of the cluster and lent its considerable expertise to the project. And a smaller leadership group examined government relations issues at the state and federal level that could impact the ultimate success of the project. It is not overstated to say that the grant fostered collaboration between organizations and leaders in the Richmond part of the region with those in the Petersburg area in unprecedented ways.

The planning process was designed from the start with multiple objectives. The goals were to: (i) inform, equip, engage, and energize stakeholders; (ii) provide timely incisive actionable strategic analysis and recommendations to the College of Engineering, the region and state in a final report; (iii) form networks of people and organizations who will work together for these common goals now and in years to come. Work groups were assembled and focused on foundational issues in cluster development – workforce, infrastructure, communications, and leadership. They conducted research and produced reports with specific recommendations. Several meetings brought all the stakeholders and work groups together to provide interim updates, to brainstorm deliverables and potential recommendations. A briefing was also conducted for a larger audience of Virginia business, research and innovation leaders to acquaint them with potential opportunities related to the supply chain and talent development.

The work groups focused on 4 pillars of cluster development:

- Infrastructure and Cluster Development: What are the key physical issues that impact the success of the cluster? What are the strengths and gaps in the supply chain, and how can it be strengthened? What are the immediate challenges that need to be addressed? What should be

the long-term vision that ties the cluster together, helps establish priorities and unleashes robust development and growth?

- Workforce: How well is the region positioned to meet the workforce demands of the cluster? What are the specific needs that need to be addressed for core cluster companies now, and in building a pipeline for the long-term? How can workforce institutions be best engaged in addressing these needs?
- Communications: How can we best describe this enormous opportunity and tell the story to the many communities in our region, and to the researchers and companies around the world who can play a part? How should the cluster be branded and talked about, both internally and externally? How can we assist local and state economic development agencies in developing the region's reputation and recruiting success for advanced pharmaceutical manufacturing?
- Leadership: How can we the people of this region organize ourselves so that we in fact act like a region and a cluster, and provide leadership, coordination and smart support to efforts which will give the cluster the best chance of success? How should the cluster capitalize on its momentum and its place at the intersection of so many vital national and social interests of the day, to obtain strategic scale support from the many and varied federal funding sources?

A summary of the key findings in each work group follows.

INFRASTRUCTURE

The 2020 BARDA initiative which sparked the development of a complex of advanced pharmaceutical manufacturing facilities in Petersburg by Phlow, AMPAC Fine Chemicals and Civica Rx is providing a powerful jumpstart for the region's advanced pharmaceutical manufacturing industry. At the same time, the infrastructure task force identified three distinct infrastructure challenges that will be a determinant of the cluster's ultimate success.

Business Ready Sites and Utility Services

The statewide Go Virginia Board has identified site development as one of its key priorities. The Virginia Economic Development Partnership (VEDP) has noted that the relative lack of business-ready sites has harmed the Commonwealth's competitive position in competing with other states, especially those in the South. Of the nine GO Virginia regions in the Commonwealth, Region 4, which encompasses Richmond-Petersburg, has the largest number of developable sites. Grow Capital Jobs, the support organization for the Region 4 GO Virginia Council, has actively promoted site development projects. It

approved and received state board funding for upgrading the MaMAC mega site in Greensville-Emporia and is currently working to obtain state approval for a project that would upgrade multiple sites in the Richmond-Petersburg area, including a number very near the AMPAC Fine Chemicals-Phlow-Civica Rx complex. Other suitable sites throughout the region were identified.

Firms considering relocating to the region will expect that all utility services necessary for their processes are in place and fully adequate. In the Petersburg area, several localities have faced challenges in upgrading their water and sewage treatment capacities. Communities that are fiscally stressed have found it difficult to make the large but necessary investments in utility enhancements to upgrade sites to business-ready and have not been able to easily access external sources of funding. This was an obstacle that had to be surmounted in recruiting Civica Rx to locate the facility for producing injectables next to Phlow. In this instance, VEDP was able to coordinate a successful solution to the challenge with the close cooperation of the City, the region, the private companies involved and other state agencies and the General Assembly, combining local resources with state economic development grants to provide the necessary funding and assurances that water and sewage treatment issues were removed as an obstacle. Given the prospect that the cluster will continue to grow in adjacent physical locations, continuing to find proactive solutions to utility infrastructure upgrades will be important.

Wet Lab and Pilot Facilities

To date, VEDP and Go Virginia supported site development projects have focused primarily on business-ready upgrades for manufacturing and logistics facilities. The Grow Capital Jobs Growth and Diversification Plan also noted, however, that a shortage of wet lab space is an obstacle to the expansion of the life sciences cluster, not only for companies seeking to relocate, but also to home grown firms seeking to expand.

This challenge has assumed new urgency with the increased activity level in growing an advanced pharmaceutical manufacturing cluster. M4ALL reports continually receiving interest from firms to locate research, development, scale up and manufacturing activities nearby. Phlow, too, reports frequent inquiries from firms looking to locate nearby. As part of this planning process Activation Capital / Virginia Bio+Tech Research Park undertook a first of its kind study on the demand and supply for laboratory space in the Richmond-Petersburg region. Activation Capital engaged the national consulting firm HR&A Advisors. The study confronted the near absence of data on lab space supply and demand in the region, and the lack of systems for collecting, analyzing and sharing that data anywhere in the region

or state. The lack of standard or systematic data sources obviously confounded the research. Other sources of information including interviews with regional stakeholders nonetheless confirmed the dearth of available space, and this at a time when the market for developing commercial laboratory space is red hot nationwide. Interviews confirmed that the lack of lab space has knocked the region out of the running for so many projects that our economic development agencies don't even keep count. And today it's delaying and deterring firms interested in locating in the region to join the emerging cluster. The study also exposed the lack of a shared understanding and systematic approach to alternate feasible models and best practices - from spec space to conversions, which other regions have used to successfully address this need in part. An immediate solution is needed to take full advantage of the momentum of the cluster in this growth phase. In the intermediate term a solution is needed to systematically support the market in financing and developing ample and appropriate lab and related space to meet the demand. Within the work group a team of experts from the public sector and private firms formed. They will use the study results, description of alternative programmatic options and operational models based on best practices and recommendations to create a demand analysis system as a springboard for an action plan to put in place new, effective and systematic ways this region can understand and satisfy the demand in a timely manner. The action plan should be one that GO Virginia and other private and public partners would be eager to support.

A Pilot and Scale up Park for Pharmaceutical Manufacturing

The Brookings study of highly successful clusters indicated that these "initiatives often create a physical center that provides a space to facilitate knowledge spillover between firms, academic researchers and related enterprises. While companies may be scattered throughout the region, these centers tie them together. " The emerging cluster has two well defined "centers", or concentrations, spanning 30 miles – the Petersburg manufacturing complex and the Virginia Bio+Tech Research Park Research Park, home to M4ALL and related university labs and private companies who want to locate beside these labs. Research parks like this, often located adjacent to universities with advanced degree programs, have become a common feature of regions and states seeking to energize bioscience activities, and provide many benefits. Developed and developable space at the Park, however, is limited, and for many firms its location in the heart of downtown Richmond is not necessary nor advantageous.

One key component of the cluster that will be required for success and does not exist here – or anywhere for that matter, is a complex of space, equipment and people where the essential work of pilot and scale up can take place. M4ALL creates its innovative chemistry and chemical engineering at

lab bench scale. There is a great amount of hard work, invention and art in growing the processes, equipment and instrumentation to commercial scale. For continuous processing advanced manufacturing of every medicine, this transition has to be made. The faster, better, cheaper it is done, the faster the technology, the industry and the cluster can grow. Such a critical mass of specialized space, equipment and expert organizations and talent would be unprecedented. Such a venue would draw national attention and provide a fitting home to a National Center of Excellence in continuous process pharmaceutical R&D and manufacturing, which is under consideration now in the U.S. Congress. The work in this pilot and scale up park would be:

- *Scaling up bench processes invented at M4ALL to pilot/kilo scale to further qualify them to be implemented at commercial scale.* For work on international public efforts to date, scale up has been contracted out to third parties. Frequently, the third party's lack of familiarity with the chemistry and innovative processes has led to less-than-optimal results, costing additional time and resources. M4All would use the Park to expand its capabilities to do this scale up work itself for all customers.

- *Further developing and extending continuous process technology and production systems.* Much more work is needed to develop equipment and instrumentation to enable efficient quality continuous processing at commercial scale even in those stages of the production process where continuous is now used. Improvements, adaptations and innovations in pumps, reactors and filtration are leading examples. This development work is closely tied to bench chemistry and lab processes but is rooted in and fully developed at the pilot and commercial scale. Many different products and many different companies will be involved. Moreover, several of the later stages of API manufacture today are out of reach of today's continuous processing technology, rather the output of a limited number of continuing process manufacturing steps is then diverted to batch processing for completion. Lead examples of later stages where breakthroughs and development are needed are crystallization, separation and drying. Developing and scaling processes and equipment for doing so under continuous process will enable production of API completely by continuous processes and unleash the full potential of the technology and industry.

- *Providing experiential learning and workforce training.* The work of the firms and organizations at the Park would offer plentiful training and work experience to students in the art of

commercial implementation and workforce training in a cGMP environment. The involvement of graduate students specializing in chemistry and engineering from VCU, VSU or other Virginia schools would be welcomed and beneficial to all. So would the involvement of students in specialized certificate courses focused on the advanced pharmaceutical manufacturing cluster and close relationships with the cluster's manufacturers.

WORKFORCE

The work group was formed to describe the existing state of the workforce to support pharmaceutical advanced manufacturing, guide the decisions of the study on how to meet short- and long-term needs, and form a working network of informed experts from key stakeholders who are equipped, enthused and ready to work together to support cluster growth in the months and years ahead. The work group's twelve members come from private industry, university, community college and economic development. In these positions, many of them have been working daily for months learning and building workforce solutions for the core cluster firms.

The focus of the work group was not on abstract future needs, but on the practical issues of assuring a sufficient and talented workforce for core cluster companies now here - AMPAC Fine Chemicals, Phlow and Civica Rx, and to some extent M4All. By focusing on and solving these needs, the region will establish strong roots for the cluster. Equally significant, collaboration with the firms currently in the region will enable the local and state workforce organizations to better project the needs of companies that will be relocating to the area in the future.

Advanced Degree Needs

The workforce needs of the advanced pharmaceutical manufacturing industry include PhD and graduate, undergraduate technical and technical production jobs. An estimate of the workforce needs of the core cluster companies shows that present supply and programs, augmented by programs which are in planning already, will meet their needs over the next 24 months as they hire out. Notably, while advanced pharmaceutical manufacturing requires many of the same skills and training as other advanced manufacturing industries which operate in highly regulated industries, unique critical needs must be met as well (e.g., core competencies in quality control and assurance, recordkeeping, clean room processes and safety.)

Anchored by VCU College of Engineering, the region is well positioned to supply top talent at *the BS, MS and PhD* level. The VCU College of Engineering is a national leader in the development of the enabling continuous process technology and in the education and training of students in the innovative approaches that give birth to the technology. VCU offers the nation's only PhD program in Pharmaceutical Engineering. The M4ALL Institute in the College assures a strong flow of graduates and post docs while its close connection with core cluster employers built into the BARDA grant assures unparalleled experiential learning opportunities and placements. In addition, the region enjoys science and engineering graduates from unique and outstanding programs at Virginia State University. Graduates from similar programs in other Virginia universities assure a rich and diverse supply of talent to employers here. Current needs can be met with high confidence.

A growing and evolving technology innovation cluster like this will require more highly trained talent and richer relationships of higher ed and industry, but again anchored by M4ALL and its existing pipeline of support, this can be accomplished. The College will need to grow enrollment in its programs, allow its programs to evolve into related areas the cluster will catalyze, such as scale up, adaptation of technologies and extension of continuous manufacturing. There will be expanded ties with industry to create experiential learning opportunities in an ever-widening cluster effort. Pathways to talent at other Virginia colleges and universities will need to be built. In addition, an advanced pharmaceutical manufacturing cluster will recruit employees with advanced degrees nationally and globally. Initial reports from Phlow, for example, suggest that the excitement of the venture and its promise of meeting crucial societal needs is leading to multiple qualified applicants for available positions.

Technical and Production Talent

The required *technical and production talent* is well within reach, given the time until startup of operations of the core cluster companies and the responsiveness and skills of local community colleges and industry collaboratives which already are at work creating solutions. VEDP's Virginia's Talent Accelerator program, in close collaboration with the community colleges, is working closely with AMPAC Fine Chemicals and Civica Rx to provide tailored workforce training for immediate needs. CCWA is working with AMPAC Fine Chemicals and Civica Rx to research, plan and build an appropriate onboarding workforce training program for the industry in the region. This can be built on core capacities at JTCC, shaped to the needs of the core companies, and modeled in part on successful

programs which have been identified in Virginia and North Carolina. Generally, this will establish an ongoing programs to train production / MT-1 workers tailored to the industry. Separately, CCAM and higher ed collaborators are launching a comprehensive program built on a successful national model (FAME) to recruit and train workers for manufacturing maintenance and support. Both programs are being designed to qualify for the support of "G3" ("Get Skilled, Get a Job, Give Back) the Commonwealth's new workforce initiative set to become law July 1, 2021. G3 funding will enable the programs to be offered to students tuition-free and to employers cost-free. The FAME program has received support from GO Virginia, and the CCWA/JTCC specialized on-ramp certificate program should be a strong candidate for GO Virginia support as well.

Despite these significant workforce strengths, the region faces a relative lack at all levels and occupations of an *experienced* workforce in pharmaceutical manufacturing. This issue is inherent in the startup of a new cluster, but focused attention must be paid while the cluster matures, and a local community of experienced workers naturally forms. The region has a strong base of advanced manufacturing labor, some in chemicals and regulated industries, such as Rolls Royce employees who are steeped in the regulated aviation industry. These sectors can be sources of talent, and cross training programs can be designed to bring employees quickly up to speed. The Virginia Talent Accelerator offers outstanding support to companies to recruit experienced talent. A strong branding and communications campaign by the cluster could also help to attract talent from across the state and nearby regions with experienced talent such as North Carolina and Maryland/DC. Overall, the Commonwealth of Virginia, the region's universities, and its community college-workforce alliances are fully capable of addressing the challenges meeting the workforce needs of the cluster. But it should be acknowledged that manufacturers in multiple industries, not only in our region, find recruiting and retaining a skilled and talented workforce the most pressing challenge and will continue to challenge manufacturing in Richmond-Petersburg as well.

COMMUNICATIONS

The mission of the work group was to gather the facts and shape the story of the cluster in a clear, coherent, and comprehensive way for the region's stakeholders; to suggest how communications could support the growth of the cluster, success of its firms and prosperity of the region; to guide the recommendations of the study; and to form a network of informed experts from key stakeholders who

are equipped to work in support cluster growth in the years ahead. Members were asked to take the point of view of the region as well as their own organizations.

The Main Narrative Elements

The communications work group thoroughly researched and wrote the extensive White Paper, which is **Appendix 2** to this Report, highlighting these four principal narrative elements.

-The emerging cluster is not simply the newest shiny object but rather the intersection of the three broader clusters which this region has historically identified as its greatest strengths and top priorities for the future: life sciences, advanced manufacturing, and logistics.

- The emerging cluster uniquely addresses a confluence of many urgent and important national interests and critical unmet social needs, to:

- Create a secure, resilient domestic supply of essential medicines for the U.S.
- Bring manufacturing back to the U.S.
- Create great jobs of the future in a high-tech high-growth industry for people across our entire region and from all our communities
- Lower the cost of medicines to increase access to healthcare in the U.S.
- Provide more lifesaving medicines to the world's poorest people and deter global pandemics
- Ensure that generic medicines in the U.S. and world are high-quality, effective and safe
- Protect the environment by slashing the waste products, energy requirements and environmental burden of manufacturing medicines
- Transition U.S. pharmaceutical manufacturing to continuous processing to improve quality and regulatory transparency

-Effective strategic communications can articulate a clear cluster identity and brand; gather and gain the support of regional stakeholders for essential infrastructure and collaborative undertakings; create a common vision that generates can; enhance the interrelatedness of actors in the cluster; create synergies; amplify the voices of thought leaders; enhance access of firms across the region and state to new opportunities for growth; recruit firms outside the region to fill supply chain gaps; entice investment; open markets; reach strategic partners and

funders; inspire and attract innovators, researchers and entrepreneurs to take on technical and business challenges ahead; and lure talent to the region.

- The opportunity perfectly embodies the challenge GO Virginia was created to address: faced with transformative growth opportunities taking shape as a regional cluster across local boundaries, how do we organize ourselves as a region to lift all boats rather than let those transformative opportunities slip by while we mind our own business?

Shaping the Message for Relevant Audiences

The communications work group emphasized the importance of shaping the message about the cluster to the relevant audiences that will be reached. One major purpose, for example, will be to gain participation and financial support from what might be considered "internal" audiences, groups in the region and the state that have the capacity to become involved in cluster development. It will be important that regional stakeholders be inspired by the vision of M4ALL, understand its positive implications for the economic well-being of the area, and be willing to become energetic and supportive participants in a public-private partnership. In addition, it will be vital to keep General Assembly members informed about how their efforts to address infrastructure challenges in the region is proceeding and what other steps under their purview can foster the success of the cluster.

In addition to internal audiences, an effective communications strategy should have primary foci on recruiting organizations to the region and branding Richmond-Petersburg as a global leader in continuous pharmaceutical manufacturing. Interest in co-locating near M4All and Phlow continues to grow organically. Linking the talent of the area's nationally recognized creative community to the economic development efforts of VEDP and the region's economic development organizations holds the potential for ramping up exponentially the level of interest in joining the cluster. A comprehensive communications strategy directed to the audiences with whom economic development works and to the opinion leaders who shape national/global perceptions about regional and state business climates should be an integral part of the cluster effort moving forward. The Commonwealth's successful recruitment of the second Amazon headquarters enabled Virginia to be ranked as the best state for business. Communications about the cluster should build upon the state's national reputation for creating a business-friendly environment.

LEADERSHIP ISSUES: ORGANIZATION, GOVERNMENT RELATIONS, UNIVERSITY-INDUSTRY COLLABORATION

A leadership work group was formed for the project with membership including the leaders of M4ALL, Phlow, AMPAC Fine Chemicals, the region's economic development organizations, Activation Capital and leaders at VCU. One purpose of the work group was to monitor the planning process to assure that it was proceeding smoothly and meeting the objectives of the grant. The leadership work group also addressed four major issues not explicitly under the purview of the other work groups: the organization/leadership necessary to move the cluster forward; governmental relations opportunities, both immediate and long-term; addressing obstacles to university-private sector collaborations that have caused friction in other efforts to commercialize scientific discoveries made in a university setting; and addressing obstacles to uniting as a region in common deliberate action in support of the emerging cluster.

Organization and Coordination of the Cluster

The Brookings institution studies of successful clusters highlight the imperative of passionate leadership and effective "headquarters" organizations. The work, vision and passion of Dr. Frank Gupton at the VCU M4ALL has been an animating force behind the emergence of the advanced pharmaceutical manufacturing cluster in this region. It is not an understatement to say that without both his scientific innovation and his personal capacity to articulate a broader vision, to enlist collaborators, and to be an effective champion of the project's potential, the possibilities for a transformative cluster would not exist. At the same time, the tasks involved in fulfilling the promise of Gupton's vision will require organized coordination at multiple levels. Infrastructure development, company recruitment, state-of-the-art workforce programs, internal and external branding of the cluster, establishing effective governmental relations at the federal, state, and regional levels is beyond the scope of any single individual. The more detailed the planning process became, the clearer was the need for a coordinating council to advance the project.

The Brookings' studies describe a range or organizational forms for the "headquarters" organizations. Milwaukee's development of a "water technologies" cluster officially incorporated The Water Council as "a 501(c)(3), corporate-led, industry cluster driver with primary members being water technology companies, academic institutions, and government." **It was grounded in the belief that "someone in the region needed to wake up every day with a laser-like focus on the … cluster and ensure a robust,**

collaborative, and highly functioning ecosystem. It could not be another group's second priority." Other clusters have formed collaborative partnerships within larger institutions. For example, Clemson University's Internal Center for Automotive Research "is an automotive cluster that is industry-based defined as BMW and the concertation of 223 automotive-related companies that concentrate in the Upstate region, including a mix of small, medium, and large businesses." It operates within Clemson University's Office of External Affairs and works in tandem with regional and state organizations to support the automotive cluster.

In most instances, cluster coordinating organizations had a relatively small staff at inception but grew over the years. The leadership work group believes that the principle undergirding the Water Council in Milwaukee that someone needs to wake up every day with a laser like focus on advanced pharmaceutical manufacturing should be reflected in this region going forward. At the same time, it is crucially important that a broader coordinating group remain involved and invested in the growth and enhancement of the cluster. The initial framework may be one that establishes an Advanced Pharmaceutical Manufacturing Council (APM Council) composed of major stakeholders in higher education, industry and government that provides overall direction and supports the organization through financial and in-kind contributions and a full-time director responsible for moving the cluster forward and leveraging the talents and resources of the key participants.

The leadership work group envisions the Advanced Pharmaceutical Manufacturing Council as an action organization that will implement the recommendations in the report and will lead, create, and support the multiple collaborations among the private and public stakeholders in the region and the state that will grow the cluster and its firms. The range of activities that will need to be undertaken to fulfill the vision of becoming a nationally/globally competitive cluster and not simply an addition the region's mix of industries is extensive and will require active coordination. The leadership work group was encouraged by the hard good work of some 50 leaders from key stakeholders in the work groups of this study. The networks they have formed and work they have done lays the foundation for implementation. The leadership work group also was encouraged by the support of the emerging cluster by VEDP as well as the agency's willingness to contribute to the funding of a full-time staff member for the proposed Council. It will be equally important for the cluster to obtain support and leadership commitment from private industry and regional organizations to develop and support the build out of the cluster's ecosystem if its promise is to be realized.

Public Policy/Government Relations

The development of successful regional clusters has typically been university-fueled, industry-driven and government funded. The role of government has been especially important at the emergence of the cluster when financial support and political legitimation of the initiative is most needed. The decision in 2020 by BARDA, a federal agency, to support the construction of two new advanced manufacturing facilities and a Strategic API Reserve by Phlow and its strategic partners has been the major catalyst to the cluster in the Richmond-Petersburg region, providing both crucial investment and public confirmation that the scientific innovation at M4ALL could be the basis for reshoring American pharmaceutical manufacturing and replenishing a strategic stockpile of essential medicines. The leadership work group recognized that public policy/government relations opportunities are many and strong and will extend beyond the original support by BARDA. The attention of the federal government is focused now intensely on multiple interests embodied by this cluster: reshoring American manufacturing; securing the supply chain of safe quality medicines for America and the world; increasing access to health care by reducing the price of medicines to all Americans; protecting the environment; and bringing economic development, infrastructure build up and job growth to communities which traditionally have not participated. At the same time, state policy levers can provide powerful support and incentive to the development of economic clusters – e.g., the major contribution just made to solving certain water and sewer infrastructure issues. The robust development of the cluster will require continuing coordination with Virginia state government, with regional economic development organizations, and with multiple local governments in the region.

The leadership work group for the project also recognized that the timing of government relations issues does not neatly conform to a planning horizon. While the coordinating council will have to develop a government relations strategy in the intermediate term, there are a set of immediate issues at the federal level that have the potential for impacting the cluster. FDA has long sought and supported the move to continuous process advanced pharmaceutical manufacturing for the US pharmaceutical industry. Now before Congress is draft legislation to create FDA Centers of Excellence related to advanced pharmaceutical manufacturing. Should such legislation pass, it would be extraordinarily important for VCU and the region to win designation and support as such a Center of Excellence for Continuous Pharmaceutical Manufacturing. The Biden administration's infrastructure bill is likely to represent another opportunity. Although it is not fully defined and will face an uncertain fate in

Congress, there should be an effort by the region to promote further support for the advanced pharmaceutical manufacturing cluster. Many programmatic areas are potential avenues to strategic funding including infrastructure, job creation, workforce, advanced manufacturing, R&D, environmental impact, national security and public health. Any one of them could make an irreplaceable contribution to the cluster. To underscore the opportunity of the moment, even apart from the infrastructure bill the Biden administration has defined pharmaceutical manufacturing as a priority interest and the region should be proactive in bringing forward significant proposals that would strategically impact the development of the cluster and the success of its firms and people.

In the short term, the leadership work group is reaching out to potential supporters in the Virginia House and Senate delegations to acquaint them with the potential of the cluster, to obtain support for a Center of Excellence in Continuing Manufacturing, and to seek their advice about establishing a more visible presence. This role should be transferred to the Advanced Pharmaceutical Manufacturing Council when it is established.

VCU and University Relations

Initiatives that combine university-driven research with industry needs have become the desired model for high end economic development across the nation. This comes as no shock to VCU. From its inception, the mission of the College of Engineering has been: "Through teaching and research, the VCU College of Engineering creates knowledge and transforms ideas in engineering and the life sciences into technologies that enhance regional and global prosperity." Under President Michael Rao and Dean Boyan the College has thrived and Medicines for All has received outstanding support. Like the bets research universities, VCU has become an anchor institutions for transformative regional economic development. Yet nevertheless, cultural and organizational differences that can impact academic-industry partnerships. The deliberative processes of academia are not always consistent with the speed necessary for business; research can be delayed in the interest of protecting intellectual property; and there can be a wide gap between the focus of basic research of academic scientists and the pressing needs of a company for R&D.

Across the Commonwealth policymakers and Virginia's universities are well aware that attention must continually be paid to these matters and seek ways to improve. The creation of the Commonwealth Center for Advanced Manufacturing (CCAM), the Commonwealth Center for Advanced Logistics Systems

(CCALS) and the Commonwealth Cyber Initiative (CCI) have been state-sponsored efforts to encourage new forms of collaboration at the nexus of academic research and practical industry challenges. Recently the Commonwealth crafted investments in its research universities in unprecedented amounts, new locales and innovative approaches to successfully recruit Amazon HQ2.

Virginia Commonwealth University has historically exhibited a strong commitment to translational research at its Health Sciences campus, Massey Cancer Center, and at the College of Engineering. M4All is, in fact, a paradigm example of the promise that translational research can hold for regional economic development. The College of Engineering and the VCU administration have made it clear that the success of M4ALL and its accompanying regional economic development initiatives are a high priority. The College has crafted a formal memorandum of understanding to enhance M4ALL's operational capacities, and M4ALL enjoys strong expressions of support from the administration and the Board of Visitors. Maintaining this support in the coming years as the cluster – and M4ALL,grows and evolves will continue to be a major determinant of project success. The great accomplishments by the faculty and students in Medicines for All and the College of Engineering, and the strong research and commercial relationship they have established across the region and the world, puts VCU in a position to take a national leadership role in the R&D, the commercialization, the education and training, the community building, the public health issues that converge in this emerging cluster. The leadership work group urges them to do so, and the region to join and support them.

RECOMMENDATIONS

M4All has been, to this point, extraordinarily successful. It has demonstrated the capacity to produce essential drugs more quickly and less expensively. Its work has received the generous support of private foundations and multiple federal agencies. The work has the potential to address a wide range of urgent and important global and social issues, from the shortage of medicines to treat HIV, TB and malaria worldwide to the national interests of the US - and many other nations, to secure the supply chain of medicines to protect their citizens. M4All has also generated one of the most exciting and important economic development opportunities that the Richmond-Petersburg region has seen. The establishment of the Phlow Corporation and its funding by BARDA, the increased activity level at AMPAC Fine Chemicals, and the decision by Civica Rx to locate a plant next to Phlow are clear indications that the region can develop a globally competitive cluster in pharmaceutical manufacturing. The successful development of this cluster is not, however a foregone conclusion, but one that will require coordinated

effort, identifying and addressing key infrastructure, workforce, and government relations issues, and successfully collaborating with potential partners across the country and around the globe. These recommendations can help fulfill the promise that Medicines for All has brought to the region. The Recommendations are summarized below and set forth in detail in **Appendix 1**.

Establish an Advanced Pharmaceutical Manufacturing Council as a headquarters organization.

1. *Establish a sustainable region-wide organization of stakeholders to lead, drive and coordinate action to develop the cluster.*

   The range of organizations, firms, and individuals that have collaborated on this Go Virginia Enhanced Capacity Grant has been unprecedented. Virginia Commonwealth University, the region's community colleges, the Virginia Economic Development Partnership, the primary economic and entrepreneurial development agencies, local governments, the advanced pharmaceutical manufacturing companies AMPAC Fine Chemicals and Phlow, all have actively participated in the process. This has created a powerful new dynamic in the region. At the same time, there is no organization that is positioned and equipped to focus, to push and to lead in the ongoing development of the cluster.

   The consensus of the participants is that the planning grant should be the start of the collaborative process and not its completion. It is imperative that a coordinating group – an Advanced Pharmaceutical Manufacturing Council, be established to lead the continued development of an advanced pharmaceutical manufacturing cluster. Without active ongoing leadership and coordination, there is considerable risk that the specific recommendations in this report and required steps to maintain the Richmond-Petersburg region's competitive advantage could be delayed or even ignored. The Council will be tasked with following through on the recommendations in each of the central thematic areas of the report: infrastructure, workforce development, communication and marketing, and government relations. The Council will recommend the appropriate adjustments to the vision and strategy as the cluster evolves in a dynamic scientific and business environment. And it will continue to partner with the regional and statewide GO Virginia organizations in obtaining support for major initiatives.

   The creation of a full-time staff leader, or Director, of this Council with significant experience in economic development will be vital to success. We recommend the leadership work group form

the basis of a leadership Board of the Council, inform the selection of the Director, and remain active setting policy. But the range of activities in the build out for the successful cluster-infrastructure, workforce, branding and marketing, government relations, coordinating local efforts- demands full time-attention. The initial conversations with the Virginia Economic Development Partnership indicate that the agency will be willing to provide approximately 50% salary support for the Director position. It will be important for other stakeholders (Higher Ed, regional economic development organizations, local governments, cluster companies, member organizations, GO Virginia, etc.) to demonstrate their commitment in terms of financial support of salary and operations, and in-kind support of time and expertise.

Address critical infrastructure issues now and improve systems.

The infrastructure section of this report identified three challenges and opportunities for the advanced pharmaceutical manufacturing cluster: issues concerning the availability of business-ready sites in Petersburg and the related challenge of addressing utility issues for a fiscally stressed locality; the overall shortage of wet lab space for firms at every level throughout the region; the absence of a concentration of pilot and scale up facilities and expertise, which creates an opportunity for an animating vision of a pilot / scale up translational development park.

The planning group has formulated recommendations to address each of these issues.

2. *Strengthen and expand infrastructure in the Petersburg area to meet the demands of the growing manufacturing cluster.*

- The Council and its members monitor and support funding and other assistance now underway to resolve infrastructure issues relating to the AMPAC / Phlow / Civica Rx sites
- VGR and partners pursue timely implementation of the GO Virginia grant that provides funding for upgrades to business-ready for multiple sites in the Crater region
- The Council coordinates efforts to identify and share a list of suitable sites around region
- Local and regional EDOs conduct briefings for site owners and developers on special needs for site readiness for manufacturing and logistics for the cluster

3. *Create ample lab facilities in Richmond and across the region to attract and serve the needs of R&D collaborators and build systems to assure future supply.*

- Under the guidance of the Council, continue the work of the Infrastructure work group on laboratory space to gather stakeholders, coordinate actions, find support, and proposes solutions (Activation Capital, VCU/M4ALL, GRP, VGR, VEDP and private users, builders and developers) .
- Build on the findings and insights of the laboratory regional market study to:
- Find the best path to most quickly meet the pressing need for some lab space at or near M4All to accommodate firms now wanting to co-locate.
- Design and launch a regional system to capture, maintain, analyze and share laboratory market data, involving GRP, VGR, VEDP and LEDOs and private sector developers, financiers and market analysts and built on best practices.
- Create and share among stakeholders an analytic framework based on regional data to evaluate feasibility of alternative long-term solutions (new shell space, conversion, landing pad plus fast track customized buildout, etc.)
- Host an event for national and local laboratory space developers, builders and other players to expose them to opportunities and need in the region
- Extend the support of GO Virginia with respect to site readiness to lab facilities and lab market data systems in Richmond-Petersburg region and around the state

4. *Evaluate creating a pilot and scale up development park.*

- Gather stakeholders and create a vision and draft business plan for a complex of facilities, equipment and participants to launch a pilot / scale up development park.
- Identify potential sites and regional and national partners.
- Seek federal strategic lead support, with private, local and state help.

Implement effective workforce strategies.

The advanced pharmaceutical manufacturing cluster will create hundreds of high paying jobs in the region in the next 12-24 months. Its growth over time may create thousands of jobs in the cluster and in the affiliated supply chain and service industries. An effective workforce strategy will respond both to immediate needs and to building a long-term talent pipeline. The region's capacity to address these needs will be a crucial factor in its success in attracting companies to the area and supporting the growth of companies already here.

5. *Offer best in the nation workforce support and workforce development pipeline; continue to expand workforce support and workforce development collaborations underway between VEDP, CCWA, community colleges, CCAM and firms to meet immediate needs and train for the future.* Specific recommendations are:

- Transform the study's Workforce work group into the core of an industry-higher ed task force to address long-term workforce issues
- Help core cluster companies achieve their near-term hiring needs by supporting *Virginia Talent Accelerator* efforts, collaborations with private firms and other means
- Support CCWA, JTCC and VEDP efforts with core cluster companies to develop best-in-class manufacturing technician programs tailored to this industry, and provide GO Virginia support
- Support the FAME program to expand the pipeline of advanced manufacturing workforce and assure a focus is on this cluster, under GO Virginia support
- Systematically inform and connect students at other Virginia colleges and universities to VCU College of Engineering programs and to employers in the cluster
- Recruit and support the conversion of experienced talent when appropriate opportunities arise in other advanced manufacturing industries, i.e., Rolls Royce and select retired military.

Organize and collaboratively implement communications, marketing and recruiting for the cluster.

The scientific innovation at Medicines for All and the manufacturing activities at AMPAC Fine Chemicals, Phlow and Civica Rx should change perceptions about the strength of the bioscience industry in the region and Commonwealth and draw the attention of industry, investors, researchers, government funders and workforce talent. To accomplish this, it is crucial to launch a strategic branding and communication initiative that capitalize on this historic opportunity and current momentum. These communications must be followed by collaborative and concerted marketing and recruiting by our local, regional and state economic development professionals..

6. *Undertake a dynamic communications campaign to internal and external audiences.*
Focus initially on four objectives:

- Engage support of regional private and public leaders and policymakers
- Attract and recruit companies
- Attract and recruit talent into the pipeline
- Prepare the groundwork for and support the launch of a thought leadership initiative for the region

7. *Economic development organizations collaborate, pool resources and expertise to advance cluster development.*

This cluster covers a wide range of technologies and has a vast supply chain. The cluster is evolving before our eyes, and fast moving. There is not enough time nor enough resources to do the marketing and recruiting that needs to be done to take advantage of this opportunity and accelerate cluster growth. The region's economic development agencies and VEDP should plan and launch a coordinated, collaborative, research based national and international marketing campaign. They should collectively engage one or more expert lead generators to create a shared resource identifying the types and names of firms to target. And they should work together to systematically handle inquiries and accommodations regarding expansion or in bound location to assure the customer's delight.

8. *Embrace and support the region's role of thought leadership in the fields of advanced pharmaceutical manufacturing and related fields and issues.*

Engage Virginia companies, universities and resources in building the supply chain and a robust ecosystem.

9. *Engage regional and state companies and entrepreneurs to become part of cluster's supply chain of both standard and innovative products and services.*

Implement a strategy for informing and involving Virginia businesses in the cluster through trade and vendor fairs, collaboration with the State Chamber and regional chambers, and affiliated organizations such as Virginia Innovation Partnership Authority, Virginia Bio, and the Virginia Manufacturers Association.

10. *Engage researchers and innovators at Virginia universities to create solutions and enter productive collaborations with researchers and firms in the cluster.*

Offer symposia and webinars to faculty and students across the Commonwealth explaining R&D needs in the short and long term, by field. Use the existing networks of university connections of CCAM and CCALS, and engage and involve VASEM, VIPA and VBHRC. Support VCU and VSU operating as a hub of a consortium of Virginia engineering schools and other interested colleges and universities and pursue experiential learning and talent development as well as research support.

11. *Facilitate creative collaborations with specialized knowledge and expertise assets in the region and state to develop the cluster.*

Involve organizations such as CCAM, CCALS, Commonwealth Center on Cloud Computing, Cybersecurity Manufacturing Innovations Institute, GENedge, Virginia Bio+Tech Research Park/ Activation Capital in planning for innovative and valuable collaborations with industry and Higher Ed in research, commercialization, workforce, thought leadership and cluster development.

Capitalize on emergent government relations opportunities.

GO Virginia was established, in part, to reduce the Commonwealth's alliance on federal defense spending and to enhance private sector job creation, with an emphasis on high paying jobs in tradeable sectors. At the same time, it is important to recognize that the federal government's expressed interest in reshoring U.S. pharmaceutical manufacturing has been a catalyst to activities in our region through BARDA's support of Phlow. In addition, the federal government continues to make decisions that will have substantial impact on the development of the sector and the competitiveness of the Richmond-Petersburg region. These decisions will be occurring soon and require a timely response. The region is not currently organized to take best advantage of the emerging opportunities and needs to address this challenge immediately.

12. *Quickly organize and begin the pursuit of federal support for transformational initiatives.*

Opportunities are hear now for transformational federal support to the cluster and cluster firms, such as long term procurement contracts, specialized workforce development funding, infrastructure development, advanced and re-shored manufacturing, green technologies, securing the nation's medical supply chain, and transforming pharmaceutical manufacturing to continuous flow for improvements in quality, cost and regulatory transparency and cost.

Immediate goals should be funding for a pilot – scale up translational development park and national center of excellence.

13. *Develop and put in motion a long-term strategy for government relations at the federal, state, regional and local levels.*

The Council should identify organizations and individuals who can lead the government relations activities beyond the short-term and how this activity can be supported. The focus should include long-term procurement contracts for cluster firms, specialized workforce development funding, support for major infrastructure improvements in the Richmond-Petersburg region and performance-based state incentives to accelerate cluster growth.

Continue to build upon the visionary commitment of VCU and the College of Engineering to assure that M4ALL continues to excel in its essential roles in support to the cluster and region - teaching and workforce preparation, R&D and the creation and commercialization of IP.

The emergence of the advanced pharmaceutical manufacturing cluster is grounded in a unique partnership between Medicines for All at the VCU College of Engineering, industry partners in the Richmond-Petersburg region and beyond, the U.S. federal government, and world class foundations. The continued success of the cluster depends on VCU's ability to perform at the highest levels in these partnerships, especially in building an efficient interface with industry.

14. *VCU continuously improves internal operations to facilitate the evolving needs of M4ALL.*

In order to delight M4All's external partners and reach its full potential, M4ALL, the College and University must continuously assess and take such actions that assure that key operations including hiring, meeting space needs, billing and procurement, grant writing, contracts, financial accounting , and the creation, capture and transaction of intellectual property all run efficiently and effectively. M4ALL's structure and leadership must enable these, as well as support the systematic pursuit of strategic initiatives and opportunities from philanthropic, government and private sector sources.

15. *VCU identifies best practices in university-industry collaboration and embraces a globe leading role in teaching, research, commercialization and thought leadership.*

VCU prepares and launches a two-year plan to identify individuals, fields and communication channels and to take first steps into the role of thought leadership for the university, cluster and region. The Council and VCU work together to secure the necessary financial and collaborative support to do so.

Continued partnership with Go Virginia.

This project was made possible by an Enhanced Capacity Building Grant from the regional Go Virginia organization. One of the most important outcomes of the planning process has been the enhanced capacity for collaboration between relevant organizations and institutions in the Richmond part of the region with those in Petersburg and the broader Crater District. The prospect of creating a new advanced pharmaceutical manufacturing cluster grounded in pioneering scientific work at VCU's Colleges of Engineering is a vision that has been shared across the region over the last year, and it is inspiring higher education, the private sector, and all the region's economic development and entrepreneurial support organizations to work together in unprecedented and innovative ways. Continued partnership with GO Virginia will be essential to affirming the energy of those involved and realizing the vision contained in this report.

16. *Develop proposals for Go Virginia support to implement the Recommendations and grow the cluster.*

The work conducted with the support of Enhanced Capacity Building grants help to frame larger proposals that can bring transformative change to a region. Recommendations that focus on infrastructure, workforce, and the establishment of a coordinating structure to address the challenges of cluster development are congruent with the priorities and strategies of Grow Capital Jobs, the Go Virginia support organization for the Richmond-Crater region. Start with support of the start-up operations of the Advanced Pharmaceutical Manufacturing Council and support other stakeholders in developing proposals that would accomplish the Recommendations or otherwise strengthen the cluster in important ways.

A FINAL THOUGHT

There are regions in Switzerland that have produced the world's finest watches for centuries. Even today, Switzerland still dominates the global manufacturing of high-end, luxury timepieces. But regions

that once focused entirely on watchmaking have now developed remarkable clusters of precision engineering that build upon the manufacturing history of the country. The Swiss regions produce dental implants, fasteners, and a host of precision and miniaturized tools, and medical, aerospace and defense manufacturers turn to them for component parts for their most sensitive instruments and devices. The Richmond-Petersburg region has a rich tradition of life sciences, advanced manufacturing (including the chemical industry) and logistics. The development of an advanced pharmaceutical manufacturing cluster would certainly be new, but it is grounded in the historical strengths of the region. In the next few years, we can be a major player in the reshoring of U.S. manufacturing; reliably supplying essential medicines to hospitals in the United States and to men, women and children in some of the world's poorest countries; addressing the global COVID-19 pandemic; and increasing access to health care for everyone by making the world's most widely used medicines more affordable. It is an extraordinarily energizing opportunity. Let's seize it!

ACKNOWLEDGMENTS

The College of Engineering expresses its appreciation to all the individuals and organizations that contributed their ideas and energies to the project. The appendices contain the full list of participants who were engaged in the multiple work groups and we are deeply indebted to all of them. The staff of Go Virginia Region 4 and the Grow Capital Jobs Foundation were not only the impetus for the Grant but also faithful and eager supporters of the work.

The College also wants to thank Bob Holsworth of DecideSmart who provided extensive planning support and counsel and led the writing of key portions of the Final Report. Our thanks also go to Activation Capital for providing the leadership and means to undertake an important study on the laboratory space market in the region, in response to critical needs identified in the course of the study.

Within VCU, many individuals gave their time and energy to support the project. The efforts of the Marketing and Communication team in the College of Engineering deserve special praise.

In particular, the College acknowledges the special contributions made by Jeff Gallagher, its lead consultant for the project. Jeff's background with a pharmaceutical startup in the region and his work as CEO of Virginia Bio where he became familiar with the work of Dr. Gupton made him the perfect leader of the study. When the initial workplan of the study was altered by the pandemic, Jeff redesigned the process to fulfill our original promise of engaging a broad range of committed stakeholders in the project. Jeff not only kept the College and wider community informed throughout the course of the study, but also was instrumental in generating the incredible enthusiasm that stakeholders have expressed for the promise of the cluster.

Recommendations

Establish a sustainable organization of stakeholders to lead, drive and coordinate support of the development of the cluster.

1. Establish an Advanced Pharmaceutical Manufacturing Council as a headquarters organization to coordinate regional action in support of development of the cluster. Build on this study's work groups to form a Leadership Board of key stakeholders and working teams of the Council.

Address critical infrastructure issues now and improve systems.

2. Strengthen and expand infrastructure in Petersburg to meet demands of the growing manufacturing cluster. Support and extend ongoing efforts to strengthen infrastructure systems in Petersburg to accommodate growth, and across the region advance the Tier Level of preferred sites for the cluster and engage owners and developers in opportunities the cluster presents.

3. Create ample lab facilities in the region to attract and serve the needs of firms wishing to collaborate with M4ALL and participate in the cluster and build systems to assure future needs are met**.** Build upon the initial lab market study performed as part of this ECB study to create a regional system to collect, analyze and maintain lab market data led by regional experts and to develop a smart actionable plan to meet the region's needs for lab space.

4. Evaluate creating a pilot and scale up development park**.** A complex of facilities, equipment, firms and talent focused on this essential step on the path from lab to commercialization would distinguish the region, support the cluster's researchers, educators and manufacturers, accelerate commercialization and provide a strong foundation to host a National Center of Excellence in Continuous Flow Advanced Pharmaceutical Manufacturing.

Implement effective collaborative strategies to assure a workforce that will enable the cluster to thrive.

5. Support workforce collaborations underway among industry, VEDP, CCWA, JTCC, CCAM and others to meet the near term needs of core cluster firms and build best in class workforce pipeline programs for the cluster; link students across Virginia and cluster firms, VCU, VSU and other higher ed preparing workforce for the cluster; find opportunities to help experienced talent in other advanced manufacturing industries transition to the industry; and support VCU Engineering's efforts to maintain national leadership in these fields.

Organize and collaboratively implement communications, marketing and recruiting for the cluster.

6. Undertake a communications campaign to internal and external audiences in coordination with key regional stakeholders, focusing initially on recruiting companies and talent to the cluster, gaining informed support of community leaders and policymakers and introducing the region's role as thought leader.

7. Economic development organizations collaborate, pool resources and expertise to advance cluster development by supporting one another and collaborating, with the input of the cluster's core companies, in serving current prospects, generating qualified leads, and marketing to target audiences and through targeted channels.

8. Embrace and support individuals and organizations in the region as they take on the role of thought leader in their fields.

Engage Virginia companies, universities and other resources in building the supply chain and a robust ecosystem.

9. Engage regional and state companies and entrepreneurs to become part of cluster's supply chain of both standard and yet-to-be-innovated products and services.

10. Engage researchers and innovators at Virginia universities to enter productive collaborations with the cluster to help find solutions to the cluster's challenges and opportunities**.**

11. Facilitate creative collaborations with specialized knowledge and expertise assets in the region and state to develop the cluster.

Capitalize on emergent government relations opportunities.

12. Pursue strategic transformational federal support promptly, including funding for a Pilot / Scale Up Park and designation as a National Center of Excellence for Continuous Flow Advanced Pharmaceutical Manufacturing, and explore state policy enhancements to accelerate development of the cluster.

13. Develop a long-term strategy for government relations at federal, state, regional and local levels.

Build upon the visionary commitment of VCU and the College of Engineering to assure M4ALL continues to excel in its essential roles in support to the cluster and region and embraces its leading role.

14. Continue to build upon the visionary commitment of VCU and the College of Engineering to assure M4ALL continues to excel in its essential roles in support to the cluster and region - teaching and workforce preparation, R&D, and the creation and commercialization of IP.

15. Identify and embrace best practices in university-industry collaborations and in taking the role of national and global thought leader in matters of teaching, R&D and commercialization which impact the cluster. Consider creating a high-profile annual symposium dedicated to engaging the leading issues.

Continuing Partnership with Go Virginia.

16. Develop proposals for Go Virginia support to implement the Recommendations and grow the cluster starting with the start-up of the Advanced Pharmaceutical Manufacturing Council.

Opportunity and Challenge	Strategies	Vision
1. Establish a sustainable region-wide organization of stakeholders to lead, drive and coordinate action to develop the cluster.		
We can accelerate cluster growth and the success of firms in the cluster by collective strategic leadership and coordinated actions by public and private stakeholders in the region But fundamentally there is no organization which is positioned and equipped to lead the effort.	• Key private and public stakeholders promptly establish a region-wide Advanced Pharmaceutical Manufacturing Council as a headquarters organization to lead and coordinate regional action in support of development of the cluster. • Key stakeholders form a Leadership Board (VCU/M4ALL, GRP, VGR, VEDP, Activation Capital, Phlow, AMPAC, Civica Rx, VSU, CCWA, GO Virginia Region 4 and select others), which sets priorities, engages a full time Director, and coordinates the implementation of these Recommendations. • Council invites charter members: LEDOs, state and regional trade association, state economic. development program authorities invited • Director is located in and supported by VEDP, and initially is the sole paid staff. • Work groups of this study transform into working groups of the Council in communications, workforce, infrastructure and government relations. • Member stakeholders provide financial and in-kind support. • Council acts as voice of the cluster in support of economic development organizations recruitment efforts. • GO Virginia embraces and supports the Council, providing organizational funding and follow-on funding for projects it develops and supports.	• The Council becomes a symbol and voice of the region's collaboration and commitment to the cluster and the important and unifying goals and values the cluster pursues. • The Council continuously reevaluates strategies and priorities, adapting to changing circumstances, evolution of the cluster and national and global needs. • The Council and cluster become a successful model for the state's strategy of identifying and supporting growing innovative high potential clusters.

Address critical infrastructure issues now and improve systems.		
2. Strengthen and expand Infrastructure in Petersburg to meet demands of the growing manufacturing cluster		
Petersburg can be the center of a nationally leading advanced pharma manufacturing cluster building upon the leading work and investments of Phlow, AMPAC Fine Chemicals and Civica Rx. But select sites in Petersburg require significant attention to infrastructure and knowledge about specific requirements of the industry and site readiness can be improved across the region.	• Under the guidance of the Council, the Infrastructure work group continues to gather stakeholders, coordinate actions, find support and proposes solutions (VGR, VEDP, Phlow, AMPAC, CivicaRx, GRP, VCU/M4ALL and others). • The Council and its members monitor and support funding and other assistance now underway to resolve infrastructure issues relating to the AMPAC / Phlow / Civica Rx sites. • VGR and partners pursue timely implementation of GO Virginia grant re site improvements across the Crater region which includes several suitable for pharmaceutical manufacturing. • The Council coordinates the identification and shared list of suitable sites around region. • Local and regional EDOs conduct briefings for site owners and developers on special needs for site readiness for manufacturing and logistics for the cluster.	• The region's infrastructure in available lab space and manufacturing sites is a magnet to firms looking to relocate or expand. • The state has improved and effective funding mechanisms and incentives that enable adequate investment in infrastructure by fiscally challenged localities and regions. • Significant federal infrastructure support opportunities are identified and won, further distinguishing the cluster and enabling underserved communities to participate.
3. Create ample lab facilities in Richmond and across the region to attract and serve the needs of R&D collaborators and build systems to assure future supply.		
Richmond can be the center for R&D for new advanced pharmaceutical manufacturing industry building upon the lead of M4All and draw leading organizations and firms. But readily available lab facilities near M4All and across the region are hard to find, and no systems are in	• Under the guidance of the Council, members of the Infrastructure work group on laboratory space gather stakeholders, coordinate actions, find support, and proposes solutions (Activation Capital, VCU/M4ALL, GRP, VGR, VEDP and private users, builders and developers).	• State public policy has been revised to provide an effective incentive for the supply of laboratory space. • The region has in place a system for capture and analysis of the laboratory market which provides a competitive

place to understand the market or address the market failure.	• The Council and key stakeholders build on the findings and insights of the laboratory regional market study to - Find the best path to most quickly meet the pressing need for some lab space at or near M4All to accommodate firms now wanting to co-locate. - Design and launch a regional system to capture, maintain, analyze and share laboratory market data, involving GRP, VGR, VEDP and LEDOs and private sector developers, financiers and market analysts. - Create and share among stakeholders an analytic framework based on regional data to evaluate feasibility of alternative long-term solutions (new shell space, conversion, landing pad plus fast track customized buildout, etc.). • Economic development organizations host an event for national and local laboratory space developers, builders and other players to expose them to opportunities and need in the region. • Go Virginia extends its support of site readiness initiatives to lab facilities and lab market data systems in Richmond-Petersburg region and around the state.	advantage to economic development agencies and private developers. • The successful lab market data system is shared across state via Virginia Bio-Connect and its regional hub partners. • Activation Capital takes a lead role across region in convening stakeholders, making plans and taking actions to assure the entire region enjoys lab and pilot space the cluster needs to succeed.
4. Evaluate creating a pilot and scale up development park.		
Richmond can be the center for the new advanced pharmaceutical manufacturing industry because its core players stand at the intersection of translating R&D into commercial processes as nowhere in the world. But significant lab and pilot space and equipment, and multiple collaborators, are required to scale up lab bench processes and pilot facilities and none exist in Richmond or elsewhere.	• The Council gathers a group of stakeholders led by M4ALL to create a vision and draft business plan for a complex of facilities, equipment and participants to launch a pilot / scale up development park. • The group identifies potential sites across the region and regional and national partners. • The Council and key stakeholders seek federal strategic lead support, with private, local and state help.	• The region features the nation's only translational research and development Park with concentrated pilot / scale up facilities, equipment and expertise for advanced pharmaceutical manufacturing. • VCU anchors a National Center of Excellence in Continuous Phlow Advanced Pharmaceutical manufacturing.

5. Implement effective collaborative strategies to assure a workforce that will enable the cluster to thrive.		
Companies currently in the cluster plan to hire for hundreds of high paying jobs across the spectrum of qualifications in the next 24 months; a strong workforce pipeline will attract and promote cluster growth and with it many more jobs. But there are potential gaps in the availability of workforce experienced in pharmaceutical manufacturing and further training programs are needed to assure the pipeline for the future.	• Under the guidance of the Council, the Workforce work group continues to drive implementation and find new solutions (CCWA, JSRCC, JTCC, RBC, VSU, VCU/M4ALL, GRP, VGR, VEDP, Phlow, AMPAC, CivicaRx, CCAM, CCALS, private agencies and others). • The Council and all stakeholders support Virginia Talent Accelerator in helping core cluster companies achieve their initial hiring needs and encourage other private and public firms to support the effort. • The Council marshals support for efforts underway by CCWA, JTCC and VEDP with core cluster companies to develop workforce training programs tailored to this industry and encourages GO Virginia support. • The Council marshals continuing support for the FAME program to expand pipeline of advanced manufacturing workforce and assure a focus is on this cluster, under GO Virginia support. • The Council encourages the collaboration of the Higher Ed community to systematically inform and connect students at other Virginia colleges and universities to VCU College of Engineering programs, relevant VSU programs and to employers in the cluster. • Workforce development organizations prepare a plan and program to recruit and support the conversion of experienced talent when appropriate opportunities arise in other advanced manufacturing industries, i.e., Rolls Royce and select retired military.	• The region boast a best in world workforce pipeline for continuous pharmaceutical manufacturing and is in the top tier for advanced pharmaceutical manufacturing generally. • Equitable access exists for all Virginians to jobs in the cluster. • VCU is widely recognized as leading institution in education and training of graduate and undergraduates in chemistry and engineering underpinning the advanced manufacturing pharmaceutical cluster. • VSU establishes special position in preparation of talent for the cluster. • VCU's FDA Center of Excellence includes nationally leading experiential education and talent development in close relationship with industry. • The workforce training programs developed by CCWA, JTCC, VEDP, CCAM and others are national models of their kind, and feature a showcase Center of Training Excellence.

Organize and collaboratively implement communications, marketing and recruiting for the cluster.		
6. Undertake a focused dynamic communications campaign.		
The story of the emerging cluster in the region is compelling, timely and unifying, and has the power internally to align the region's stakeholders and externally to attract firms and talent and strategic opportunities and support. But the story has not been shaped and told to external or internal audiences, nor are the region's multiple stakeholders aligned in their messaging.	• Under the guidance of the Council, an expanded Communications work group gathers stakeholders, coordinates actions, finds support and proposes solutions (VCU/M4ALL, GRP, VGR, VEDP, Activation Capital, Phlow, AMPAC, CivicaRx and private communication firms.) • Council engages a communications expert to lead efforts. • The expert works with the Communications work group in creating a brand and core messaging, gaining alignment and supporting stakeholders and local differentiation. • The Council and key stakeholders launch a full communications campaign with initial focus: - Engage support of regional private and public leaders and policymakers - Attract and recruit companies - Attract and recruit talent into the pipeline - Launch the region's thought leadership initiative. • The Council directs the creation of a curated and shared communications asset resource (photos, videos, text) and a news clearinghouse for all stakeholders. • The Council keeps stakeholders informed and up to date.	• The region and state are known globally for the cluster, and this compliments other branding of the region and its localities. • All major stakeholders and marketers of the region use the brand consistently and collaborate on planning and messaging.

7. Economic development organizations collaborate, pool resources and expertise to advance cluster development.		
The technology, industry and cluster are in development and growth stage. Many firms are now investigating whether and how to locate in the region and participate in the cluster. They can be quick successes and extend the region's lead. And other potential candidates to locate here around the world are not aware of the emerging cluster. But the opportunity has come upon us quickly. Players in the region are not yet fully equipped to respond effectively and promptly, nor to reach out proactively, and this will take scarce resources to do quickly and well.	• State, regional and local economic development organizations establish processes and relationships to handle new candidates approaching the region because of the cluster. • Core cluster companies, M4ALL and other stakeholders support these efforts as requested. • With the support of the Council, the key economic development organizations launch a coordinated sustained national and international marketing campaign to recruit businesses. • The key economic development organizations collectively engage one or more expert lead generators to create a shared resource identifying the types and identity of firms as priority targets. • The key economic development organizations host a virtual trade fair for the cluster and region.	• The Region provides and is recognized for prompt and high-quality assistance provided to in bound candidates, expansions and startups. • Target audiences are systematically communicated with through the most appropriate channels, and the region sees a steady flow of qualified leads to participate in the cluster. • Cluster marketing and recruiting is fully integrated into the systematic efforts of state, regional and local economic development organizations and marketers. • The localities of the region enjoy strong volumes and high success rates with candidate companies.
8. Embrace and support the region's role of thought leadership in advanced pharmaceutical manufacturing and related fields and issues.		
The congruence of technological innovation, industry disruption and priority national interests cries out for thought leadership in science, academia, public policy, industry and communications, to vision cast and to engage collaborators and broad support. But this is only occurring ad hoc and in silos, and it has been left to voices outside the region.	• Key stakeholders seek out and embrace roles as thought leaders in the fields and interests touched by the emerging cluster. • The Council convenes and supports a regional thought leader team across business, academia, government, health care, nonprofit, and create a strategy for success. • The Council produces a thought leaders series of podcasts, videos, in person events, social media, etc. integrated with the overall cluster communications plan • The Council coordinates an international speakers program with the collaboration of stakeholders to	• The region and its stakeholders regularly host global virtual and in person conferences and seminars on key topics in advanced pharmaceutical manufacturing and the national interests the cluster serves. • The region enjoys a reputation as a though leader in issues including access to affordable medicine, reshoring, supply chain security and global access to medicine.

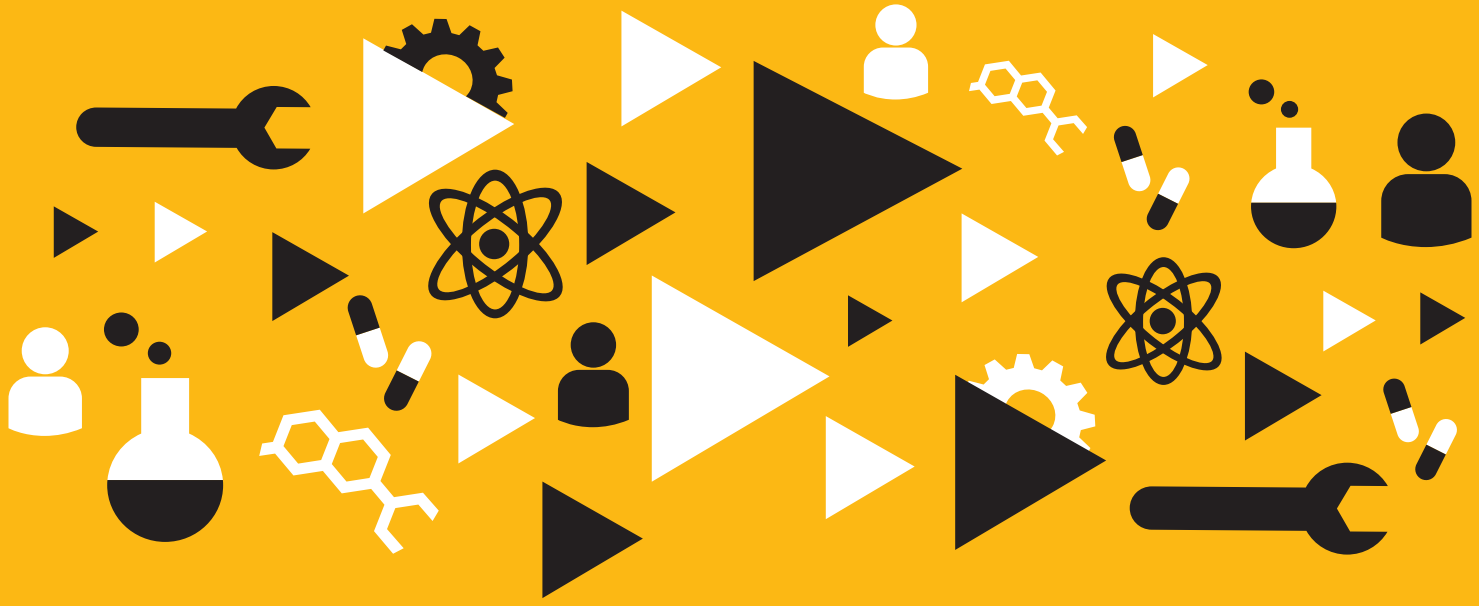
	inform the region and introduce the world's experts to the region's leadership. • M4All undertakes national and international fellows' and visiting scholars programs.	• The region hosts gatherings of global philanthropic and public sector organizations on matters of global access to medicine.
Engage Virginia companies, universities and resources in building the supply chain and a robust ecosystem.		
9. Engage regional and state companies and entrepreneurs to become part of cluster's supply chain of both standard and innovative products and services.		
Virginia's private sector has much to offer and much to gain from becoming involved in the cluster by co-developing technologies, products and services or becoming part of the supply chain. But Virginia companies are not aware of the opportunity of the cluster and do not have actionable information or good contacts.	• The Council and its economic development member organizations host virtual and in person supply chain/ vendor events describing in actionable level of detail the supply chain and providing contact with core cluster companies. • Special forums focus on gaps in technology, equipment or processes which require adaptation or other innovation, bring together potential collaborators and facilitate access to funding sources including VBHRC, CIT and SBIR/STTR experts. • The Council facilitates collaboration with organizations able to reach potential suppliers across Virginia including state, local and regional EDOs, state, local and regional chambers of commerce, Hopewell Manufacturers Association, VA BIO, Center for Innovative Technology, VBHRC and Virginia Manufacturers Association.	• The cluster enjoys a strong supply chain which includes many regional and Virginia companies. Many of these suppliers have become cluster innovators themselves.

10. Engage researchers and innovators at Virginia universities to create solutions and enter productive collaborations with the cluster.		
Virginia universities have much to offer and much to gain through multidimensional relationships with industry including faculty and student involvement in research and development, talent formation and attracting additional resources. But universities across the state have limited understanding of the opportunity, and effective university / industry interface takes special effort.	• The Council coordinates symposia and webinars to faculty and students across the state explaining near and long-term needs of the cluster for R&D, engaging such statewide expert organizations as VASEM and CIT for assistance. • CCAM and CCALS use their existing networks of university connections to develop opportunities to support cluster activities with special expertise. • VCU and VSU serve as a combined be hub of the wheel of a consortium of Virginia engineering schools and other interested colleges and universities who find and develop opportunities for collaboration in research, development, teaching and experiential learning.	• Well defined and well operating structures of collaboration among Virginia universities are in place on the science and technology of the cluster, enriching existing efforts and innovating where necessary . • Collaborations of firms and university researchers are winning federal funding for strategic research across many fields at far greater rates than in the past. • Several universities offer new programs or departments, and several inter-university collaborations have formed, to extend the research and education needs of the cluster as it evolves.
11. Facilitate creative collaborations with specialized knowledge and expertise assets in the region and state to develop the cluster.		
The region and state are rich with other assets with the potential to contribute to the development of the cluster. But they are not aligned, equipped, resourced and engaged to take on this categorically different opportunity.	• The Council works to create collaborations involving industry and Higher Ed in research, commercialization, workforce, thought leadership and cluster development and to identify potential sources of support, focusing first on: - CCAM, CCALS, Commonwealth Center on Cloud Computing, Cybersecurity Manufacturing Innovations Institute, GENedge and Activation Capital.	• The major specialized knowledge and expertise asset organizations of the state develop and find support for new programs and relationship which impact the cluster. • The new programs and collaborations gain national support and national recognition, and further distinguish the cluster and attract firms and talent to the cluster.

Capitalize on emergent government relations opportunities.		
12. Quickly organize and begin the pursuit of federal support for transformational initiatives.		
This is a historic moment with the potential of large sums and different streams of federal funding available to address key issues which are being addressed by the cluster. But no one is looking for or pursuing these very large opportunities for strategic transformative federal support.	• The Council organizes and secures funding to pursue strategic and transformational federal support. • The Leadership Board of the Council focuses and leads action; a small group of leaders is selected, briefed and supported in effort to have personal communication with region's Congressional delegations, principally Rep. McEachin Sen. Kaine alerting them to the opportunity and requesting engage their ongoing help. • The Council engages an expert in finding and pursuing existing federal program opportunities in support of the cluster. • The Council engages an expert to lead effort to develop strategic legislative opportunities. • The initial objectives are: - Pilot / Scale up Park - National Center of Excellence for Continuous Flow Pharmaceutical Manufacturing.	• Virginia's Congressional delegation anchors a caucus on advanced pharmaceutical manufacturing. • The federal government provides strategic level financial support for a pilot / scaleup park as a national resource. • VCU becomes an FDA Center of Excellence for Continuous Flow Manufacturing in a broad collaboration with cluster firms and key stakeholders. • Major Infrastructure funding is secured for sites which can support the cluster in the Richmond/Petersburg region. • Cluster firms are awarded long term procurement contracts. • Multiple collaborative translational R&D projects for key technologies in continuous flow earn significant funding. • Innovative and specialized workforce development funding receives federal support and recognition. • Significant federal support accelerates the cluster's commercialization of green chemistries for the pharmaceutical manufacturing industry worldwide. • The region's efforts to extend the opportunities of the cluster to historically excluded individuals and communities receives federal funding support.

13. Develop and put in motion a long-term strategy for government relations at federal, state, regional and local levels.		
This is a historic moment with the potential of large sums and different streams of federal funding available to address key issues which are being addressed by the cluster. But no one is looking for or pursuing these very large opportunities for strategic transformative federal support.	• The Leadership Board forms a task force to carefully examine federal and state public policies which would enhance cluster development, including long term procurement contracts, specialized workforce development funding sources, support for major infrastructure projects and tax incentives to accelerate the growth of reshoring, advanced manufacturing or cluster economic developments.	The Commonwealth has a new and coherent set of incentives which positively impact growth of the cluster, its firms and workers, and which may include tax incentives for lab space builds or conversions; tax incentives for cap ex supporting advanced pharmaceutical manufacturing; special incentives supporting busines expansion or attraction in support of the cluster; and innovative workforce training or development incentives or programs.
14. Continue to build upon the visionary commitment of VCU and the College of Engineering to assure M4ALL continues to excel in its essential roles in support to the cluster and region and embraces its leading role.		
14. VCU continuously improves internal operations to meet the evolving needs of M4ALL.		
VCU/M4ALL is positioned to be a world leader in sponsored R&D, education and training, commercialization of innovations in support of the emerging cluster. But business and philanthropic partners require high speed and agility. In an academic institution this requires continuous effort and special attention.	• VCU continues to improve the ease and effectiveness of M4ALL operations re: hiring, space, billing and procurement, grant writing, contracts and accountability. • The Board of Visitors continues to be informed and engaged. • M4ALL continues to develop systems to create, capture and offer IP. • M4ALL builds into its leadership and structure resources dedicated to strategic busines and program development – philanthropic, government and private sector.	• M4ALL, the College and university are recognized by firms in the cluster and the stakeholders in the region for excellence in how they work across all areas – R&D, education and training, contracts, communications, commercialization and community engagement, and they enjoy national recognition for same.

15. VCU identifies best practices in university-industry collaboration and embraces a globe leading role in teaching, research, commercialization and thought leadership.		
VCU/M4ALL is positioned to be a world leader in sponsored R&D, education and training, commercialization of innovations in support of the emerging cluster. But with the many important goals of the University, even wonderful opportunities can pass by if attention is not focused, and actions not prioritized.	• M4ALL puts laser focus on best practices for interface with industry. • VCU embraces the role of global leadership with the support of the Council and key stakeholders. • VCU prepares a two-year strategic plan to step into thought leadership roles in select areas.	• VCU hosts a highly regarded and well attended annual symposium for the academy, industry, philanthropy and government on leading technical, business and social issues which the cluster impacts.
16. Develop proposals for Go Virginia support to implement the Recommendations and grow the cluster.		
GO Virginia stands ready to support regional efforts like this cluster building initiative, and it is a proven partner and open to continuing to support the cluster. But unless we communicate well, focus on appropriate and ripe projects and act quickly, we'll not take full advantage of this resource and impair the growth of the cluster.	• The Council sparks the development of proposals with collaborators to implement select Recommendations, beginning with support of the start-up operations of the Advanced Pharmaceutical Manufacturing Council. • The Council supports and encourages other stakeholders in developing proposals that would strengthen the cluster in important ways.	• The support of GO Virginia for the cluster in coordination with other economic development players is a model that helps other regions and other clusters succeed.



Building a global cluster of advanced pharmaceutical manufacturing and R&D in Richmond/Petersburg

Improving access to safe, effective and affordable medicines

VCU College of Engineering, under a strategic planning grant from GO Virginia Region 4

VCU College of Engineering

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Executive summary

Building a global cluster of advanced pharmaceutical manufacturing and R&D in Richmond/Petersburg
Improving access to safe, effective and affordable medicines

Researchers and companies in Virginia's Richmond/Petersburg region are changing the paradigm for pharmaceutical manufacturing with advanced chemistries and engineering. The new methods have been proven to provide dramatic cost savings, reduce environmental impact and yield high-quality pharmaceutical products. Together they enhance security of the U.S. pharmaceutical supply chain, offer a solution to lack of quality affordable essential medicines in much of the world, and offer the region a historic opportunity to grow an emerging industrial cluster. This project was funded in part by GO VIRGINIA, a state-funded initiative administered by the Virginia Department of Housing and Community Development that strengthens and diversifies Virginia's economy and fosters the creation of higher wage jobs in strategic industries.

The Need

The U.S. needs a secure, dependable and resilient supply chain of affordable, high-quality, effective and safe essential medicines. So does the rest of the world. Our region and commonwealth need economic development opportunities of tomorrow, that is, in high-growth, high-tech, high-wage tradable sectors, which create, grow and attract companies and jobs that reach all members of all of our communities. An opportunity is at hand, but to achieve the vision we need to come together as a region as perhaps never before, with leaders and stakeholders working with urgency, priority and creativity.

The Technology

A leader in this effort is B. Frank Gupton, Ph.D., an internationally renowned pharmaceutical engineering innovator with the Virginia Commonwealth University College of Engineering. Gupton has pioneered the use of novel chemistries and chemical engineering — plus an innovative, practical approach to the choice of starting materials — to make major breakthroughs in process intensification in the manufacture of certain medicines and enabled the use of certain advanced manufacturing techniques.

The Platform

To advance these new pharmaceutical manufacturing paradigms and build access to medicines in the developing world, Gupton founded the Medicines for All Institute (M4ALL) in VCU's College of Engineering

with funding from the Bill & Melinda Gates Foundation. Since 2014, M4ALL has been driving down the cost and environmental footprint of manufacturing HIV/AIDS medicines.

The Capabilities

To bring sustainable access to medicines and supply chain independence to the United States, Richmond-based startup Phlow Corp. brought together M4ALL, Civica Rx and Petersburg-based AMPAC Fine Chemicals to lead a multiyear effort to supply and stockpile active pharmaceutical ingredients (APIs) for essential medicines and to create new continuous processing manufacturing capability. In 2020, the U.S. Department of Health and Human Services' Biomedical Advanced Research and Development Authority (BARDA) awarded a $354 million, four-year contract to Phlow to advance this mission-critical initiative.

The Goal

The emerging cluster's focus is development of advanced manufacturing platforms, including continuous processing, for approved, in-market, small molecule active pharmaceutical ingredients. This focus is narrow enough to reflect the region's competitive advantages, yet broad enough to allow development and growth.

The Personnel

The workforce and talent needed for an innovative advanced manufacturing cluster such as this includes experienced, newly trained graduate degree holders, college graduates and technical/production personnel. VCU and its College of Engineering, along with Virginia's robust community college system, are equipped to supply existing industry and companies that will co-locate to the region with a high-tech, highly skilled workforce.

The Location

The presence of VCU Engineering, M4ALL and Phlow make the Richmond/Petersburg region the nation's leader in expertise in advanced pharmaceutical manufacturing innovation for domestic production of essential medicines. The fact that the region is also home to two university consortia dedicated to thought leadership in advanced manufacturing and advanced logistics systems further attests that Richmond/Petersburg is ideally equipped to lead the nation in pharmaceutical supply chain independence.

About this paper

VCU College of Engineering is led by Dean Barbara D. Boyan, Ph.D.[1] Her leadership and support made possible the GO Virginia grant under which this white paper is prepared and provided investment and support to the work described here by Medicines for All (M4ALL).

The mission of the College of Engineering is:
"Through teaching and research, the VCU College of Engineering creates knowledge and transforms ideas in engineering and the life sciences into technologies that enhance regional and global prosperity."

Over the course of years covered by this white paper, the college's strategic themes have been:

- Build upon our legacy of student-centered learning to prepare the interdisciplinary leaders of tomorrow
- Conduct research that makes a positive difference in our community and humankind
- Create and nurture a highly collaborative, creative, innovative and entrepreneurial culture
- Provide a global, real-world perspective of engineering in the learning experience[2]

This white paper was prepared by the Communications Working Group of the planning process, based on its own work and that of the other working groups, project staff, interviews and review of printed materials. Members were Kendra Gerlach, VCU Engineering, co-leader; Michael Ivey, Greater Richmond Partnership; Kevin Miller, Virginia Economic Development Partnership; Betsey Odell, Commonwealth Center for Advanced Manufacturing; Kemi Osoba, City of Petersburg, and Jill Vaughan, Virginia's Gateway Region, co-leader.

[1] VCU College of Engineering. "Biography," *Dean's Office*. https://egr.vcu.edu/about/dean/
[2] VCU College of Engineering. *Strategic Plan*. https://egr.vcu.edu/about/strategic-plan/

Introduction

A once-in-a-lifetime opportunity is at hand

A once-in-a-lifetime opportunity is before the region and state to spark the development of a transformational advanced pharmaceutical manufacturing cluster, create thousands of high-tech, high-wage jobs and expand reliable access to affordable, quality medicines for Virginia, the nation and world.

Researchers and industry veterans at Virginia Commonwealth University College of Engineering have pioneered simpler, faster, cleaner and less expensive chemistries to synthesize active pharmaceutical ingredients for the world's most widely used medications. The innovations also enable the development of entirely new advanced pharmaceutical manufacturing platforms, most importantly, the continuous manufacturing process. Together, these breakthroughs create an opportunity to reinvent the pharmaceutical supply chain and greatly increase secure access to high-quality, affordable pharmaceuticals in the U.S. and world.

The technology has already produced enormous scientific, public health and economic development results. The Medicines for All Institute at VCU Engineering was established with funding from the Bill & Melinda Gates Foundation.[3] M4ALL's mission is to enable access to life-saving medications for the world's poorest people by developing innovative syntheses to drive down the cost of manufacturing medicines that treat the world's major infectious diseases: AIDS, malaria, tuberculosis and now COVID-19. VCU is the leading intellectual and research center in the nation for this innovative approach.

The approach also is the core of an enormous federal effort to create a national strategic stockpile of critical medicines and to jump-start reshoring pharmaceutical manufacturing to the U.S. Recently, BARDA[4] awarded a $354 million[5] contract to Phlow Corp.[6] of Richmond, in collaboration with M4ALL, AMPAC Fine Chemicals[7] at its Petersburg site and Civica Rx[8], an association of leading U.S. hospital systems. In

[3] Ugincius, Leila (Aug. 24, 2017). "VCU Engineering's Medicines for All awarded $25 million to increase access to lifesaving medications." *VCU News*. https://news.vcu.edu/article/24gates

[4] U.S. Department of Health and Human Services. "Biomedical Advanced Research and Development Authority," *Public Health Emergency*. https://www.phe.gov/about/barda/Pages/default.aspx

[5] If milestones are met, the contract calls for a total of $840 million in work and deliverables.

[6] Phlow.https://www.phlow-usa.com/

[7] AMPAC Fine Chemicals. https://ampacfinechemicals.com

[8] Civica Rx. https://civicarx.org/ Also see Gargulio, Louis (July 1, 2019). "Ending Generic Drug Shortages at Hospitals: A Capitalist Goes Nonprofit." *Life Science Leader*. https://www.lifescienceleader.com/doc/ending-generic-drug-shortages-at-hospitals-a-capitalist-goes-nonprofit-0001 It features Martin VanTrieste, president and CEO of Civica Rx and a member of Phlow's Board of Directors. See also VanTrieste's Oct. 5, 2020, opinion piece in *STAT News*: "The U.S. needs to support American-made medicines." https://www.statnews.com/2020/10/05/us-needs-to-support-american-made-medicines/

Petersburg, the collaborators will create a national strategic reserve of essential medicines and build a secure and dependable domestic manufacturing capability for finished drugs, active pharmaceutical ingredients (APIs) and eventually key starting materials (KSMs) using new advanced manufacturing methods.

Together, these two seminal developments bring together more elements than anywhere in the world and create an opportunity for this region to develop a cluster of research and development and advanced pharmaceutical manufacturing of global significance. With innovative chemistry and chemical engineering research and development established in VCU Engineering, the Virginia Bio+Tech Park and Richmond, and advanced pharmaceutical manufacturing established in Petersburg, the stage is set for the addition of complementary and related supply chain growth across the region and state. This region enjoys a lead for now. Domestic and foreign firms and organizations are contacting the region weekly to investigate locating here. But other regions and nations are pursuing these goals, as well. Urgent, focused attention, collaboration of leaders and stakeholders, and speedy and concerted action are needed to maximize this opportunity.

With the support of GO Virginia[9] Region 4, the VCU Engineering has led a strategic planning process bringing together regional and state stakeholders into a highly functioning network of allies to create a shared understanding of the significance and urgency of the opportunity, key drivers for success and a shared vision. This collaborative planning process has delivered a Final Report and Recommendations to the region to advance and commercialize the technology, develop the required talent and grow this cluster. Along the way, members of the working networks have found opportunities to support current efforts, seize significant, immediate opportunities and plant seeds for long-term strategic opportunities.

Intended audience and use

This white paper is prepared for a varied audience of regional stakeholders who wish to become deeply informed and have at their fingertips a complete account of this opportunity from which to draw and shape messages to their audiences and stakeholders.

This white paper begins with an identification of significant and critical unmet needs, then describes the innovative approach and technology that offer a solution to many of these needs and create this enormous opportunity. The paper traces the development of the technology and the home created for the technology and talent in M4ALL at VCU Engineering.

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[9] GO Virginia. *About GO Virginia.* https://govirginia.org/about/ The study was conducted under Commonwealth of Virginia GO Virginia, per Capital Allocation Grant Contract Number 20-GOVA-04A.

The paper sets forth the two different elements of potential impact: (i) lower-cost, high-quality medicines, and (ii) enabling innovative manufacturing platform technologies, and the interactions between the two. The paper demonstrates the success already achieved by M4ALL — first, on the global stage, largely in collaboration with the Bill & Melinda Gates Foundation and second, on the national stage, as the spark for the large BARDA grant to Richmond's Phlow and its local and national collaborators.

Finally, this work considers the special opportunity these two activities create for this region. Drawing from a look at the cluster now in its early stages of development, this white paper forecasts a future state of the cluster and defines the existing resources that make the region competitive.

An opportunity to address unmet needs for high-quality, affordable medicine

This opportunity begins with enormous unmet needs — needs that command the attention of the region, nation and world. The emerging pharmaceutical manufacturing cluster in the Richmond/Petersburg region can meet these needs and deliver these outcomes:

- ***Create a secure, resilient domestic supply of essential medicines.*** The COVID-19 pandemic revealed the vulnerability of the U.S. supply chain for essential medicines and medical devices.[10] In response, government agencies have launched initiatives to reduce this dependence, including the BARDA grant to Phlow Corp. In Petersburg, Phlow and its collaborators, AMPAC Fine Chemicals and Civica Rx, will create a national strategic reserve of essential medicines and build a secure, dependable end-to-end domestic manufacturing capability for finished drugs, active pharmaceutical ingredients and eventually key starting materials using new advanced manufacturing methods. The 2018 investigative book *China Rx*[11] discusses this in more detail.
- ***Bring manufacturing back to the U.S.*** The call to reshore manufacturing is heard everywhere for multiple reasons. Creation of good jobs and continued economic growth and well-being are among the most prominent. Despite the wish to bring manufacturing back to the U.S., it is unlikely to occur except in industries where advanced manufacturing techniques can be developed and deployed. This is because innovation in advanced manufacturing makes the U.S. more competitive; thus, reshoring pharmaceutical production is feasible. Reshoring pharmaceutical manufacturing has been a strategic goal for years.[12] The COVID-19 pandemic has underscored the need, and increased attention on advanced manufacturing to do so.[13]

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[10] For an overview by FDA of the drug shortages list, procedures and history, see:
U.S. Food and Drug Administration. "Drug Shortages." https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages. See also Hahn, Stephen, FDA Commissioner, and Anand Shah, FDA Deputy Commissioner (September 10, 2020). "The Coronavirus pandemic underscores the need to bring drug manufacturing back to the U.S." CNBC. https://www.cnbc.com/2020/09/10/op-ed-the-coronavirus-pandemic-underscores-the-need-to-bring-drug-manufacturing-back-to-us.html

[11] Gibson, Rosemary and Janardan Prasad Singh (2018). *China Rx: Exposing the Risks of America's Dependence on China for Medicine*. New York: Prometheus Books. Gibson and Singh describe U.S. dependence on Chinese manufacturers for finished drugs, APIs and key starting materials, essentially making U.S. citizens significantly dependent on China for essential medicines. This book also discusses the vulnerability of that supply chain to economic, physical and political risk. More analysis is available at Singleton, Marilyn, M.D., J.D. (June 8, 2019). "China Rx: Exposing the Risks of America's Dependence on China for Medicine." *Association of American Physicians and Surgeons*. https://aapsonline.org/book-review-china-rx-exposing-the-risks-of-americas-dependence-on-china-for-medicine/
Rosemary Gibson serves on the Board of Directors for Phlow.

[12] National Archives. "U.S. Strategy for American Leadership in Advanced Manufacturing, A Report by the Subcommittee on Advanced Manufacturing Committee on Technology of the National Science and Technology Council, Office of the President, October 2018." *Trump White House Archives*. https://trumpwhitehouse.archives.gov/wp-content/uploads/2018/10/Advanced-Manufacturing-Strategic-Plan-2018.pdf This White House report outlines national strategy to reshore manufacturing in key sectors, including pharmaceuticals, by accelerating advanced manufacturing and technology innovation. It also addresses the key role of clusters and workforce in doing so.

[13] Hahn, Stephen, FDA Commissioner and Shah, Anand, FDA Deputy Commissioner (September 10, 2020). "The coronavirus pandemic under-

- ***Lower the cost of medicines to increase access to healthcare in the U.S.*** Chemistry and chemical engineering innovations currently underway in this region enable cost-effective manufacturing of active pharmaceutical ingredients (APIs), and these savings will be passed on. In addition, new advanced manufacturing platforms enable disruption of the inefficient and expensive supply chain system now in place for finished medicines. Together, the new cheaper, more direct, more efficient model will cut costs for consumers by reducing premiums, out-of-pocket expenses and co-pays. It can also reduce the amount the state now spends on medications for multiple programs.

- ***Ensure access to lifesaving medicines by the world's poorest people by improving security of supply to medicines that treat the world's major infectious diseases including AIDS, malaria, tuberculosis and COVID-19.*** Global philanthropies fund organizations that specialize in distributing select medications made with this technology already. Next-generation distributed manufacturing platforms will help ensure security of supply to developing nations and regions by enabling them to manufacture their own supply of essential medicines at a sustainable cost and quality.

- ***Ensure that generic medicines in the U.S. are high-quality, effective and safe.*** In 2019's *Bottle of Lies,*[14] investigative author Katherine Eban reveals that issues of quality and dependability are systemic problems in generic drugs from India and China. Even in the U.S., which gets the best of the lot, the quality of generics is increasingly recognized as a serious issue with clinical implications. On-shore production with advanced pharmaceutical manufacturing would greatly reduce that problem. Many of the generics that are made overseas and prescribed in the U.S. may be of lower quality and may affect patients differently than the branded product.[15]

- ***Protect the environment.*** The pharmaceutical manufacturing industry is large, and current manufacturing methods generate considerable waste. Indeed, a major factor motivating U.S. companies to offshore drug manufacturing to China and India in the last three decades has been the lower costs of compliance with those countries' more relaxed environmental standards. The innovative and intensified chemistries and innovative manufacturing processes discussed here use fewer solvents and generate significantly less waste and enable a dramatic reduction in environmental impact. These technologies

scores the need to bring drug manufacturing back home." CNBC. https://www.cnbc.com/2020/09/10/op-ed-the-coronavirus-pandemic-underscores-the-need-to-bring-drug-manufacturing-back-to-us.html

[14] Eban, K. (2019). *Bottle of Lies*. New York: Harper Collins. Eban describes the poor quality of generic medicines worldwide, including those we use in the U.S., and the intractable problems of assuring quality faced by the FDA with as much as 90% of all these drugs sourced in part overseas. See also this May 12, 2019, NPR Book Review: https://www.npr.org/sections/health-shots/2019/05/12/722216512/bottle-of-lies-exposes-the-dark-side-of-the-generic-drug-boom

[15] The WHO Global Surveillance and Monitoring System for substandard and falsified medicines, vaccines and in-vitro diagnostic tests was launched in July 2013 and issued its first report in 2017. See World Health Organization. "Substandard and Falsified Medical Products Fact Sheet." https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products Circumstances in different regions of the world differ markedly, and there is a wide range of estimates of the percent of substandard and falsified medicines in various areas of the world which have been investigated. See also Peter Behner, Marie-Lyn Hecht and Fabian Wahl's 2017 white paper "Fighting counterfeit pharmaceuticals: new defenses for an underestimated – and growing – menace." Strategy&. PWC network.

have won multiple green chemistry awards in the U.S. and internationally in the last several years.[16]

- ***Improve the quality, safety and regulatory transparency of medicines by transitioning U.S.-based pharmaceutical manufacturing to the continuous processing advanced pharmaceutical manufacturing model.*** The U.S. Food and Drug Administration (FDA) has a long-held objective to transition U.S.-based pharmaceutical manufacturing to more advanced methods, including continuous processing. The benefits are better quality, cost efficiency, regulatory compliance and information management.[17]

- ***Create high-wage, high-tech job growth in tradable sectors across the commonwealth of Virginia.*** A major goal of Virginia's economic policymakers is to provide a range of employment opportunities to people in no-growth as well as high-growth regions.[18] This opportunity will create high-wage, high-tech jobs in the economically challenged Petersburg area, as well as in Richmond, and the jobs will span the full spectrum of required education and training.

- ***Connect Virginia's research universities more closely with industry, spurring and commercializing innovation and economic development.*** For years, the state has sought to increase the return on investment in public research universities by encouraging innovation leading to job creation and keeping talented Virginians employed in-state after graduation. VCU Engineering itself was founded to help the

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[16] Gupton is the recipient of the 2018 American Chemical Society Award for Affordable Green Chemistry, and in the same year, he received the Presidential Award for Green Chemistry. In 2019, he received the Peter J. Dunn Award for Green Chemistry and Engineering Impact in the Pharmaceutical Industry from the ACS Green Chemistry Institute Pharmaceutical Roundtable. These awards were for Gupton's work on a highly efficient process to produce nevirapine, a first-line treatment in HIV therapy. More details are available at: https://egr.vcu.edu/news-events/news/archive/mcquade-gupton-award.html# and https://egr.vcu.edu/news-events/news/archive/gupton-mcquade-green-chem-award.html#

[17] U.S. Food and Drug Administration (October 30, 2019). *Safeguarding Pharmaceutical Supply Chains in a Global Economy, Testimony of Janet Woodcock, M.D., Commissioner of Food and Drugs - FDA, before the U.S. House of Representatives Committee on Energy and Commerce, Subcommittee on Health*. https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019. Dr. Woodcock testified that, "[advanced] manufacturing offers many advantages over traditional pharmaceutical manufacturing, and if the United States invests in this technology, it can be used to reduce the nation's dependence on foreign sources of APIs, increase the resilience of our domestic manufacturing base, and reduce quality issues that trigger drug shortages or recalls. For example:

- Product quality can be precisely controlled with modern automation and control systems and can be closely monitored during production by using high-resolution analytics.
- High technology, computer-controlled production facilities are better able to rapidly respond to changes in demand because they typically do not have the equipment scale-up issues associated with traditional methods and can be capable of seamlessly producing a variety of dosages and even dosage forms.
- Advanced manufacturing platforms also have a much smaller footprint than traditional manufacturing platforms, and the equipment can be made portable so that it can be moved closer to markets, reducing the need for transcontinental shipping of components.
- Medicines can be produced at lower cost than by traditional methods.
- Environmental impact of manufacturing is significantly reduced.

"By supporting the growth of advanced manufacturing in the United States, we can reduce our dependence on China and other overseas manufacturers for APIs as well as improve the resilience and responsiveness of our manufacturing base and reduce drug shortages. FDA's advanced manufacturing initiative is fostering this growth in several ways."
See also: *U.S. Food and Drug Administration. Securing the U.S. Drug Supply Chain: Oversight of FDA's Foreign Inspection Program, Testimony of Janet Woodcock, M.D., Commissioner of Food and Drugs - FDA, before the U.S. House of Representatives Committee on Energy and Commerce, Subcommittee on Health (December 10, 2019)*. P.19. https://www.fda.gov/news-events/congressional-testimony/securing-us-drug-supply-chain-oversight-fdas-foreign-inspection-program-12102019

[18] GO Virginia Region 4 Updated Economic Growth and Diversification Plan (2019). PP. 89, 104-106. http://growcapitaljobs.org/region-4-growth-diversification-plan-2019.pdf This plan reaffirms the region's focus on cluster building, prioritizes life sciences, advanced manufacturing and logistics clusters, and notes how those areas intersect with Gupton's work at VCU Engineering.

state capital region – one of the largest urban areas in the state then without an engineering school, spur economic development through research and preparing talent. Indeed, this opportunity exemplifies its mission. Most recently these goals have been pursued through the creation and efforts of Virginia Research Innovation Council (VRIC) as a component of the GO Virginia initiative.[19]

[19] The Virginia Research Investment Committee (VRIC) and the Virginia Research Investment Fund (VRIF) were established by the General Assembly in 2016 as a part of the GO Virginia Initiative (https://govirginia.org/about/vric/). VRIC is now administered by the Center for Innovative Technology (CIT) (https://www.cit.org/vrif.html).

The innovation, technology and talent creating the opportunity

It all starts with an innovative, yet practical, approach to synthetic chemistry. B. Frank Gupton, Ph.D., spent 30 years in industry, completing his career as executive director of process development at Boehringer Ingelheim Chemicals in Petersburg in 2007. Soon after, he was recruited to VCU College of Engineering to join the Department of Chemical and Life Science Engineering. Now 13 years later, he is a professor, the Floyd D. Gottwald, Jr. Chair in Pharmaceutical Engineering and the chair of the thriving department.

Gupton came to the university with an idea born from his years in industry. He recognized the pharmaceutical industry was lagging behind other industries in innovative chemistry and chemical engineering. The reasons for this are many and widely known. Pharmaceutical manufacturing is a highly regulated industry – down to the processes used to make the pharmaceuticals. The cost structure of medicines is unusual, and the value of speed, due to the limited lifetime of a pharmaceutical patent, is amplified. Even "straightforward" drug development includes myriad risks, and thus the pressure to reduce risk by avoiding change is high.[20] Gupton sought to unleash young minds with fresh viewpoints to reimagine key aspects of traditional pharmaceutical manufacturing to reduce cost and improve access to a wide range of essential medicines.

The access-related opportunity is significant. To understand this, it is important to consider several unusual dynamics in the cost structure of medicines. Because of enormous research and development costs, the cost of active pharmaceutical ingredients (APIs) makes up only between 5% to 10% of the price of a new patented product. Thus, there is little incentive to make efficiencies and improvements in API manufacturing processes. Before the final clinical trials start, the API process is locked down and companies focus on getting the drug to market as quickly as possible before patent expiration. And the process is one that is tried and true, to avoid any risk of regulatory uncertainty.[21]

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[20] Badman, Clive; Charles Cooney, Florence Alastair, Konstantin Konstantinov, Marcus Krumme, Salvatore Mascia, Moheb Nasr and Bernhardt Trout (August 2, 2019). "Why We Need Continuous Pharmaceutical Manufacturing and How to Make It Happen." *Journal of Pharmaceutical Sciences* 108 (2019) 3521-3523 https://www.jpharmsci.org/article/S0022-3549(19)30451-4/fulltext

[21] Gottlieb, Scott (July 13, 2018). "FDA Budget Matters: Investing in Advanced Domestic Manufacturing." U.S. Food and Drug Administration. "Many of the technologies currently used in traditional "batch" drug manufacturing – where the ultimate finished product is made after many stops and starts in a series of steps – are decades old. This shouldn't come as a complete surprise. Drug development is a risky endeavor. After drug makers have navigated the years of risk involved in discovering and developing a new medicine, the last thing they want to do is inject a whole bunch of uncertainty at the last step toward approval – the adoption of the manufacturing process. So, most drug makers have continued to use tried and true methods, even if these conventional processes have shortcomings ... PCAST [President's Council of Advisors on Science and Technology, an advisory group of the nation's leading scientists and engineers who directly advise the President and the Executive Office of the President] estimates that 'Continuous manufacturing may reduce manufacturing costs, which currently consume as much as 27 percent of the revenue for many pharmaceutical companies, by up to 40 to 50 percent.'" https://www.fda.gov/news-events/fda-voices/fda-budget-matters-investing-advanced-domestic-manufacturing

That means in the lifecycle of a drug in the U.S., there is about an 18-month window for process development on the APIs.

But that's only part of the story. When an innovator drug reaches the end of its patent life, the FDA receives abbreviated new drug applications (ANDA) from other drug companies for permission to make and market a generic version of the drug. Those applications are evaluated on whether they establish "equivalency" to the original drug. Again, time is of the essence to bring the first generic on the market. Thus, generic companies are disincentivized from making changes to the innovator company's process for fear that FDA approval would be delayed or denied, and routinely stick as closely as possible to how the drug was originally made. The result is that a process developed 20 years ago to synthesize a complex molecule under circumstances in which there was no incentive to reduce costs is retained into the generic lifecycle and often carries on for decades without change.

While the cost of making the API is only a small percent of the price of a branded product, it is significant to note that the cost of making the API for a generic constitutes a much higher fraction (up to 70%) of the market price of the drug. This creates an enormous opportunity to reduce the price of generic medicines by cutting the cost of production. A process that reduces the cost of making APIs for generic medicines can significantly reduce their price and thus expand access to medicine and health care for all.

Toward that end, Gupton and his group at VCU Engineering have pioneered the use of novel chemistries and chemical engineering — plus an innovative practical approach to the choice of starting materials, to make major breakthroughs in the manufacture of certain medicines.

The group focuses on "small molecule" medicines. Small molecule medicines comprise a large portion of generic drugs as well as all new drugs approved by the FDA. Two out of every three new drug approvals by the FDA in 2019 were small molecule drugs,[22] and account for many of the innovative treatments and specialty drugs in development.[23] Together, nine of the top 10, and 17 of the top 20 most prescribed drugs in the U.S. in 2014 were small molecules.[24] Small molecules are broadly distinguished from large molecule drugs, such as proteins and polypeptides, not only by size and shape, but also by the manner in which they

[22] Small molecule drugs accounted for 32 of 48 of the drugs approved by FDA in 2019. See Blank, Christine (Feb. 10, 2020). "Small molecular drugs led 2019." *Formulary Watch*. https://www.formularywatch.com/view/small-molecular-drugs-led-2019-approvals/. See also U.S. Food and Drug Administration. *New Drug Therapy Approvals 2019*. https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/new-drug-therapy-approvals-2019

[23] Bates, Gordon (Dec. 5, 2019). "Why Small Molecules are still a big deal." *Medicine Maker*. https://themedicinemaker.com/manufacture/why-small-molecules-are-still-a-big-deal

[24] Cohen, Yuval (November 23, 2015). "Small Molecules: The Silent majority of Pharmaceutical Pipelines." *Xconomy Boston*. https://xconomy.com/boston/2015/11/23/small-molecules-the-silent-majority-of-pharmaceutical-pipelines/

are manufactured as medicines. Small molecules are typically made by synthetic chemistry. Large molecule drugs are manufactured using biological processes; thus, they are often called "biologics."[25]

In synthetic chemistry, a small molecule API is constructed step by step, a bit like constructing with Tinkertoys®, with one fragment added at a time in a set sequence. For any one small molecule, there are potentially many sequences of steps, or routes, of synthesis. There is a range of starting materials from which to choose, and depending on those, different steps requiring different reagents, solvents and intermediate processing. Every chemical reaction is unique, and each step on each path has different energy requirements, yield, efficiency and waste. Given the freedom and reason to do so, researchers can develop new chemistry synthetic pathways for any small molecule.

The approach Gupton and colleagues have pursued to design a chemical synthesis pathway is "process intensification." Process intensification includes a wide range of innovative changes in how a molecule is synthesized that results in fewer operations, higher yields, fewer inputs, less impurities, less waste, less time, less human effort and less expense. M4ALL does this at the intersection of chemistry and chemical engineering, drawing on chemistry, equipment, raw materials, waste minimization and catalysis. It incorporates 21st century advances in technology from other industries. It approaches the problem with an innovative/disruption mindset. There are common elements that can be applied to every situation – new catalysts, green chemistries or different starting materials, for example. But they must be brought to bear in a different, innovative way for every different API. M4ALL starts by analyzing actual costs of manufacturing in the real world, and that means looking closely for ways to use common solvents, reagents and commodity-based starting materials and creative pathways that eliminate unneeded operations and improve yields.[26]

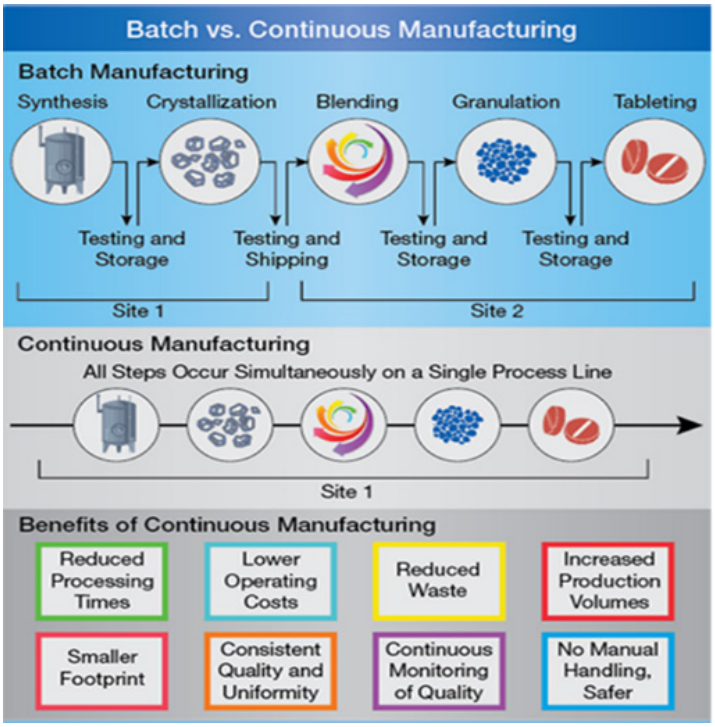
This new chemistry may be used to great benefit in batch processing, which dominates pharmaceutical manufacturing today. The new chemistry can make batch processes cheaper because it requires fewer steps and inputs and produces less waste. This alone is an enormous benefit with immense implications. Several drugs already are being manufactured with the new chemistry in batch processing around the globe.

But there's another world of benefit as well. Because of the simplicity of the chemistry, process intensification allows the development of new and alternative advanced pharmaceutical manufacturing platforms that unleash a host of additional benefits. The leading alternative is continuous flow processing. The following diagram provides a basic overview of continuous vs. batch processing of a finished drug formulation and

[25] For a comparison of features of small and large molecules see Buvailo, Andreii (July 11, 2018). "Will Biologics Surpass Small Molecules In The Pharma Race?" *BioPharma Trend.* https://www.biopharmatrend.com/post/67-will-small-molecules-sustain-pharmaceutical-race-with-biologics/

[26] Wright, Rob (January 4, 2021). "Frank Gupton – Revolutionizing Pharma Manufacturing from the Outside In." *Life Science Leader.* https://www.lifescienceleader.com/doc/frank-gupton-revolutionizing-pharma-manufacturing-from-the-outside-in-0001

highlights the benefits.[27]



Continuous process manufacturing results in:

- less time
- less expense
- less storage and shipping
- less environmental impact
- higher and more replicable quality
- greater transparency for regulatory bodies
- scalability
- instantaneous process control
- increased supply chain resiliency

For these reasons, the transition to continuous processing in pharmaceutical manufacturing is sought and supported by the FDA to improve product quality and reduce drug shortages and recalls,[28] but to date has been technically out of reach in small molecule pharma manufacturing. Enormous capital investments,

[27] This diagram is from Kuehn, Steve (December 2018). "Pharmaceutical Manufacturing: Current Trends and What's Next." *CEP (Chemical Engineering Progress)*. American Institute of Chemical Engineers. https://www.aiche.org/resources/publications/cep/2018/december/pharmaceutical-manufacturing-current-trends-and-whats-next

[28] Lee, Sau (Larry), Ph.D. (May 17, 2017). "Modernizing the way drugs are made: A transition to Continuous Manufacturing." U.S. Food and Drug Administration.https://www.fda.gov/drugs/news-events-human-drugs/modernizing-way-drugs-are-made-transition-continuous-manufacturing

products and services, and workforce fortify the legacy status of batch processing. Continuous process systems are widely used in other chemical manufacturing industries. However, for the sophisticated and highly regulated field of pharmaceuticals, continuous processing is in its early stages of development. Many components must still be created, imported and tweaked, tested, qualified and certified. Inventing and developing those components so they are ready for cost-effective industrial application in an intensely regulated environment requires significant R&D strongly associated with the underlying chemistries, and thus with the core technology. In each of these stages, there is much work to be done in pharmaceuticals, and much of it will require VCU Engineering R&D.

Medicines for All Institute at the VCU College of Engineering

Successful collaboration with the Bill & Melinda Gates Foundation working to drive down the costs of medicines worldwide

The global public health community purchases and distributes billions of dollars of medicines to treat HIV, TB, malaria and other leading infectious diseases annually to people around the world who cannot afford them. Even at these levels of spending, not enough medicines are distributed. If the cost of the medications could be reduced, more people could be reached.

In 2014, the Gates Foundation awarded Gupton and collaborators a grant to identify a more efficient, cost-saving manufacturing route to nevirapine. The first-generation nevirapine commercial process consisted of six steps and 21-unit operations. With a yield of 59%, the cost of manufacture was $135 to $225/kg of produced nevirapine. Gupton and his colleagues got to work. They made changes in the starting materials and intensified the process. The result of their work was a process which required about one-third the number of steps of the original and provided a 92% yield. It cut the unit operations to 4.[29] This cut the amount and cost of raw materials required to make the product. Within two years of the introduction into the global market of nevirapine manufactured in this way, the average global price dropped approximately 12%.[30]

Based on the success of the nevirapine grant, the Gates Foundation awarded Gupton another grant for two other widely used anti-HIV medications, tenofovir and dolutegravir. Gupton's team successfully reinvented the chemical synthesis routes for these APIs as well.

Finally, in 2017, the Gates Foundation made a grant to create the Medicines for All Institute (M4ALL)[31] at VCU Engineering to provide innovative chemistry synthesis pathways to 13 additional critical global medicines over the next five years. The mission of M4ALL is to improve global access to high-quality medications. By re-imagining manufacturing processes, the institute's chemical engineers and chemists optimize active pharmaceutical ingredient production and provide open access to manufacturers around the world to enhance the security of medicine supply chains. As a research-focused institute within the university, M4ALL

[29] Peters, Eric (Spring 2020). "Medicines for All: Revolutionizing the Global Supply Chain." *The Next/MCV Foundation*. https://medicines4all.vcu.edu/media/medicines4all/assets/documents/Medicines%20for%20All%20featured%20in%20Spring%202020%20issue%20of%20next%20MCVF%20pub.pdf

[30] Oral presentation by Dr. Gupton (via Zoom) to Virginia companies and researchers as part of this strategic planning process. February 2, 2021. Ref. slide 12.

[31] Ugincius, Leila (August 24, 2017). "VCU Engineering's Medicines for All awarded $25 million to increase access to lifesaving medications." *VCU News*. Virginia Commonwealth University. https://egr.vcu.edu/news-events/news/archive/m4all-award.html#

strives to educate and train the next generation of chemists and engineers by imparting the principles and foundations of innovative concepts that will lead to affordable, high-quality medicines. This approach allows engineering students and fellows to design processes with immediate impact on global health and to expand the workforce to meet the 21st century's needs.

Through this work, M4ALL has developed a systematized and unique approach to reinventing the chemical manufacturing process for a drug combining novel chemistry with the fundamental elements of process intensification.[32] M4ALL has developed a technical model with the following well-defined components:

1. Paper Study
2. Synthesis & Route Scouting
3. Optimization & Multi-gram Scale-up
4. Market Engagement and Technology Transfer
5. Market Surveillance[33]

The analyses build on several key approaches:

- Vertical integration of advanced starting materials prepared from commodity chemicals
- Consolidation of high-yielding reactions into a minimal number of unit operations with common solvents and limited intermediate isolations
- Evaluation of alternative manufacturing platforms

Other potential benefits from the M4ALL strategic approach include a shift toward commodity chemicals, lower conversion costs, reduced development costs, lower waste and environmental costs, more sources of supply in lower-cost regions and increased security of supply.[34]

M4ALL is located in Biotech Eight, at Virginia's Bio+Tech Research Park in downtown Richmond. M4ALL occupies 15,000 square feet over three floors. Both the commonwealth and the university have generously supplied funding and equipment required for its innovative R&D. Several private companies are located in the same building and work closely with the institute. The Bio+Tech Park is located about a mile from the Monroe Park campus of VCU, where the College of Engineering has recently opened a new Engineering Research Building with special space for industry collaborations.[35]

[32] Medicines for All Institute. "Integrated Approach for Cost Reduction." *Overview*. https://medicines4all.vcu.edu/our-portfolio/overview/
[33] Ibid.
[34] Oral presentation by Dr. Gupton (via Zoom) to Virginia companies and researchers as part of this strategic planning process. February 2, 2021. Ref. slide 13.
[35] VCU College of Engineering. "Engineering Research Building." https://egr.vcu.edu/giving/engineering-research-building/

By early 2021, the M4ALL team had grown to 19 full-time staff, four faculty, 27 post-doctoral fellows and graduate students and seven undergraduates and continues to grow with new projects. A unique feature is the co-working integration of chemists and chemical engineers in every lab. The labs feature a great variety and depth of equipment needed to push the bounds, including Nuclear Magnetic Resonance instruments.

Another lab co-located at BioTech Eight and also run by Gupton is the Center for Rational Catalyst Synthesis (CeRCaS), a National Science Foundation industry and university cooperative research center that brings together experts from the University of South Carolina and VCU to advance new approaches to developing more powerful catalysis. A hidden but high-impact science,[36] catalysis is focused on increasing rates of chemical reactions and is a key contributor to process intensification. Research at CeRCaS develops better catalysts – and better ways to develop better catalysts, with which M4ALL researchers can build new and improved chemical pathways for small molecule API synthesis. Optimized catalysts allow chemical conversions to be achieved in the most efficient, economical and environmentally responsible manner and thereby reduce raw material usage, energy requirements and greenhouse gas emissions.[37] This cuts manufacturing costs and helps satisfy strict environmental regulatory standards, and in both ways ensures the sustainability and vitality of the global supply chain.

M4ALL has been working on drugs that hold promise for treating COVID-19, including Gilead Sciences' remdesivir and molnupiravir (formerly EIDD-2801), which is being developed by Merck & Co. in collaboration with Ridgeback Biotherapeutics. M4ALL recently developed and published a process to produce an intermediate material required for remdesivir that requires fewer steps and uses more readily sourced raw materials, making the overall process more efficient and less vulnerable to supply chain risk.[38]

[36] Virginia Commonwealth University. "Catalysis Lab." https://pilabs.vcu.edu/about-us/our-research/catalysis-lab/ Catalysis is at the heart of the energy, specialty and fine chemical including pharmaceutical, commodity chemical and environmental, textiles and agricultural products industries. Approximately one-third of the world's economy depends directly or indirectly on catalysis.

[37] Ibid. As described there, the Center for Rational Catalyst Synthesis (CeRCaS) is the world's first and only research center on the chemical fundamentals of catalyst synthesis. In spite of their immense importance, new approaches to catalysis have remained time-consuming and expensive to develop. At the center, world-leading expertise in metal catalyst synthesis allows researchers to demonstrate rational, scalable, bottom-up syntheses of supported single metal and bimetallic catalysts with previously unachievable control of metal nanoparticle size and metal1-metal2 interactions. CeRCaS is working to streamline catalyst development through research and improved design and controlled synthesis of catalytic structures in the following key areas: fundamentals of metal deposition; thermodynamics and kinetics of solid-solid bonding; in-situ spectroscopy and microscopy of metal deposition and nanoparticle formation; predicting sintering/wetting and particle size, shape and composition; precision control of single and bimetallic catalytic site synthesis for specific reactions; and simple, scalable synthesis of mono- and multi-metallic catalytic sites in well dispersed supported nanoparticles.

[38] Paymode, Dinesh J.; Flavio S. P. Cardoso, Toolika Agrawal, John W. Tomlin, Daniel W. Cook, Justina M. Burns, Rodger W. Stringham, Joshua D. Sieber, B. Frank Gupton and David R. Snead (2020)." Expanding Access to Remdesivir via an Improved Pyrrolotriazine Synthesis: Supply Centered Synthesis." *Org. Lett.* 22 (19), 7656–7661. https://doi.org/10.1021/acs.orglett.0c02848

Efforts in global medicine and public health

As part of its access to medicines mission, M4ALL also has been working to address underlying issues relating to security of supply to essential medicines. These issues include expensive or unavailable starting materials, limited manufacturing capacity due to environmental issues, limited manufacturing capacity due to proprietary syntheses/processes and lack of local manufacturing capacity. With respect to this last issue, M4ALL has been working to develop solutions to drug supply chain issues in Africa.

With support from the U.S. Agency for International Development (USAID)[39] and USP, M4ALL is seeking to use process intensified chemistry to enable new manufacturing platforms — highly automated, self-contained manufacturing modules, that can be widely distributed, owned and operated by these countries to establish their own manufacturing capabilities or supplement or replace their reliance on the global generic drug market. Medicines for All is also training research scientists from these countries with the skills and expertise they will need to realize this vision.[40]

[39] Bell, Anne (October 2, 2019). "USP selected by USAID to strengthen systems that improve the quality of medical products in low- and middle-income countries (October 22, 2019)." USP. https://www.usp.org/news/usp-selected-by-usaid

[40] Gerlach, Kendra (Nov. 8, 2018). "Ivory Coast, VCU form partnership to improve access to lifesaving medicines." *VCU News*. Virginia Commonwealth University. https://www.news.vcu.edu/article/Ivory_Coast_VCU_form_partnership_to_improve_access_to_lifesaving

The 2020 federal initiative to secure the nation's supply of essential medicines

In May 2020, the U.S. Department of Health and Human Services announced an historic effort to secure the supply of essential medicines in America.[41] The U.S. Biomedical Advanced Research and Development Authority (BARDA)[42] awarded a contract to Richmond-based Phlow Corp.[43] to lead a multiyear effort with strategic partners M4ALL, Ampac Fine Chemicals and Civica Rx. The contract includes a four-year base award of $354 million and $458 million more in potential long-term options for a total value of $812 million.[44]

The BARDA contract marks an important and multi-pronged initiative to secure the supply of quality essential medicines in the U.S. Over the past 20 years, the United States has faced chronic and acute shortages of essential medicines. This supply chains failure is caused in large part because the manufacture of APIs and essential generic medicines has been offshored. The U.S. is heavily dependent on foreign sources for its supply of generic medications, the APIs and the KSMs from which APIs are made and this dependency has increased sharply in recent years.[45] A compounding cause is that the supply chain has become increasingly fragmented, or specialized, and the supply chain paths therefore multi-step and complex.[46] The great majority

[41] PR Newswire (May 19, 2020). "Phlow Corporation Awarded $354 Million HHS/ASPR/BARDA Contract to Manufacture Essential Medicines in Shortage." https://www.prnewswire.com/news-releases/phlow-corporation-awarded-354-million-hhsasprbarda-contract-to-manufacture-essential-medicines-in-shortage-301061648.html?tc=eml_cleartime

[42] The Biomedical Advanced Research and Development Authority known as BARDA is part of the office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services. BARDA invests in the innovation, advanced research and development, acquisition, and manufacturing of medical countermeasures – vaccines, drugs, therapeutics, diagnostic tools, and non-pharmaceutical products – needed to combat health security threats and is playing a leading role in the COVID-19 response efforts. BARDA has long focused on expanding pharmaceutical manufacturing infrastructure in the United States, not only to develop and produce vaccines, but also for essential medicines, and their key ingredients used to make these drugs. See U.S. Department of Health and Human Services. "Biomedical Advanced Research and Development Authority." *Public Health Emergency*. https://www.phe.gov/about/barda/Pages/default.aspx

[43] Phlow. "About Us." https://www.phlow-usa.com/about-us/ Phlow was founded in 2020 as a public benefit corporation dedicated to reliably supplying affordable, high-quality essential medicines through the U.S.-based advanced manufacturing processes.

[44] PR Newswire (May 19, 2020). "Phlow Corporation Awarded $354 Million HHS/ASPR/BARDA Contract to Manufacture Essential Medicines in Shortage." https://www.prnewswire.com/news-releases/phlow-corporation-awarded-354-million-hhsasprbarda-contract-to-manufacture-essential-medicines-in-shortage-301061648.html?tc=eml_cleartime

[45] Accurate figures are difficult to ascertain because of insufficient, incomplete and inconsistent data. The FDA only gathers data on the number of U.S. and foreign establishments certified to produce drugs or API for the domestic market, and not the source, by volume or dollar value of medications sold or used in the United States. FDA figures show 72% of establishments registered to produce API are outside the United States. See U.S. Food and Drug Administration (October 30, 2019). *Safeguarding Pharmaceutical Supply Chains in a Global Economy, Testimony of Janet Woodcock, M.D., Commissioner of Food and Drugs - FDA, before the U.S. House of Representatives Committee on Energy and Commerce, Subcommittee on Health.* P 1. https://www.fda.gov/news-events/congressional-testimony/safeguarding-pharmaceutical-supply-chains-global-economy-10302019 The foreign/domestic breakdowns vary at the different stages of generic manufacture: chemical precursors/KSM, APIs and finished formulations. Phlow itself estimates the foreign/domestic breakdown for APIs for generics is 80%/20%. See also Phlow. "Securing our Nation's Pharmaceuticals through U.S. Manufacturing." https://www.phlow-usa.com/

[46] U.S. Food and Drug Administration (July 7, 2011). "Pathway to Global Product Safety and Quality - A Special Report." https://www.hsdl.org/?abstract&did=4123: "Companies will not only be producing more FDA-regulated products abroad, but the products will follow complex paths through multi-step supply chains to reach the U.S. One example of this complexity is an increased number of processing steps and number of entities touching a given product. The market for contract manufacturing outsourcing in pharmaceutical production is evidence of this trend, growing to an estimated $46 billion in 2010, more than double the size of the market nine years ago, as seen in Exhibit 6."

of essential medicines at risk of shortage are generic, and among dosage forms the majority are sterile injectables.[47]

The BARDA contract calls for Phlow and its strategic partners immediately to ramp up U.S.-based surge capacity and also to develop a U.S.-based advanced manufacturing infrastructure by accomplishing five staged tasks[48]:

- Deliver finished essential generic pharmaceuticals of strategic importance to the Strategic National Stockpile, including drugs required for the treatment of COVID-19
- Develop essential APIs and chemical precursor ingredients to support COVID-19 response
- Create and supply the Strategic API Reserve (SAPIR) to fix a weakened manufacturing and distribution chain for essential medicines at risk of shortage.
- Develop a U.S.-based advanced manufacturing infrastructure incorporating advanced continuous flow processes
- Connect the U.S.-based end-to-end manufacturing infrastructure from bulk chemicals to KSM to API to finished drug products (FDP)

Since the BARDA award, Phlow and its strategic partners have completed the first two staged tasks. Via Civica Rx, they have delivered more than two million doses of five essential generic medicines used to treat COVID-19 patients to the U.S. Strategic National Stockpile (SNS), including medicines used for sedation to help patients requiring ventilator support, medicines for pain management and certain essential antibiotics.[49] Phlow and its partners also have initiated manufacturing chemical precursor ingredients, APIs, and, via Civica Rx, finished dosage forms for more than a dozen essential medicines to treat hospitalized patients with COVID-19-related illnesses.

SAPIR, the Strategic API Reserve, will be the first long-term, national stockpile to secure key ingredients used to manufacture the most essential medicines on U.S. soil. Modeled after the Strategic Petroleum Reserve, SAPIR will hold a stockpile of KSMs and APIs that can be quickly converted into essential medicines. Because both KSMs and APIs have significantly longer shelf life than finished pharmaceuticals, SAPIR will dramatically reduce waste and cost, adding a significant new tool to enhance the nation's supply

[47] Inter-Agency Drug Shortages Task Force, FDA. (October 2019, Updated February 21, 2020). "Drug Shortages: Root Causes and Potential Solutions." P.5. https://www.fda.gov/media/132058/download
[48] U.S. Department of Health and Human Services (May 19, 2020). "HHS, Industry Partners Expand U.S.-Based Pharmaceutical Manufacturing for COVID-19 Response." https://www.hhs.gov/about/news/2020/05/19/hhs-industry-partners-expand-us-based-pharmaceutical-manufacturing-covid-19-response.html
[49] Civica Rx (May 19, 2020). "Civica Update: Civica Rx Partners on COVID-19 Response and 'End-to-End' U.S. Based Generic Drug Manufacturing." https://civicarx.org/civica-update-civica-rx-partners-on-covid-19-response-and-end-to-end-u-s-based-generic-drug-manufacturing/

chain for essential medicines at risk of shortage.[50] A state of the art warehouse and distribution system is under construction by Phlow immediately adjacent to the AMPAC Fine Chemicals site in Petersburg.

Phlow also has initiated construction of a multimillion-dollar advanced manufacturing facility, co-located with AMPAC Fine Chemicals in Petersburg. The facility will include a development, pilot and kilo facility, and a stand-alone hybrid manufacturing facility (HMF) for API. The HMF will provide Phlow the capability to manufacture virtually any API of interest in the most cost efficient, quality assured method, whether traditional bulk processing or newly developed continuous flow. The kilo development unit and HMF will comprise the nation's most advanced facility for the manufacture of APIs for essential medicines. The Phlow facilities will open in the spring and summer of 2022.

M4ALL is providing strategic support for the BARDA initiative in multiple ways. M4ALL is developing improved and innovative chemistry and process design for APIs and KSMs for both traditional and continuous flow advanced manufacturing processes. M4ALL will transfer these processes to Phlow and its partners to manufacture affordable, quality medicines and create end-to-end drug manufacturing using flow chemistry and other continuous advanced manufacturing processes. M4ALL also is responsible for educating and leading workforce development programs for undergraduate and graduate chemists and chemical engineers to provide the talent required to develop and operate this innovative manufacturing complex.

AMPAC Fine Chemicals[51] is a U.S.-based custom manufacturer of APIs, drug substances and registered intermediaries, with an API manufacturing facility in Petersburg, Virginia. AMPAC Fine Chemicals specializes in process development, scale-up, and production from kilograms to multi-ton quantities, and is a recognized leader in the movement to commercialize continuous flow manufacture of APIs. AMPAC Fine Chemicals will manufacture KSM and APIs for Phlow and Civica Rx, principally at its Petersburg facility. The facility encompasses 197 acres and has 45,000 gallons (170.34 m^3) of total capacity. Production spans multiple lines with individual reactor capacity ranging from 200 gallons (0.75 m^3) to 2,000 gallons (7.57 m^3) to support clinical stage development requirements as well as commercial development.[52] In order to rapidly begin producing medicines under the BARDA initiative for patients in need, AMPAC Fine Chemicals already is supplying Phlow with APIs for the manufacturing of essential medicines. AMPAC Fine Chemicals also is

[50] Flammia, Anthony, Richard Manning, Kristina McKean and Patricia Watson (August 2020). "An Integrated Supply Chain, A Whitepaper on Addressing Essential Medicine Shortages." *Phlow Corporation*. https://www.phlow-usa.com/integrated-supply-chain-white-paper/
[51] AMPAC Fine Chemicals. "About." https://ampacfinechemicals.com/: "AMPAC Fine Chemicals (AFC) solves problems through technology and innovation to reliably deliver quality products that save and improve lives. With more than 75 years of experience, AFC has mastered challenging chemistries, enabling it to provide the highest quality services to our customers. AFC's fully cGMP compliant facilities located in California, Texas and Virginia specialize in process development, scale-up, and production from kilograms to multi-ton quantities. AFC has expanded its capabilities to include contract analytical services. These services are conducted at AMPAC Analytical, located near its headquarters in California."
[52] AFC-VA supports development of high potency, energetic chemistry, controlled substances and cGMP manufacturing at all scales. AFC-VA has specifically expanded the ability to develop and manufacture controlled substances (Schedule I-IV). See AMPAC Fine Chemicals. "Facilities." https://ampacfinechemicals.com/facilities/

working closely with Phlow as Phlow designs, builds and recruits talent for its advanced manufacturing facility, and on the integration of operations between the two facilities and will play a key role in the operation of the Phlow manufacturing facility.[53]

Civica Rx is a nonprofit organization established in 2018 by health systems and philanthropies nationwide to reduce chronic generic drug shortages and related high prices in the United States. It exists in the public interest as a non-profit, non-stock corporation committed to stabilizing the supply of essential generic medications.[54] Under the BARDA contract, Civica Rx will produce finished sterile injectable medications used in hospitals for COVID-19 patient care, emergency room and intensive-care unit treatments, surgeries, treatments for other serious conditions and for the U.S. Strategic National Stockpile.[55] To do so, Civica Rx is building a state-of-the-art, highly automated sterile injectable fill and finish facility adjacent to the AMPAC Fine Chemicals site in Petersburg and will be using APIs manufactured by AMPAC and Phlow on site. The new 120,000 square foot facility[56] will include disposable technology and advanced technology filling lines to produce 90 million vials and 50 million pre-filled syringes a year, steam sterilization capability, automated visual inspection and packaging lines, and controlled temperature warehousing of raw materials and finished medications. The new plant represents a $124.5 million investment and will be built to accommodate future growth to help ensure a safe, stable and affordable supply of essential generic medicines for U.S. patients. Operations are expected to begin by 2024, at which time the new facility will employ more than 180 people. Hiring the team to build and staff the facility began Q1 2021 and will continue over two years. This will be Civica's first in-house manufacturing facility and is intended to complement its extensive partnerships with multiple quality generic drug manufacturers now successfully in place.[57]

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[53] PR Newswire (May 19, 2020). "Phlow Corporation Awarded $354 Million HHS/ASPR/BARDA Contract to Manufacture Essential Medicines in Shortage." https://www.prnewswire.com/news-releases/phlow-corporation-awarded-354-million-hhsasprbarda-contract-to-manufacture-essential-medicines-in-shortage-301061648.html?tc=eml_cleartime

[54] Harrison, Marc (March 14, 2019). "How the not-for-profit Civica Rx will disrupt the generic drug industry." STAT https://www.statnews.com/2019/03/14/how-civica-rx-will-disrupt-generic-drug-industry/

[55] U.S. Food and Drug Administration. "Strategic National Stockpile." *Public Health Emergency.* https://www.phe.gov/about/sns/Pages/default.aspx The Strategic National Stockpile's role is to supplement state and local medical supplies and equipment during public health emergencies. The supplies, medicines and devices for lifesaving care contained in the stockpile can be used as a short-term, stopgap buffer when the immediate supply of these materials may not be available or sufficient. The Strategic National Stockpile contains finished dosage medications only, not API.

[56] Civica Rx. (Jan. 21, 2021). "Civica to Build an Essential Medicines Manufacturing Facility in Virginia." https://civicarx.org/civica-to-build-an-essential-medicines-manufacturing-facility-in-virginia/

[57] Ibid. To date, Civica Rx has worked with multiple quality generic drug manufacturers that have FDA-approved manufacturing facilities and capacity to produce Civica Rx-labeled medications as a way to deliver shortage medications to market immediately. Civica Rx now has 41 different generic medications available for hospitals in multiple dosage forms and is building to 100 drugs by 2023. Civica Rx has provided approximately 25 million vials or syringes of essential generic medications to hospitals, which have been or are being used to treat approximately 10 million patients. Civica Rx serves more than 50 health systems, representing more than 1,350 hospitals and more than 30 percent of all licensed hospital beds in the United States (Civica Rx also supplies the U.S. Department of Veterans Affairs, the U.S. Department of Defense and "340B" hospitals, which care for vulnerable patients in some of the most underserved areas of the country. In just over a year, Civica Rx launched 20 sterile injectable medications and expects to launch another 20 medications this year, building toward 100 by 2023. Civica Rx ensures it has dedicated manufacturing capacity for the medications that are most needed through redundant manufacturing and a strategic safety stock of medications. See also "Phlow Corporation Awarded $354 Million HHS/ASPR/BARDA Contract to Manufacture Essential Medicines in Shortage." https://www.prnewswire.com/news-releases/phlow-corporation-awarded-354-million-hhsasprbarda-contract-to-manufacture-essential-medicines-in-shortage-301061648.html?tc=eml_cleartime

To summarize, the BARDA initiative creates all of the elements of a solution to the essential medicine shortages in the U.S, anchored by a small number of strategic partners and geographically focused on the Richmond-Petersburg region. It provides strategies for near-term relief, a first-of-its-kind surge capacity SAPIR, and an ambitious long-term vision for U.S. based end-to-end advanced manufacturing infrastructure for essential and at-risk-of-shortage medicines. It will improve overall pharmaceutical quality. It will integrate with existing innovative distribution network programs to provide resiliency in the system. And it will level the playing field for essential medicine manufacturing and affordability through a proven advanced manufacturing platform and innovative distribution solutions.

The scope of the BARDA initiative and leadership and stature of the strategic partners are already drawing interest from the industry leaders. In February 2021, United States Pharmacopeia (USP) announced that it will establish an operation beside the laboratories of Phlow and M4ALL in Richmond's Virginia Bio+Tech Research Park and form a strategic alliance to support the development of analytical processes and quality standards for continuous manufacturing of pharmaceuticals.[58] USP is a nearly 200-year-old independent, scientific non-profit organization that collaborates with the world's top experts in health and science to develop quality standards for the manufacture of medicines which are referenced by the FDA and other global regulatory agencies. At its Richmond laboratories, USP will work with Phlow and M4ALL to develop standards for analytic methods and early scientific and regulatory guidelines to establish and assure quality in the new continuous processes manufacturing of small molecule medicines.[59] The methods and standards developed through the strategic alliance will be made available for use by the FDA and other domestic generic manufacturers to establish a foundation for broader adoption of this new manufacturing process in order to strengthen the U.S. drug supply.[60]

[58] Business Newswire (Feb. 22, 2021). "Phlow Corp. and USP Announce Strategic Alliance Focused on Pharmaceutical Continuous Manufacturing to Increase Supply of Essential Medicines for U.S. Patients." https://www.businesswire.com/news/home/20210222005551/en/Phlow-Corp.-and-USP-Announce-Strategic-Alliance-Focused-on-Pharmaceutical-Continuous-Manufacturing-to-Increase-Supply-of-Essential-Medicines-for-U.S.-Patients

[59] Edney, Anna. (Feb. 22, 2021). "Researchers in a Virginia Lab Lay Groundwork for U.S.-Made Drugs." Bloomberg. https://www.bloomberg.com/news/articles/2021-02-22/researchers-in-a-virginia-lab-lay-groundwork-for-u-s-made-drugs

[60] For further background on the importance to FDA of developing quality standards and regulatory expertise for the regulation and commercialization of continuous manufacturing of pharmaceuticals, see Hahn, Stephen (FDA Commissioner) and Anand Shah (Deputy Commissioner for Medical and Scientific Affairs, FDA) (August 3, 2020). "Investing in Advanced Manufacturing to Support Public Health Preparedness." U.S. Food and Drug Administration. https://www.fda.gov/news-events/fda-voices/investing-advanced-manufacturing-support-public-health-preparedness

The emerging cluster of advanced pharmaceutical manufacturing and R&D

Cluster analysis in economic development

The previous sections describe an impressive array of initiatives and achievements in pharmaceutical manufacturing and R&D in the Richmond/Petersburg, Virginia region by a growing list of impressive players. The field of economic development provides tools to better understand such an array. Cluster analysis is a leading tool, and provides a framework for revealing strengths and gaps, opportunities and threats, and ways to help firms and the regional economy thrive. Cultivating target industry clusters is a specific strategy of the current Administration's Comprehensive Economic Development Policy for the Commonwealth.[61] Regional clusters are a cornerstone of the GO Virginia approach to economic development,[62] and cluster analysis is the framework for the Region 4 Economic Growth and Diversification Plan.[63]

Amy Liu, vice president and director of the Brookings Institution's Metropolitan Policy Program, explains that industry clusters form the foundation of regional economies and understanding a cluster's unique composition is essential to improving the performance of a regional economy[64]:

> Advanced technology-based industries comprise the most important clusters in a region, and the majority are located in metropolitan areas. Globalization and technology have not dispersed these market assets but instead have further concentrated them in cities and metropolitan regions because innovation today reinforces the power of place ... collaborations are most readily forged through the networks formed within metropolitan regions. Clusters are comprised of anchor firms, supply chains, supporting entities and organizations, research centers and specialized knowledge assets ... including applied research and technical expertise, supports for entrepreneurial activity, robust pipelines of skilled labor, deep benches of suppliers and related firms, globally connected infrastructure, and responsive, predictable governance to maintain them all.

[61] Governor Ralph S. Northam (December 7, 2018). "A Comprehensive Economic Development Policy for the Commonwealth." P.11. https://www.governor.virginia.gov/media/governorvirginiagov/governor-of-virginia/pdf/A-Comprehensive-Economic-Development-Policy-for-the-Commonwealth.pdf

[62] GO Virginia. "About the Virginia Growth and Opportunity Board." https://govirginia.org/about/state-board/. Responsibilities of the GO Virginia board include "organizing advisory committees around industry clusters and other areas of opportunity to inform the work of the regions." See also https://govirginia.org/2017/12/2017-go-virginia-annual-report/ GO Virginia. *2017 Annual Report*. P.3: "DHCD also worked in collab oration with the Virginia Economic Development Partnership (VEDP) in the development of the RFP and served on the committee that selected McKinsey and IBM to complete the 'Target Industry Economic Growth Strategy for the Commonwealth,' which included a cluster analysis for each of the nine GO Virginia regions. This cluster analysis was used by each of the regions in the selection of priority industry clusters for their respective regional Economic Growth and Diversification plans."

[63] GO Virginia (2017). *Grow Capital Jobs Economic Growth and Diversification Plan*. P.9. See also GO Virginia (2019). *Region 4 Updated Economic Growth and Diversification Plan.* P.17. http://growcapitaljobs.org/region-4-growth-diversification-plan-2019.pdf

[64] Liu, A (2016). *Remaking Economic Development: The Markets and Civics of Continuous Growth and Prosperity.* The Brookings Institution Metropolitan Policy Program. PP.12-13. https://www.brookings.edu/wp-content/uploads/2016/02/BMPP_RemakingEconomicDevelopment_Feb25LoRes-1.pdf

The key characteristics are geographical concentration and significant economic interrelatedness — the degree to which firms share products and services, supply chains, occupations and/or technological know-how.[65] It's the synergy among them that engenders collaborations that create value and generate income and growth.

This white paper now looks back with the tool of cluster analysis at the players, activities and relationships in the region earlier described. The starting point is a focused and precise definition of the cluster, followed by identification and assessment of key drivers, and then a picture of what this emerging cluster can become. The white paper closes by offering fundamental observations on how we can move forward as a region to realize the promise.

Defining the emerging cluster

A cluster definition should be sufficiently focused to enable a clear description of assets and comparison of the region's competitive position, yet broad enough to anticipate dynamic growth and development. The more specific the definition, the easier for stakeholders to discriminate between core and peripheral strengths, weaknesses, opportunities and threats. Specificity also helps to set priorities for goals, action and investment. A good cluster definition is clear to an informed audience and understandable to a lay audience. It is the foundation for alignment of stakeholders, and clear communication to all audiences, internal and external.

The emerging cluster in the Richmond/Petersburg region can be defined as follows:

- Advanced pharmaceutical manufacturing of small molecule medicines, from key starting materials to active pharmaceutical ingredients (APIs) to finished formulations
- Continuing development and deployment of continuous processing and other innovative pharmaceutical manufacturing platforms
- Chemical and engineering research and development which creates and applies the technology to individual molecules and medicines and enables the advanced processing technologies which produce them in new and better ways
- End-to-end supply chain integration and resiliency for these medicines through innovation
- The talent that makes it all happen

This cluster addresses the profound, unmet need to ensure a safe, affordable, reliable supply of medicines in the U.S. and the developing world, starting with essential generic medicines.

[65] Grow Capital Jobs Foundation (2017). "Economic Growth and Diversification Plan." *GO Virginia Region 4*. P.32. http://growcapitaljobs.org/gdplan.html

It is important to note in the definition several key terms, which differentiate the emerging cluster from life sciences broadly, and even from drug discovery and development.

The focus of the cluster is *manufacturing*. The seminal R&D in chemistry and chemical engineering by M4ALL at VCU Engineering is focused on transforming the ways medicines are manufactured. The collaborators create and deploy the advanced technologies that are enabled by those discoveries. Most observers accept that the U.S. has the potential to compete globally in manufacturing if we employ "*advanced manufacturing*." Advanced manufacturing includes and implies application of information technology (IT) and operational technology (OT), as well as sensors, imaging, measurement, quality control and quality assurance, advanced processing techniques and automation. In the pharmaceutical setting this especially includes continuous flow processes. Without adopting advanced manufacturing, the effort to reshore pharmaceutical manufacturing will be unsustainable, no matter how well-intentioned. This draws on the considerable talent and advanced manufacturing in the Petersburg region[66] and is a target industry of the commonwealth[67] and region.

The cluster as defined focuses on small molecule medicines only. This maintains the focus on synthetic chemistry and chemical engineering in which M4ALL now has a strong advantage, and not microbiology and bioreactors, which are the technologies of large molecule/biologics medicine manufacturing. While "big pharma" pursues blockbuster large molecules and biosimilars, small molecule medicines are the exclusive focus of Phlow Corp. and its collaborators under the BARDA initiative and distinguish this cluster's mission. The field is enormous, as small molecule drugs comprise the vast majority of therapeutics in today's pharmaceutical market.[68]

The focus is further limited initially to *generic* small molecule medicines. Generic, small molecule drugs are responsible for 90% of all prescriptions filled in the US, and most of the medicines in the world by volume.[69] They include many, if not most, short-supply and essential drugs.[70] With this focus, the cluster can demonstrate leadership in opening access to affordable health care and ensuring reliable availability of high-quality medicines. Importantly, with the cluster anchored at the extremely low-risk end of the drug

[66] Ibid. P.85.
[67] Governor Ralph S. Northam (December 7, 2018). "A Comprehensive Economic Development Policy for the Commonwealth." P.11. https://www.governor.virginia.gov/media/governorvirginiagov/governor-of-virginia/pdf/A-Comprehensive-Economic-Development-Policy-for-the-Commonwealth.pdf
[68] "Small molecule drugs still account for about 90 percent of the therapeutics in today's pharmaceutical market." Cohen, Yuval (November 23, 2015). "Small Molecules: The Silent Majority of Pharmaceutical Pipelines." *Xconomy Boston* https://xconomy.com/boston/2015/11/23/small-molecules-the-silent-majority-of-pharmaceutical-pipelines/
[69] Association for Accessible Medicines (2020). *Generics and Biosimilars Industry Response to COVID-19*. https://accessiblemeds.org/sites/default/files/2020-04/AAM-industry-response-and-supply-chain-COVID-19_0.pdf
[70] Flammia, Anthony, Richard Manning, Kristina McKean and Patricia Watson (August 2020). "An Integrated Supply Chain, A Whitepaper on Addressing Essential Medicine Shortages." *Phlow Corporation*. See Figure 1 "Injectable drugs on both the FDA Drug Shortages List and WHO Essential Medicines List (as of July 7, 2020)." https://www.phlow-usa.com/integrated-supply-chain-white-paper/

development continuum, lay and expert audiences alike will understand this is different than drug discovery or development clusters as exist in other regions of the U.S. All the drugs manufactured in this cluster have already been discovered, developed, approved and have a track record of safety and efficacy.[71]

Supply chain innovation is a distinct and essential element of the emerging cluster that actually starts with the R&D. A key, innovative approach at M4ALL is to create new synthetic routes and chemical processes by reimagining the identity of key starting materials with an eye to the source, cost and reliability of their supply. A goal of the BARDA initiative and its collaborators is to create new structures and processes to deliver essential medicines reliably into the hands of providers and patients,[72] both in the developed and developing world.

Evaluating the emerging cluster: It is localized, has leading drivers and is strongly economic interdependent

Essential features of a strong cluster include geographic proximity, leading market drivers, a strong economic interdependence of firms and institutions, and a robust talent pipeline. The emerging advanced pharmaceutical manufacturing cluster in the Richmond/Petersburg region has them all.

Geographic proximity

Geographically, all of the essential elements of the cluster are within our region. The cluster has a bimodal profile spanning the region, with R&D now concentrated at and around M4ALL in downtown Richmond and at VCU, and manufacturing in Petersburg at the AMPAC Fine Chemicals site. It is at or adjacent to that site where both Phlow and Civica Rx are constructing their manufacturing and distribution centers. Both of the Richmond and Petersburg locations are immediately adjacent to Interstate I-95 and a direct 30-minute drive from one another. Many industrial and office developments in various localities are only minutes away, off I-95 by Interstate or U.S. highways throughout the region. The entire corridor and surrounding regions boast rich transportation, infrastructure and logistics resources, as well as access to a broad and diverse pool of technical and manufacturing talent. The neighboring city of Hopewell boasts a strong chemical manufacturing industry and a successful history of advanced manufacturing in other industries.

The leading technology, researchers and facilities in the field are at Medicines for All in the VCU College of Engineering

[71] The technology and talent that powers this cluster may equally be applied to branded approved small-molecule drugs if the opportunity arises, as well as to innovator small molecule drugs. Those products would represent somewhat different markets, competitors, economics and risk profiles, moving toward the riskier discovery end of the drug development continuum. Legacy pharmaceutical companies may come to see the benefit of the innovations which power this cluster and choose to adopt them for these products, or the U.S. Food and Drug Administration (FDA) may require them to be adopted. If and when this occurs, the cluster will be well positioned – perhaps best positioned — to lead that expansion.

[72] Flammia, Anthony, Richard Manning, Kristina McKean and Patricia Watson (August 2020). "An Integrated Supply Chain, A Whitepaper on Addressing Essential Medicine Shortages." *Phlow Corporation*. https://www.phlow-usa.com/integrated-supply-chain-white-paper/

New chemistry and chemical engineering methods are at the root of the new pharmaceutical industry paradigm. Virtually every company will be faced with performing new R&D on their products or services to integrate them with new advanced manufacturing platforms. VCU leads in this now. This chemistry forms the basis for the work of the BARDA collaborators.

VCU College of Engineering will be a magnet for companies seeking to join the cluster for advanced pharmaceutical manufacturing. VCU's R&D will be a development engine for the equipment, supplies, technologies, systems and services that will comprise the advanced manufacturing cluster. Companies will be interested to co-develop and co-locate R&D at VCU. This will further entice other companies to locate their development and manufacturing in the region.

The M4ALL team has a successful track record with a growing list of APIs that demonstrate the effectiveness of its innovative approach. M4ALL's researchers have shown they can cut the costs of production and externalities, even in legacy batch production manufacturing. M4ALL has developed a wealth of data that demonstrates their approach works; in concept, in the lab, in industry — and around the world. M4ALL's years of leadership in this space has helped them to establish collaborative relationships across the country, resulting in a broad and effective research network. VCU College of Engineering's work has earned it a global reputation.

The nation's leading commercial effort to create end-to-end, continuous flow advanced pharmaceutical manufacturing: Phlow, AMPAC Fine Chemicals and Civica Rx

Because of the BARDA initiative, Petersburg has become home to the leading national investment in accelerating continuous process advanced pharma manufacturing and pharmaceutical reshoring. On its one-of-a-kind campus, Phlow, AMPAC and Civica Rx are manufacturing and creating a national strategic reserve of the nation's most essential active pharmaceutical ingredients, developing continuous-process advanced manufacturing capabilities for APIs, key starting materials and finished injectable formulations, and manufacturing finished injectable formulations for the nation's hospitals and strategic reserve. They are deeply linked with M4ALL for research and development and training the talent for R&D and manufacturing.

This cluster will create breakthroughs. It will also surface needs for collaboration, create employment opportunities and draw a core of talent to the region. Other cluster companies and institutions locating here will support the cluster. The decision by United States Pharmacopeia (USP) to locate a satellite lab in Richmond is an early and telling example. Their strategic alliance with Phlow and M4ALL will create the quality standards that will serve as the reference for the continuous flow manufacturing of small molecule pharmaceuticals.[73] Petersburg is close to Richmond, and also neighbors Hopewell, a city that boasts a strong

[73] Business Newswire (Feb. 22, 2021). "Phlow Corp. and USP Announce Strategic Alliance Focused on Pharmaceutical Continuous Manu-

chemical manufacturing industry and a successful history of advanced manufacturing in other industries. The region as a whole is known for its logistics capabilities, thanks to its strategic location and network of transportation and logistics resources.

Economic interdependence

The leading drivers of the industry in the cluster are indeed at the forefront of their fields, and they are also deeply and necessarily interconnected. The advanced manufacturing techniques rely on sustained R&D. Phlow and AMPAC Fine Chemicals rely on M4ALL chemistry for their products and processes. VCU and M4ALL are essential suppliers of talent at the undergraduate and specialty graduate levels that are needed. The point of the BARDA grant is for the three firms to closely collaborate with one another and VCU, to progress through the stages of the contract. The supply chain for the companies will have many common threads.

The talent to thrive

A cluster is not only composed of technology, firms, products and services, it is the right mix and concentration of talented people as well. It's the talent who enables the growth of companies and organizations in the region and attracts outsiders to come here to work, invest, innovate, open and grow operations.

This emerging cluster with its ambitious R&D, advanced manufacturing technologies and reimagined supply chain requires a wide and diverse community of talent. This includes career experienced workers and newly matriculated graduate and undergraduate technical degree holders, and a strong backbone of middle-skill level technicians. The constituent firms in the cluster will need large numbers of technical and production personnel who won't require a four-year degree. In its growth phase, the cluster will need both to fill today's needs and establish a robust workforce pipeline to sustain the future. Building this workforce requires vision, structure, communication and collaborative relationships from all corners of industry, high schools, community colleges and universities, and local, regional and state economic development entities.

Ph.D. and master's degree talent is required to spearhead the innovative chemistry and chemical engineering that powers this cluster and will translate and develop it into competitive advanced manufacturing facilities. VCU College of Engineering is perhaps the leading producer of talent in this field in the world. In the classes and labs, chemists and chemical engineers learn and work side by side. They are trained in the unique framework of M4ALL.[74] VCU's Ph.D. program in pharmaceutical engineering is the only one of

facturing to Increase Supply of Essential Medicines for U.S. Patients." https://www.businesswire.com/news/home/20210222005551/en/Phlow-Corp.-and-USP-Announce-Strategic-Alliance-Focused-on-Pharmaceutical-Continuous-Manufacturing-to-Increase-Supply-of-Essential-Medicines-for-U.S.-Patients

[74] Wright, Rob (January 4, 2021). "Frank Gupton – Revolutionizing Pharma Manufacturing from the Outside In. " *Life Science Leader*.

its kind in the country.[75] VCU is home to the interdisciplinary Center for Pharmaceutical Engineering and Sciences,[76] a collaboration between the VCU School of Pharmacy and VCU Engineering – one of only a few such centers in the country. VCU Engineering organizes its undergraduate programs in this field differently from other schools, and it has proven amazingly effective. Students are offered the ability to study for both a chemistry and chemical engineering undergraduate degree. This option is so popular that 70% of VCU chemical engineering students graduate with double majors.[77] The BARDA initiative provides significant financial support for VCU to educate and train these specialized students in close collaboration with the Phlow and its strategic partners, the firms building the emerging cluster. This strengthens VCU's focus and excellence in educating the talent for the new chemistries and processes which are foundational to advanced pharmaceutical manufacturing and the manufacturing processes and products of Phlow and its collaborators. Recently VCU was funded for workforce, training and research in cybersecurity of advanced manufacturing.[78]

Complementing VCU's unique strengths are chemistry and engineering programs at the many and diverse colleges and universities across Virginia.[79] These include the College of Engineering and Technology and the College of Natural and Health Sciences at Virginia State University,[80] whose campus lies just a few miles from AMPAC's Petersburg manufacturing site. VSU offers the state's only Bachelor's Degree program in Manufacturing Engineering and Information Logistics Technology.[81] This deep pool of talent at Virginia universities is looking for the opportunity to stay in Virginia and the greater Richmond area is an attractive destination.

Virginia's Community College System has long embraced industry partnerships to design and implement programs that benefit students and the commonwealth's employers. In the Community College Workforce

https://www.lifescienceleader.com/doc/frank-gupton-revolutionizing-pharma-manufacturing-from-the-outside-in-0001

[75] "VCU has first pharmaceutical engineering PhD program"(Aug. 11, 2019). *Richmond Times-Dispatch*. https://www.richmond.com/news/local/education/vcu-has-first-pharmaceutical-engineering-phd-program/article_3aba6266-09b7-5265-8e03-aec87cc003d5.html

[76] "Center for Pharmaceutical Engineering and Sciences." Virginia Commonwealth University. https://pharmegr.vcu.edu/

[77] Wright, Rob (January 4, 2021). "Frank Gupton – Revolutionizing Pharma Manufacturing from the Outside In." *Life Science Leader* https://www.lifescienceleader.com/doc/frank-gupton-revolutionizing-pharma-manufacturing-from-the-outside-in-0001

[78] Gerlach, Kendra and Emily Guajardo (November 19, 2020). "VCU Part of $111M cybersecurity manufacturing partnership." *VCU News*. Virginia Commonwealth University. https://news.vcu.edu/faculty-and-staff/VCU_part_of_111M_cybersecurity_manufacturing_partnership
The US Department of Energy in November 2020 awarded $111 million to the public private partnership Cybersecurity Manufacturing Innovation Institute, a consortium of 59 members including VCU Engineering. The Goal of the award is to introduce advanced cybersecurity to automated and advanced manufacturing, securing the nation's supply chain, and building a national program for education and workforce development.

[79] Other higher education institutions in Virginia offering engineering programs are Christopher Newport University, George Mason University, Hampton University, James Madison University, Liberty University, Norfolk State University, Old Dominion University, Sweet Briar College, the University of Virginia, Virginia Military Institute, Virginia State University, Virginia Tech and Washington and Lee University.

[80] "College of Engineering and Technology." Virginia State University. https://www.vsu.edu/cet/index.php

[81] Virginia State University College of Engineering and Technology. "Manufacturing Engineering." https://www.vsu.edu/cet/departments/engineering/programs/manufacturing-engineering/index.php Indeed it is the only such program between Pennsylvania and Georgia. See also GO Virginia Region 4 (2017). "Economic Growth and Diversification Plan." *Grow Capital Jobs Foundation*. P.86.

Alliance (CCWA), the region has a unique asset.[82] CCWA is an industry-facing workforce initiative conceived and supported by two of the region's community colleges — John Tyler Community College[83] and J. Sargeant Reynolds Community College.[84] CCWA aligns its efforts and pools its deep experience in meeting the workforce needs of the region's industries and potential workers. Through CCWA, the two institutions are already working with AMPAC and Civica Rx in planning tailored workforce training programs for the specific needs of pharmaceutical manufacturing that lie ahead.

Supplementing the workforce efforts of higher education are local, regional and state-level public policies and programs. Virginia was ranked the top state in the country for both Education and Workforce (two separate categories) by CNBC in 2019,[85] reflecting that workforce is a top priority of the state's economic development authorities. In Virginia, companies building new or expanding facilities are able to quickly attract and train high-quality workers by their choice between two of America's best workforce incentive programs[86] run by the Virginia Economic Development Partnership (VEDP). One offers new or expanding companies grants to reimburse a large portion of recruitment and training costs, and the other offers tailored workforce solutions services at no cost to employers. VEDP officials are already working with AMPAC and Civica Rx to help meet their workforce needs.

Virginia also hosts two university-industry statewide consortia with foundational expertise for this emerging cluster. Both are located in this region. They both provide ready collaborators with specialized research, development and technical support, along with employee training, experiential learning placements, talent identification and recruitment.

The Commonwealth Center for Advanced Manufacturing (CCAM) is a public-private collaborative research center that undertakes research critical to advanced manufacturing industries tailored to the region's needs.[87] CCAM's mission is to bridge the gap between leading edge research and product development, and to do so it stays at the forefront of new manufacturing processes. Five of Virginia's leading academic

[82] Community College Workforce Alliance. http://ccwatraining.org/
[83] John Tyler Community College. https://jtcc.edu/
[84] J. Sargeant Reynolds Community College. https://www.reynolds.edu/
[85] Cohn, S. (July 10, 2019). "Amazon had it right: Virginia is America's Top State for Business in 2019." CNBC. https://www.cnbc.com/2019/07/09/virginia-is-americas-top-state-for-business-in-2019.html
[86] "Recruitment and Training Incentives." *Virginia Economic Development Program*. https://www.vedp.org/incentives#incentive7 The Virginia Talent Accelerator Program provides world-class training and recruitment solutions that are fully customized to a company's unique operations, equipment, standards and culture. All program services are provided at no cost to qualified new and expanding companies as an incentive for job creation. The Virginia Jobs Investment Program (VJIP) provides services and funding to companies creating new jobs or implementing technological change to reduce human resource development costs for new companies, expanding companies and companies retraining their employees.
[87] CCAM has an ongoing research thrust in distributed manufacturing, which focuses on understanding capability and capacity, quality validation and distribution of production to a global, dynamic network of local manufacturing assets. CCAM's skills in the application of new and developing technologies in advanced sensing, digital interconnectivity, data typing and semantics, data analytics and system-of-processes intelligence. Interviews with CCAM leadership.

research universities are organizing members of CCAM.[88] Just a five-minute drive from the AMPAC/Phlow/Civica Rx site in Petersburg, CCAM's 62,000-sq. ft. Manufacturing Research Center features computational and engineering research labs, high bay production space for commercial scale equipment and tools required for research in manufacturing systems.

CCAM works with the region's industries and higher ed to create and operate innovative and needed workforce training programs. In February 2021, CCAM and Petersburg's Richard Bland College of William and Mary received funding to launch an Advanced Manufacturing Academy based on the nationally recognized Advanced Manufacturing Technician program associated with the FAME network and the National Association of Manufacturers.[89] This successful model recruits, trains and provides cooperative on-site work experience to candidates just entering the field of advanced manufacturing.

The Commonwealth Center for Advanced Logistics Systems (CCALS) is a consortium of Virginia universities with focus in advanced logistics systems.[90] CCALS provides research-intensive, project-based work for private industry and public organizations with professor-led teams of students. The collective expertise of CCALS scholars and industry veterans has the potential to contribute to a world-class understanding of the complete global supply chain impacting the manufacture and distribution of medicines, as well as to train and introduce students to firms in the cluster.

The work of the emerging cluster is fully aligned with the region's economic development planning and with compelling and timely national interests

This emerging advanced pharmaceutical manufacturing cluster aligns perfectly with the Region's GO Virginia economic development plans. This cluster stands at the intersection of three more broadly defined clusters identified as the top priorities for Region 4: life sciences, advanced manufacturing and logistics.[91] In this way, it draws on regional strengths, and adds focus. As defined, the cluster is characterized by strengths highly regarded in the Region 4 Plan, namely, that efforts in the life science cluster: (i) be focused on life science business that provide tradable sector goods and services (that is, exchanged for value with those outside

[88] Commonwealth Center for Advanced Manufacturing. "Members: Academia." *CCAM.* https://ccam-va.com/members-academia/. The five are Old Dominion University, University of Virginia, Virginia Tech, Virginia Commonwealth University and Virginia State University. The engineering schools at these universities combined have more than 500 faculty members conducting research and educational programs in disciplines such as: aerospace engineering, mechanical engineering, industrial engineering, systems engineering, and materials science and engineering.
[89] FAME students will be housed at Richard Bland College and will have paid co-op or part-time jobs with regional employers, including AMPAC Fine Chemicals and Phlow. They will learn not only technical job skills but also manufacturing practices and culture, while receiving formal education toward an associate's degree. See Crater Planning District Commission (January 27, 2021). "Approved Projects by the Region 4 Regional Council," distributed in advance of a public Zoom meeting of the Comprehensive Economic Development Strategy Committee meeting held February 27, 2021.
[90] Commonwealth Center for Advanced Logistics Systems https://www.ccals.com/ The universities are Longwood University, Old Dominion University, University of Virginia, Virginia Commonwealth University and Virginia State University.
[91] Grow Capital Jobs Foundation (2017). "Economic Growth and Diversification Plan." *GO Virginia Region 4.* PP. 89, 104-106. http://growcapitaljobs.org/gdplan.html

the region),[92] and (ii) have that "crucial" connection with research and innovation at VCU.[93] Importantly and uniquely, this cluster both relies on and provides benefits widely to diverse locales within the region (geographically, economically and socially).[94] It fully satisfies GO Virginia's stated prioritization of industries with high average wages and high growth and those that draw revenues and investment from outside Virginia. Indeed, the Region 4 Plan specifically identified and prioritized M4ALL's activities as a significant and transformative cluster development project.[95] The activities of VCU, private sector and leading federal and philanthropic funders exemplifies the recommendations of the study commissioned by GO Virginia's sister initiative Virginia Research Investment Council.[96]

From the national perspective, the efforts of M4ALL, Phlow and other firms comprising the emerging cluster align with multiple fundamental market, social and public policy national interests. The emerging cluster is an extraordinary convergence of both urgent and important national interests and values. These are unifying, non-partisan, and have enjoyed increasingly strong support from all administrations and congresses. The COVID-19 pandemic has highlighted the importance of these interests and made the case for the emerging cluster even more compelling and urgent across the political spectrum.

The extraordinary alignment with regional and national interests and aspirations means that the forces and factors driving the development of this emerging cluster are powerful, profound and enduring. While this emerging cluster has developed impressively over the last year, vigorous growth is at hand. Understanding that the cluster is in the development stage suggests which opportunities and gaps should be attended to, and which players will be interested to come. It underscores the urgency of the moment. And lifts our head to look ahead at what a mature cluster might be.

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[92] Ibid. P.8. "The Council should promote health, life science and wellness innovations that develop products, processes, firms and institutions with tradeable, competitive advantages." It is evident that the manufacture of the world's most essential medicines and the discovery, development and manufacture of advanced pharmaceutical manufacturing techniques, sells to a national and global market and is a tradable sector.

[93] Ibid. P.8. "On industry clusters, the plan notes that the health, life sciences, bioscience cluster is perceived by stakeholders to have the region's highest potential for growth. Commercializing research innovations at Virginia Commonwealth University will be *crucial* to tapping this potential." (Emphasis added.)

[94] Liu, A. (2016). Remaking Economic Development: The Markets and Civics of Continuous Growth and Prosperity. The Brookings Institution Metropolitan Policy Program. P.13. "As leaders strengthen and align their assets to the demands of the global economy, they must be conscientious about engaging people and places all across the region if they are to put their metro areas on a higher growth trajectory to attain deep prosperity." https://govirginia.org/2016/02/remaking-economic-development-the-markets-and-civics-of-continuous-growth-and-prosperity/

[95] Grow Capital Jobs Foundation (2017). "Economic Growth and Diversification Plan." *GO Virginia Region 4*. P.89. See also Grow Capital Jobs Foundation (2019). "Economic Growth and Diversification Plan." *GO Virginia Region 4*. P.66.

[96] GO Virginia. (2019). "Virginia Research Investment Committee." https://govirginia.org/about/vric/#:~:text=The%20Virginia%20Research%20Investment%20Committee,of%20the%20GO%20Virginia%20Initiative.&text=Through%20Virginia's%20State%20Council%20for,Partners%2C%20LLC%20for%20this%20purpose Among the key recommendations of a report of current research assets were that Virginia universities: (i) set their sight on being more competitive for federally funded research centers, and (ii) bridging the disconnect between university research and Virginia -based company innovation. "Virginia needs to create statewide linkages to maximize its growth potential for innovation and incorporate strategic thinking to better geographically connect university activity with industry to realize its growth potential in each area." The report specifically identified the "key opportunity" presented to the state by M4All's revolutionizing the manufacturing of small molecule drugs for the goal of leveraging university research for economic development. VRIC commissioned TEConomy Partners, LLC, to produce this report.

A vision of the cluster in years to come

This white paper has provided a comprehensive description of the region's current firms and activities in advanced pharmaceutical manufacturing and assessed that they constitute a strong foundation for the growth of a cluster with enormous potential. Indeed, this region has assembled leading players and the momentum, and the mission aligns with compelling unmet needs of our time. Yet without a shared and clear vision, it will be impossible to build a collective commitment and align actions on clear practical steps to grow this important activity. So, what is the vision, and what will success look like?

The mature cluster of R&D and advanced pharmaceutical manufacturing will be concentrated in Richmond and Petersburg and draw from and extend benefits across the entire region and state. The region will showcase laboratory, pilot production and full-scale manufacturing infrastructure that is ready for use now, and ample to meet the needs of future robust growth. Firms here will lead in the development of the technologies, products and services. They will manufacture medicines, equipment and instrumentation that enables competitive manufacturing. And they will deliver the products and technologies that support an agile, innovative, end-to-end supply chain. The mature cluster will provide thousands of high-paying jobs. While some will require a Ph.D., many great careers will be possible with a high school diploma and post-secondary education and training delivered nearby. The region will boast a superb pipeline to recruit and train the talent to fill these very important jobs and send other talent out to lead the world. The firms and universities in the cluster will have an enormous impact on the health and security of the nation and the world.

The cluster will be the home to dozens of firms who lead the world in the invention, development, validation and deployment of new advanced manufacturing methods, unlocking the potential of continuous flow for the pharmaceutical industry. Some will be recognized industry leaders who set up an outpost here to be proximate to the center of the new industry. Others will be homegrown innovators and entrepreneurs. They will find and fill gaps and anticipate needs of the new industry for sensors, analytical chemistry, measurement, quality control instrumentation, information systems, processing equipment and automation for the new processes. Many will hail from other industries where continuous flow processes are well established, lending their expertise to adapt equipment and instrumentation to the rigorous demand of highly regulated pharmaceutical manufacturing. Experts in information technology, operations technology, enterprise systems, big data and cybersecurity will contribute significantly. So will organizations developing the quality control and assurance standards and instrumentation, who will provide the foundation for FDA regulatory review of continuous process manufacturing. As will the manufacturers of this specialized instrumentation and equipment.

This is already happening. Several years ago, when Gupton's lab was in the early stages of adapting its chemistry to continuous flow processing, they encountered a roadblock. In a certain chemical synthesis pathway under development, the researchers needed to measure the chirality of the molecules they made. At the time, chirality[97] of a molecule in solution could only be measured by halting the continuous process, removing a sample and testing it using a separate instrument. At an industry meetup event, Gupton met a scientist from Charlottesville startup BrightSpec.[98] BrightSpec created and manufactured instruments capable of measuring chirality using innovative and highly advanced technology licensed from federal radio astronomy labs. BrightSpec adapted its technology to provide accurate measurements of chirality in liquid flows.[99] This enabled Gupton's R&D to proceed and created an opportunity to manufacture new instruments to supply the emerging pharmaceutical continuous processing in Charlottesville.

New manufacturing platforms will be conceived and designed, manufactured and serviced here. M4ALL technologies enable distributed manufacturing systems and modules, and these are now under consideration to be developed and supplied around the world so that nations can produce as well as procure essential medicines and bring the quality and cost of such medicines under their control. Organizations and firms in the region will be key players in the global effort to reinvent and provide the poorest regions of the globe with the ability to secure reliable high-quality affordable essential medicines.

AMPAC, Phlow and other firms will manufacture APIs, and, in time, key starting materials. Multiple firms will manufacture finished formulations, among them Civica Rx, Phlow and perhaps others also will seek to create innovative supply chain solutions to get their products to users.

The technologies and talent will enable and inspire firms here to pioneer innovative end-to-end supply chain solutions. The cluster will include sophisticated warehousing, supply, distribution and logistics solutions, as the presence of strategic API reserves (SAPIR) will require sophisticated facilities and capabilities.
Led by M4ALL, Phlow and its partners, the cluster will be the intellectual and scientific center for the new industry. Year after year, the cluster will grow the number of students trained and placed, the chemistries reinvented, the networks of collaboration and support of sponsored research. M4ALL, collaborators at other Virginia universities, and firms in the cluster will increasingly invent, protect and employ intellectual property which creates the field in chemistry, chemical engineering and processing, measurement and control technology and systems. M4ALL will draw increasing financial support from an ever-wider range of sources, grow innovative R&D programs for U.S. and global health, and for the private and public sector. M4ALL's

[97] Chirality is a quality of the shape of asymmetric molecules, often described as "left- or right-handedness." A molecule's chirality impacts its behavior and may impact the effect of a medicine; thus, the FDA demands chirality be accurately measured, tightly controlled and reported.
[98] BrightSpec. http://brightspec.com/
[99] Neill, J. L.; Y Yang, M.T. Muckle, R.L. Reynolds, L. Evangelisti, R.E. Sonstrom, B.H. Pate and B.F. Gupton (2019). "On-line Stereochemical Process Monitoring by Molecular Rotational Resonance Spectroscopy." *Organic Process Research & Development*, 23 (5), PP.1046-1051. https://pubs.acs.org/doi/10.1021/acs.oprd.9b00089

global network of collaborators will enrich the entire cluster.

Firms and organizations in the cluster will be thought leaders as well as those leading the build-out of the development of advanced manufacturing, reshoring of pharmaceutical manufacturing and supply chain reinvention. The area will become a hub for global conferences for firms in the private sector, investors, philanthropic and government supporters.

The region will be home to private and public centers of excellence. Leading private companies will establish continuous flow development centers here, to be close to the researchers and first adapters of their products and services. Federal regulatory agencies and independent nonprofit organizations will fund and locate centers of excellence here to support their efforts in advanced pharmaceutical manufacturing. The region would be an ideal home to an FDA Center of Excellence in the Continuous Manufacture of API. Private and public stakeholders in the region will find opportunities to create or tailor existing centers of excellence such as a Commonwealth Center of Advanced Pharmaceutical Manufacturing Excellence which could provide competitive resources such as: rapid-launch facilities, process improvement and pilot labs, exhibitions of next-generation manufacturing and control systems, and a platform for companies, faculty and students to collaborate.[100]

The region will have the infrastructure required to service the firms here and attract new firms to the region. Increased laboratory space will be available for immediate use, both in close proximity to established players and across the region. One or more facilities will be available and designed to be easy-to-use landing spots for companies seeking to locate here. The stock of laboratory facilities will include an ample supply of pilot or scale-up space, and perhaps a single concentrated pilot / scale up translational park, in recognition of the special need of this cluster that stands at the translational or development end of the drug industry spectrum. One or more developers or localities will put in place basic spec lab space plus a system for assuring quick buildout or conversion of space for mid- and long-term needs. The commercial real estate and commercial real estate financial sectors will be aware and familiar with the economics and financial tools available to this industry. The region will have in place a system of private, local and state support with up-to-date information on supply and demand of laboratory and related space in existence or within quick reach by conversion.

[100] Institute for Advanced Learning and Research. "IALR To Build Center For Manufacturing Advancement." *In the News*. https://www.ialr.org/ialr-to-build-center-for-manufacturing-advancement/ This Center for Manufacturing Advancement, located in Danville, Virginia, will provide pre-competitive resources including: (i) rapid-launch facilities that will enable new businesses to begin limited operations while awaiting completion of their new or conversion factory to be constructed, equipped and brought into full operations; (ii) process improvement and pilot labs that will enable new and existing businesses to improve their processes without taking productive lines out of service; (iii) an exhibition of next-generation manufacturing systems, and (iv) a platform for collaborative innovation that allows manufacturing companies, technology companies and engineering students to work together to discover, integrate and showcase emerging technology, products and services.

Manufacturing facilities and sites will exist which are ready for regional firms or inbound firms to use to meet their needs, as well as a current inventory of such sites and their characteristics. A concentration will be at and near the Petersburg locus, but others will locate around the region, seeing different advantages in different locales. Some may wish to be at the northern reaches of the region and an hour away from Washington, D.C., a world-class city and home to the nation's public policy and regulatory powers over the industry. Others may prefer otherwise, and locate closer to the beach, or the mountains, or the complementary ecosystem at Research Triangle Park in North Carolina.

The cluster will enjoy a strong soft infrastructure as well, with the knowledgeable and enthusiastic support of economic development, industry and university organizations. Greater Richmond Partnership and Virginia's Gateway Region and their local economic development organization members, the Virginia Economic Development Partnership will be ready partners. Statewide, the Center for Innovative Technology, the Virginia Bioscience Health Research Corporation and GO Virginia will provide expert support. Local and statewide industry groups such as Virginia Bio, Virginia Manufacturers Association and Hopewell Manufacturers Association, and the tech transfer offices at the research universities will be at the ready to collaborate and support.

Again, led by VCU, the region will have the nation's best talent pipeline to support advanced pharmaceutical manufacturing of small molecule medicines. To make this work and drive it forward will require the collaborative systems which create and sustain a strong and responsive workforce pipeline. The talent pipeline exists. We recruit and retain from within Virginia as multiple organizations working together, anticipating needs. Strong job growth is anticipated across the region geographically, from Richmond to Petersburg and across the rest of the region, including strong job growth across the spectrum of occupations, from those requiring Ph.D.s to those requiring special training but no academic credentials beyond high school diplomas. Excitement will be present in high schools and community colleges throughout Virginia. Virginia's track record as a top place for talent will be extended to pharmaceutical advanced manufacturing.

There will be a well-known, easily identifiable, prestigious organization of stakeholders, driven by the private sector but fully supported by the public sector at the local, regional and state level, which leads the region's efforts to support firms and organizations in the cluster, and recruit others to move here and start here.[101]

[101] Liu, A. (2016). "Remaking Economic Development: The Markets and Civics of Continuous Growth and Prosperity." The Brookings Institution Metropolitan Policy Program. PP.15-16. https://govirginia.org/2016/02/remaking-economic-development-the-markets-and-civics-of-continuous-growth-and-prosperity. Liu explains, "Networked regions need strong flexible cross-sector institutional infrastructure and capacity with staying power. Leaders need to work through designated quarterback organizations capable of building trust and maintaining communications to keep everyone on the same page. And they need an equally able implementation organization to carry out the work."

This group of leaders will help the region look ahead and think strategically. They will identify challenges and propose solutions. They will make sure the relationships are in place to support the growth of the cluster day in and day out and monitor the region's collective commitments in workforce, infrastructure, cluster building, communications and other areas.

The region will identify itself and be known to the world as a cluster of advanced pharmaceutical manufacturing and R&D.[102] Localities and regional organizations will embrace and market that identity with clear concise messaging, in collaboration and coordination with one another. This will draw a steady stream of individuals and firms from across the nation and world who look to locate here and inspire and direct careers of Virginia students and curricula of Virginia higher education.

Local and state incentives which make sense and allocate benefits and risks for this cluster will be in place. Some of these will offer solutions for the need for long-term investment in utilities and services in infrastructure, especially overcoming challenges of fiscally constrained localities. Others will be tailored to the innovation and technology of this cluster, much like the successful data farm tax incentives were structured to support that industry.

The organizations and firms in the cluster will make an enormous impact on the region and state. They will create many high-paying, high-tech jobs. These will include jobs for highly trained scientific and engineering professionals. But more than half the jobs created will be in production and technical and require training but not a higher education degree. And the jobs will be distributed across the region and state, including some of the region's most economically distressed areas. They will provide opportunities for innovators and entrepreneurs, and for the expansion of local firms. The increased economic activity will make a big contribution to the fiscal well-being of localities and the coffers of the state. The demand for students and the opportunities for sponsored research will strengthen the community colleges and universities of the region and state.

The women and men at work in the cluster will have an enormous impact on the health and security of the nation and world. This work will lower the price and increase the quality of available medicines, including medicines now largely unavailable for children's rare diseases. Hospitals and health care systems will benefit from more predictable pricing and availability of medications. The reduced cost of generics will positively impact costs of government health care such as Medicare and Medicaid, as well as employer-based health insurance programs. The nation will have a more secure and resilient supply chain for the most essential medicines, and will be more able to withstand the pressures of global crises and pandemic. Many other

[102] Grow Capital Jobs Foundation (2017). *Economic Growth and Diversification Plan. GO Virginia Region 4.* Communicating and branding the region's appeal will be essential to enhancing competitive position.

nations and regions of the world will have their own dependable source of essential medicines for the first time in history. These and other impacts will be a great source of satisfaction and pride for these men and women, and for our university, region and commonwealth.

Moving ahead

"This is not just about chemistry, it's about vision and the right players. We are not just bringing molecules together; we're bringing people together to solve a problem." — Dr. Frank Gupton[103]

The potential of the emerging cluster of advanced pharmaceutical manufacturing is a compelling vision for the region, the commonwealth, the nation and the world. The interests are many and fundamental. At this moment in history, they are converging and hold a rare power to unify and motivate us.[104] How can we make the vision real? The Final Report recommends specific strategies. The first recommendation is essential: We must build on the extraordinary collaborative effort of countless stakeholders in performing this strategic planning process and organize a sustaining and resourced coalition powerful which will gather stakeholders, nurture the vision and lead the region's effort to realize this dream.

Yet without something deeper, we will be unable to bring this or any recommendations to life. This strategic planning process was not designed simply to produce a Final Report and recommendations. Every bit as important we gathered stakeholders, formed working relationships and created a treasury of common knowledge, shared values and attitudes. This is the rich soil in which we need to plant the recommendations of the Final Report.

- We will keep in mind the multiple and extraordinary ends that this work can achieve for our neighbors, our region and the world.
- We are grateful for and humbled by the responsibility to steward this opportunity and will do our utmost to bring it to its fullest potential for the nation and world.
- We will bring a sense of urgency and a sense of patience that are needed for fundamental change.
- We will act with exceptional collaboration and communication, creating a dynamic network of public and private entities including private firms, academics, philanthropies and all levels of government.
- We will make a significant investment of our attention, passion, time and resources, and hard work day after day.
- We will offer our leadership.
- We will bring an attitude to embrace and the skills to solve the challenges we know well – from

[103] Jones, R. (December 18, 2017). "A Meeting of the Minds: Thought Leaders Converge at VCU's Inaugural Medicines for All Summit. " *VCU College of Engineering.* https://egr.vcu.edu/news-events/news/archive/m4all-recap.html#
104 Allen, G. and T. McAuliffe (October 5, 2020). "Returning Drug Production to the United States is Good for All." *Morning Consult.* https://morningconsult.com/opinions/returning-drug-production-to-the-united-states-is-good-for-all/. See also Haymore, Todd (January 31, 2021). "Go Virginia's vision becoming a reality in Central Virginia." *Richmond Times Dispatch.* D-1. https://richmond.com/opinion/columnists/todd-p-haymore-column-go-virginias-vision-becoming-a-reality-in-central-virginia/article_e9fbf9b6-abbc-5348-bd09-23c8e4e41ae2.html

workforce to infrastructure, and novel challenges we will encounter, plus an openness to fresh approaches when old ways don't work.

- We will work for the common good of the region, finding ways and structures to do so while honoring our allegiances and commitments to our localities, confident that in supporting the regional cluster we will advance our individual interests as well.

To the extent we do so, then with the Final Report as a guide, with the talented and committed team of stakeholders who have brought this study to life and more who will join us, we will surely make the most of this opportunity for our region and the world.

Report of the Cluster Development Work Group

The Work Group (sometimes called the Infrastructure work group) was formed to describe the cluster infrastructure and supply chain, assess strengths, weaknesses and opportunities, guide the study by suggesting recommendations and form a working network of informed experts from key stakeholders who are equipped, enthused and ready to work together to support the cluster in the years ahead. The Work Group's fifteen members come from private industry, local, regional and state economic development organizations and economic development authorities. In these positions, many of them have been working daily for months learning and building solutions for the core cluster firms. **(Attachment 1)**

The emerging cluster

Over the last several years, a cluster of advanced pharmaceutical manufacturing and R&D has indeed emerged in the region. A timeline of milestones in the development of the emerging cluster is set forth as **Appendix 2**. The emerging cluster in the Richmond/Petersburg region can be defined as follows:

> Advanced pharmaceutical manufacturing of small molecule medicines, from key starting materials to active pharmaceutical ingredients (APIs) to finished formulations. Continuing development and deployment of continuous processing and other innovative pharmaceutical manufacturing platforms. Chemical and engineering research and development which creates and applies the technology to individual molecules and medicines and enables the advanced processing technologies which produce them in new and better ways. End-to-end supply chain integration and resiliency for these medicines through innovation; and the talent that makes it all happen. This cluster addresses the profound, unmet need to ensure a safe, affordable, reliable supply of medicines in the U.S. and the developing world, starting with essential generic medicines.

Four elements are to be noted: this is a cluster rooted in the manufacturing, not discovery, of medicines, and on small molecule medicines which are produced using synthetic chemistry, as opposed to, say, biologics which are manufactured using live biologic cells in fermentation and other processes. The initial focus is generic medicines, that is, medicines which have been approved, used for long time by many people with well establish safety and efficacy data, the vast majority of medicines used in the US and world today. Finally, the vision of the emerging cluster not only is manufacture, but reinvention of the supply chain, as evidenced by the BARDA contract to establish and operate a Strategic API Reserve, and the mission of CivicaRx to provide a direct source of supply of essential medicines at risk of shortage to its members - the nation's leading hospital and health care systems.

The key elements of a potentially dynamic cluster are present – geographic proximity, economic interrelatedness, a leading R&D institution in the cluster's distinguishing technology, anchor firms, specialized knowledge assets and a robust pipeline of educated and skilled talent capable of supporting the cluster's needs in R&D and manufacturing. The White Paper describes this in detail. **(Appendix 1 to the Final Report, at pp. 28-36)**.

A summary SWOT analysis (Strengths, Weaknesses, Opportunities and Threats) for the emerging cluster is set forth as **Attachment 3.** The analysis reveals compelling strengths and enormous opportunities and select weaknesses that can and must be addressed and are addressed in the Recommendations of this report. Two strengths stand out as powerful, unique and essential pillars– the Medicines for All Institute

at VCU College of Engineering and the innovative commercial strategic partnership of Phlow, AMPAC Fine Chemicals, Civica Rx and M4ALL under the 2020 BARDA contract to Phlow.

Because VCU is the source of the pioneering innovative R&D work in chemistry and chemical engineering that gives rise to the technology, VCU will be a magnet for companies and organizations looking to take part in the development and growth of advanced pharma manufacturing. VCU R&D will be an engine for development of the equipment, supplies, technologies, systems and services which will comprise the advanced manufacturing cluster. Companies will be interested in co-developing and co-locating R&D at VCU, and proximity to VCU R&D will entice companies to locate their development and manufacturing here.

The BARDA contract represents the first sizeable federal investment in a lasting solution to the vulnerability of the US supply chain of medicines. Advances in pharmaceutical manufacturing provide a long-sought financially competitive and sustainable path to reshoring the manufacturing of essential medicines. Continuous process manufacturing in particular promises to be faster, cheaper, more scalable, consume less energy, use fewer inputs and produce less waste, require a smaller footprint, have lower total labor costs, enable real time precise quality control and offer greater transparency to regulators. Phlow and its strategic partners will be building and operating the most advanced manufacturing complex to deliver on this promise. Their focus of supplying essential medicines at risk of shortage to the nation's hospitals and to the newly formed Strategic API Reserve, assures them a foundational role in the transformation of the industry underway. These companies indeed form the core of the new industry. And it can extend and expand in many directions. An end-to-end solution for the supply chain is the ultimate vision championed by Phlow. To the manufacture of key starting materials at the one end, to innovative approaches downstream to get medicine effectively and affordably to the provide or person who needs it when it is needed. Civica Rx is leading one supply chain revolution by manufacturing for member hospitals their own supply of essential medicines at risk of shortage. The recently announced Children's Hospital Coalition powered by Phlow is another example. Many more can spring from the cluster, attract new participants, and cause new growth and development in yet unimaginable ways.

The need and opportunity to build supply chain

A thriving cluster is characterized by a strong and broad supply chain for the innovation, goods and services it requires to operate and grow. Indeed, one characteristic of a true cluster is geographic concentration of interrelated members of a supply chain. Advanced pharmaceutical manufacturing is an emerging cluster in this region where little pharmaceutical manufacturing has occurred for years. And by its nature this is an innovative technology with many aspects still under development. Finding practical steps to close these gaps quickly will strengthen the cluster.

Attachment 4 provides a conceptual supply chain map for generic pharmaceutical manufacturing. The supply chain for continuous flow advanced manufacturing will differ in many respects. Though the commercial industry is in its infancy, its special needs for equipment and instrumentation, controls and other products and services is well discussed in the literature.[1] The Work Group interviewed leaders

[1] See for example

E*quipment and Analytical Companies Meeting Continuous Challenges May 20-21, 2014 Continuous Manufacturing Symposium*. Page T, Dubina H, Fillipi G, Guidat R, Patnaik S, Poechlauer P, Shering P, Guinn M, Mcdonnell P, Johnston C.J Pharm Sci. 2015 Mar;104(3):821-831. doi: 10.1002/jps.24282. Epub 2016 Jan 8.PMID: 28756844

from the core cluster firms and M4AL to identify priorities areas to help develop the technology and grow the cluster, and hence priority targets to recruit to the cluster and support. They focused on these key components of continuous flow pharmaceutical manufacturing systems which still demand significant development and adaptation: reactors, static mixers, pump systems and peak bed systems, sensors, software processes controls, quality control equipment, quality standards, analytical equipment and methods development, instrumentation, and plastic for tubing and hosing. Equipment and expert services for pilot and scale up also are needed. In the longer term, the cluster will engage in end-to-end continuous pharmaceutical manufacturing – from key starting materials at the one end to finished formulations at the other. And it will extend to completing the supply chain of finished formulations to patients and providers. Supply chain logistics for medicines and everything that is attendant, is needed, from warehouses, to transportation, to data systems, and big data if the cluster is to make major breakthroughs on anticipating supply chain disruption .

Collaborative action can help the cluster develop by a range of actions that can fill gaps and strengthening the supply chain. During the course of this strategic planning process, a zoom presentation was organized for Virginia companies and researchers to learn about the mission, players, technology and supply chain needs of the cluster from leaders at Medicines for All, Plow and AMPAC. Over 100 different organizations registered and attended. They also heard form Charlottesville based BrightSpec, on its successful collaboration with M4ALL in the develop of innovative instrumentation. In response to a follow up survey, responses from approximately 20% of attendees showed the program was very received, and attendees are eager for more and actionable information on what is needed and who to contact at the organizations.

Building Sites for new manufacturing and distribution facilities, and infrastructure

New pharmaceutical manufacturing and distribution facilities are under construction in the region. The locus of the facilities to date is at and adjacent to the AMPAC Fine Chemicals facility at the northeast quadrant of I-95 and US 460 (Wagner Road) just three miles south of Petersburg's central business district. There in 2019 AMPAC reopened the API manufacturing facility on site and since then has been expanding production, both for its own needs and recently to meet its responsibilities to Phlow under

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Control systems engineering in continuous pharmaceutical manufacturing. May 20-21, 2014 Continuous Manufacturing Symposium. Myerson AS, Krumme M, Nasr M, Thomas H, Braatz RD.J Pharm Sci. 2015 Mar;104(3):832-9. doi: 10.1002/jps.24311. Epub 2014 Dec 26.PMID: 25546650 Review.

Achieving continuous manufacturing: technologies and approaches for synthesis, workup, and isolation of drug substance. May 20-21, 2014 Continuous Manufacturing Symposium. Baxendale IR, Braatz RD, Hodnett BK, Jensen KF, Johnson MD, Sharratt P, Sherlock JP, Florence AJ.J Pharm Sci. 2015 Mar;104(3):781-91. doi: 10.1002/jps.24252. Epub 2014 Dec 2.PMID: 25470351 Review.

Achieving continuous manufacturing for final dosage formation: challenges and how to meet them. May 20-21, 2014 Continuous Manufacturing Symposium. Byrn S, Futran M, Thomas H, Jayjock E, Maron N, Meyer RF, Myerson AS, Thien MP, Trout BL.J Pharm Sci. 2015 Mar;104(3):792-802. doi: 10.1002/jps.24247. Epub 2014 Dec 12.PMID: 25501530 Review.

The synthesis of active pharmaceutical ingredients (APIs) using continuous flow chemistry. Baumann M, Baxendale IR.Beilstein J Org Chem. 2015 Jul 17;11:1194-219. doi: 10.3762/bjoc.11.134. eCollection 2015.PMID: 26425178 Review.

The Future of Pharmaceutical Manufacturing Sciences. Rantanen J, Khinast J.J Pharm Sci. 2015 Nov;104(11):3612-3638. doi: 10.1002/jps.24594. Epub 2015 Aug 17.PMID: 26280993 Review

the BARDA contract partnership. Phlow is building pilot and hybrid manufacturing facilities on site for the manufacture of API. Across N. Normandy Drive CivicaRx is building a new manufacturing and distribution facility for finished vial and syringe formulations. Adjacent to the Civica Rx site, Phlow is constructing the U.S. Strategic API Reserve for essential medicines.

The concentration of the facilities of these innovators promises to be a magnet to pharmaceutical manufacturers searching for a site to build a new facility to supply and participate in the new industry. Yet even with the pull of this "magnet" site selection is highly competitive. Pharmaceutical manufacturers are searching for ready sites. Companies want to make decisions quickly, complete negotiations quickly, start the build quickly, accept delivery quickly and begin operations as soon as possible. Time is money, and the time frame of decision-making is getting shorter. Ready sites also limit risk - the further along the site development continuum the fewer opportunities for surprise. It's easier for the company to control the project budget, and it's also easier for the state/region to formulate a development assistance and incentives proposal.

Site readiness is measured along the Site Characterization Tier Level continuum. The readiest sites are Tier 4 and 5. Tier 4 is defined as all infrastructure in place or deliverable within 12 months; all permit issues identified and quantified (often called "decision ready"). Tier 5 is that plus all permits are in place and the site is ready for site disturbance permit from locality. ("shovel ready").[2]. While Tier 5 is further advanced along the continuum, in some cases those extra pre-qualifications may actually complicate and delay the process if the permits are not exactly what is required. As a result, Tier 4 sites generally are considered suitably ready.

The region has a supply of sites ready for pharmaceutical manufacturing and the supply is increasing. Over the last several years state and regional economic development officials have made increasing the supply of ready sites a top priority. The Virginia Business Ready Sites Program (VBRSP) offers financial assistance to Virginia localities to develop and market existing industrial or commercial sites to prospective businesses. Under VBRSP, Phase I grants are awarded to localities and regions to assess industrial or commercial sites and determine their Site Characterization Tier Level. Phase II grants are awarded to assist in moving a site up to the next Characterization Tier Level. The program has been very well received and heavily used. GO Virginia has added its support to this effort by awarding grants to

[2] Virginia Business Ready Sites Program, Site Characterization Guidelines and Application 2019 https://www.vedp.org/sites/default/files/2019-03/VBRSP_Site_Characterization_Guidelines_and_Application_032719.pdf

help increase site readiness. It's having an impact across the region. Petersburg is a participant in a pending application to GO Virginia for funding to up–Tier 15 sites that were prioritized in a previous study. Five of these are specially suitable to support the cluster, as they are adjacent or near the AMPAC site and would be equipped to support advanced manufacturing and distribution.

Other sites across the Richmond - Petersburg Region identified by the work group which are ready to support pharmaceutical manufacturing include:

Crosspointe Centre (Prince George Co)(Rolls Royce)
Deepwater Industrial Park (City of Richmond)
Green Plains (Hopewell)*
Holland Axselle (Hanover Co)
Holland PG (Prince George Co)
James River Industrial Center (Chesterfield Co)
Meadowville Technology Park (Chesterfield Co)
Watkins Centre (Chesterfield Co)
West Creek Business Park (Goochland Co)
White Oak Technology Park (Henrico Co)

The utilities and other infrastructure required for pharma manufacturing sites are not categorically unusual, but there may be unusual specifications and importance on account of the type of facility and the nature of the manufacturing activity occurring, for example the use of flammable and/or toxic solvents often used in a synthetic chemical manufacturing process. Key site attributes and general regional assessment include principally: electric (rarely at issue as Dominion is responsive to additional needs); water (pressure and volume; some site accommodation can be made by adding pumps on site); gas (assume it is required, costly to supply if not present); fire (measured by response time; generally, adequate water assures adequate fire response); HazMat (measured by response time; generally, tracks with Fire); sewer(capacity measured by volume; risk measured by age and condition); Fiber/Data (generally sufficient or readily upgraded); transportation (typically within 1 mile of interstate highway is preferred); warehousing (nearby, including cold storage); and workforce (within ready access.)

Certain infrastructure concerns arose in the development of the Phlow and Civica Rx sites at and around the AMPAC site in Peterburg. Concerted action by local and state public officials and economic development agencies and state policymakers have addressed this and laid the foundation for fixing anticipated needs. The 2021-22 Virginia Budget includes a special funding item, Budget Item 112 #1c Commerce and Trade Economic Development Incentive Payments, which provides $10.0 million from the general fund to support water and sewer improvements necessary to sustain a regional pharmaceutical manufacturing cluster at and around the AMPAC complex in the City of Petersburg. State support was facilitated by the Virginia Economic Development Partnership, builds on commitments from Phlow and the City of Petersburg and involves use of the Department of Environmental Quality's Virginia Clean Water Revolving Loan Fund.

Recently, the seven locality members of Virginia Gateway Region (Colonial Heights, Hopewell and Petersburg cities, and surrounding counties of Dinwiddie, Prince George, Surry and Sussex) have created a Regional Industrial Facility Authority (RIFA) which will enable them to develop, own and operate one or more facilities on a cooperative basis. RIFAs are frequently used to deliver tailored infrastructure solutions and are part of the region's tool box for building the infrastructure and ready sites which the cluster will require.

Laboratory space

Initial interviews of stakeholders and discussions among the work group confirmed that the region lacks sufficient available lab space. This sharply constrains cluster growth now: lack of available lab space has delayed or prevented wiling collaborators with M4All and Phlow to bring operations here, and this will continue until and unless it is fixed. Solving this issue in the short term and implementing systematic improvements for the long term are top needs of the cluster. Initial interviews also revealed that accurate, comprehensive and timely data on the lab space market in the region does not exist.

In response to these initial findings the ECB study work plan was revised to engage Activation Capital to undertake a study on the supply and demand of lab space in the Richmond / Petersburg region. Activation Capital engaged nationally known consultant HR&A which conducted interviews with key stakeholders and experts in this region and regions across the country, researched publicly available databases and prepared a study report (**Attachment 5**.) The study was designed to produce a report with a preliminary analysis of: demand, segmented by tenant type including start-ups, emerging businesses, and large-scale enterprises; supply, including preliminary analysis accounting for potential conversion space; and emerging market gaps in the data on supply and demand. The report also was designed to provide a preliminary description of alternative programmatic options and operational models based on national best practices, and a preliminary outline of recommendation to create a demand analysis system which would be used to provide potential funders and developers with an idea for market appetite and to inform financial forecasting. The study confirmed the lack of available lab space in the region, save a small amount in a privately owned building in the Virginia Bio+Tech Research Park and which has proven to be out of range for many potential lessees. The study also confirmed the lack of planning in process to develop additional space which would become available, except for the Park's Project 8L. The scarcity of space and lack of development activity in the region contrasts sharply with other regions across the country. Lab and associated space has been one of the strongest segments of the commercial real estate market over the last decade. The pandemic highlighted the segment's resiliency and strength and the substantial recent investments by national industry leaders such as Alexandria Real Estate (Bethesda, MD) and BioMed Realty. See, e.g., *Biotech Offices Draw Billions of Dollars as Others Languish,* Wall Street Journal, July 2014, 2020, and *Blackstone Buys Lab Buildings for $3.45 Billion* Wall Street Journal, December 15, 2020. Importantly, the study also called attention to the lack of systematic information on the supply and demand for lab space in this region, and the significance of that lack to the potential of the region to increase lab space. The region does not have in place processes or structures to gather, harmonize, analyze and share meaningful information on the lab market. No commercial real estate services track life sciences / biotech / lab as a primary or secondary tracking point for this market, although this is commonly done in other more well-developed markets.

This is an important gap and closing this gap is an important step for the long-term growth of the cluster. Without such data, explicit demand is not quantifiable. This hinders the ability to plan, and the ability to demonstrate financial feasibility. The region needs to create a system to capture, record, analyze and share up to date information on current and projected demand and supply of lab and related space. Such systems exist in different forms in different US markets, and consultants will report shortly on best practices. One approach is to knit together a collaboration involving GRP, VGR, VEDP, Activation Capital, VCU, private sector firms and industry experts. Such information, once readily at hand, will support a range of daily economic development activities including recruiting new and supporting existing businesses. It will provide actionable information to private and public lab space developers and funders. Once established this system may be a model for other regions of the state directly or through the statewide network VABio-Connect, which recently was established with GOVirginia Competitive Grant funding. In addition or in connection with such a system, the region

should make an effort to entice a commercial real estate data firm to track the laboratory market in the region.

Another tool to address the lab space shortage is an open house for developers, builders, financial firms, architects and engineers from within and outside the region. Regional experts would provide best available data and describe the lack of lab space, the significance of the cluster and the opportunities it creates. Helpful guidance for such a program may be found in a different program in the region several years ago created to solve a different but similar problem. In 2016 the Greater Richmond Partnership Perhaps mounted an effort to showcase the need for and opportunities for spec industrial space development in the region. GRP hosted a familiarity tour for developers, an in-market visit, and an Investor Forum featuring a panel of regional experts. After this initiative, several developers from within and outside the region became active in developing space and today there is significantly greater supply of spec industrial space in the region. https://richmond.com/business/local/article_6f1a85ac-bc05-521e-8e08-e54bed319fe5.html

The question of what exactly is the "lab space" which is in demand and how it can be supplied is complex and requires study and a strategy. A selection of members of the work group focused on this issue and brought in other experts to help. Companies looking for space present different profiles and have different needs. Large companies typically prefer to design and build their own facilities anew. Startups and small companies often can use small, less differentiated and shared space. A common situation seen now in the context of this cluster is a large firm headquartered outside the region which hopes to start a small satellite R&D operation here to get in early on the new technology and cluster. The company has an immediate need for lab plus office space for a small team, say 10 or fewer employees, but it hopes to grow and expand its lab space, and if successful set up a manufacturing facility in the region. The company needs a landing spot which is near the action and quickly available and it needs to see a clear path to expansion. Given this variety in demand, what is the configuration of space, utilities and amenities of spec space which would best fill the need? Few companies are looking for fully built out lab space because each different use demands different configuration and support systems. What are the essential minimum features and how much flexibility should be built into spec space? How can a client be assured the path to a custom buildout is short, direct and affordable? Finally, it's increasingly common to see existing industrial or commercial space converted into lab space. Even vacant commercial retail is being converted to lab space, and even in this region for a significant user. The consultants will deliver a preliminary framework for analysis for including conversion space in the supply analysis. A workable solution to the lack of available lab space in the region will bring all these factors into consideration.

Pilot and Scale Up facilities

The focus of the cluster is manufacturing, not drug discovery; its distinguishing strength is not basic research but translating chemistry and chemical engineering innovations to commercial reality. This brings focus to the scale up stage of process development, and it requires special facilities, equipment, supplies, services, expertise and talent. The more scaleup expertise in the cluster, the faster and stronger its growth. One implication is that economic development organizations and cluster firms should seek out, encourage and recruit existing companies that provide specialized products and expert services for the scale up or pilot phase to locate her and collaborate with the cluster.

Another implication is that the development in the region of a distinguishing capacity and expertise in scale up of innovations in continuous flow and advanced pharmaceutical manufacturing could power the success of the cluster. This deserves special consideration. One intriguing idea is to create a pilot / scale up translational development park to draw a critical mass of talent and firms to spur the

development of the industry. As imagined the park would be a collection of lab and scale up and pilot facilities, equipment and space, perhaps in an industrial area of the region. The work would focus on four areas: (i) scaling up processes which are invented at bench scale by M4All to pilot/kilo scale to further qualify them to be implemented at commercial scale; (ii) developing and extending continuous process technology, quality control, analytic and production systems at commercial scale, including for example improvements, adaptations and innovations in pumps, reactors and filtration; (iii) extending continuous processing to later stages of manufacture which are now out of reach, such as crystallization, separation and drying; and, (iv) training and providing work experience in commercial implementation and a cGMP environment to students and workers. It would feature individual space for firms, including space suitable for an immediate landing by inbound or start-up companies plus the option of space suitable to build to suit within a short time. The park would offer select shared equipment and space. Such a complex would provide a striking physical foundation to support other aspirations of the cluster, for example a National Center of Excellence in Continuous Pharmaceutical Manufacturing. In such a Center university and industry experts would push the boundaries of the technology, accelerate the development of commercial processes and develop the talent the new industry will require, and the Center would itself become another strategic pillar for the cluster.

Building a robust ecosystem including specialized knowledge assets and others

A successful cluster is enriched and bound together by specialized knowledge assets and other organizations which create special value and connections. The region has many such assets with expertise critically important to the mission of the cluster, and each has a potential to play in supporting and extending the reach of the cluster, including the Commonwealth Center for Advanced Manufacturing, the Commonwealth Center for Advanced Logistics Systems, the new Commonwealth Center for Cloud Computing, the Commonwealth Center for Cyber, Virginia State University, Activation Capital and the Virginia Bio+Tech Park, and the recently announced national Cybersecurity Manufacturing Innovation Institute (CyManII) which includes Virginia Tech, George Mason and VCU as participating institutions. These organizations can make a wide range of valuable contributions from filling a gap in the workforce pipeline to supplying expertise or equipment to overcome a need in the supply chain.

An example which illustrates the possibilities is the 51,000-square-foot Center for Manufacturing Advancement (CMA) now under development by the Institute for Advanced Learning and Research (IALR) in Danville. The CMA will provide training and manufacturing technology resources for manufacturing companies establishing or expanding their presence in Southern Virginia, including rapid-launch facilities that will enable new businesses to begin limited operations while waiting for their factory to be constructed and equipped, a shared ISO-certified inspection lab, and process improvement labs that will enable businesses to improve their production processes expeditiously without shutting down production lines actually in service. https://www.ialr.org/ialr-november-december-2020-newsletter/

Separately, it's important to assure that members of the cluster are well connected with opportunities offered by standing economic development programs in the state supporting R&D and commercialization including the Center for Innovative Technologies (CIT), the Virginia Innovation Partnership Authority (VIPA) and the Virginia Bioscience Health Research Corporation (VBHRC, or the Catalyst), as well as dynamic industry associations including the many local and regional Chambers of Commerce and the Virginia Chamber of Commerce, Virginia Bio and the new statewide Virginia Bio-Connect network, the Virginia Manufacturers Association and the Hopewell Manufacturers Association.

Organizing economic development efforts for success

Effective leadership is a key to cluster success, perhaps particularly so in the fast-paced emergent cluster when opportunities are many and momentum is strong. The region needs a quarterback to gather the stakeholders, push the agenda, focus attentions, set priorities, urge collaboration and hold stakeholders accountable for results. But no single organization exits which spans the region and has the mission and expertise to play that tole. The region's key stakeholders can form a coalition to do so. This may be as simple as formalizing the organization and work groups that arose during this ECB Study, redirecting effort to implementation of the study recommendations and other action. Whatever the structure VEDP has a key role to play. VEDP's stature and statewide identity can help the coalition form an identity that spans localities and shine under the spotlight of national and international attention. VEDP has the greatest depth and breadth of staff and economic development resources to support this work. And VEDP recognizes the strategic importance of cluster development, its central role in GOVirginia and potential to benefit the entire state.

Finally, the cluster provides the need and opportunity for local and regional economic development organizations in the region to collaborate in new ways. The region is experiencing a rush of contacts by firms investigating a move here to join the young cluster. We've got to ramp up the expertise and resources to handle this demand now. Then let's find ways to pool resources so that we not only respond to these calls but launch a sustained and compelling effort to create more opportunities, seeking firms to fill critical gaps in the supply chain and add new and different R&D and manufacturing to the cluster.

Recommendations

Organize for success

1. **Form a sustainable regional cluster organization** to lead the collaborative efforts needed to put these recommendations in place and drive cluster growth. Form work groups on key areas discussed in this report: supply chain, lab and pilot space, and ready manufacturing/distribution sites and infrastructure.

2. **Economic development organizations collaborate, pool resources and expertise to advance cluster development by** skillfully and knowledgeably handling the opportunities coming our way now, generating and sharing qualified leads, and marketing to target audiences and channels.

Accelerate the build of the Supply Chain

3. **Engage regional and state companies and entrepreneurs** in providing products and services to supply chain of cluster by a series of in person or zoom detailed and actionable briefings and meet ups on gaps and needs with core cluster firms and M4ALL.

4. Engage **researchers and innovators** at Virginia universities and engineering schools through colloquia on key issues to solve and briefings with key player to create innovation and product development collaborations, sponsored research agreements, joint funding opportunities, SBIR and STTR opportunities, including core cluster firms and M4ALL.

5. **Facilitate and spur the interaction of cluster firms and higher ed with state assets located in the region: Commonwealth Center for Advanced Manufacturing, the Commonwealth Center of Advanced Logistics Systems, Commonwealth Center for Cloud Computing, and the Commonwealth Cyber Initiative** to create collaborations in industry assistance, workforce training, thought leadership, center of excellence and help them find the collaborators they need to successfully find financial support for these.

Create more available laboratory space now and a system for right sizing lab space supply in the future

6. **Research, analyze and prepare models for feasible actionable solutions to bridge the gap and assure future right size, through** a work group of experts on lab space to undertake location, space and financial analyses needed to prepare detailed alternate models of feasible actionable solutions to bridge the gap and assure region has the lab space to support now and future growth

7. **Court lab space builders, developers and financers** from within and outside region by producing a series of city/site visits and investment Forums to share information on the needs and opportunities, share research on alternative development models in this market, and introduce them to potential development partners for needed space in this region.

8. **Create a system to capture, maintain and make readily available data and relevant information on lab space supply and demand** in the region through a collaboration of GRP, VGR, VEDP, Activation Capital, local economic development organizations and private developers and real estate professionals. .

Strengthen the readiness of sites and infrastructure to support manufacturing and distribution in the growing cluster

9. Establish clear understanding of site readiness for advanced pharma manufacturing and hold workshops with developers and owner in the region to equip them to best prepare their sites. Include sites which would be attractive to pharmaceutical manufacturing in site readiness efforts.

10. Act as a voice for the cluster to support private parties and public entities seeking necessary water, wastewater and other infrastructure support at sites in use and likely to be in use to support additional advanced pharmaceutical manufacturing expansion

Pursue strategic funding and public policy opportunities to accelerate the cluster development

11. Organize and fund efforts to **pursue federal strategic support for infrastructure and cluster building projects**, including:

    a. Nation's first *translational* R&D park for advanced pharma manufacturing which uniquely features pilot and scale up capabilities and would be a magnet to all suppliers and instrumentation firms who want to be in at the ground floor of creating the equipment, processes and standards for the new manufacturing technology; and,

b. FDA National Center of Excellence for Continuous Flow Pharmaceutical Manufacturing.

12. **Pursue state policy solutions to accelerate development of the cluster**, including to support and incentivize relevant infrastructure improvements and tailored incentives to this industry.

Attachment 1

Members of the Work Group

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Attachment 2 - Milestones in the growth of the cluster April 2014 – March 2021

2014 - 16	
	Dr. Gupton and VCU College of Engineering awarded I**nitial proof of concept grants** re the active pharmaceutical ingredients Nevirapine, Tenofovir and Dolutegravir
2016	
June	**BioTech 8 acquired** by VCU; begin infrastructure build, relocation, expansion of **M4ALL lab facilities**
2017	
July	Dr. Gupton and VCU College of Engineering awarded **5-Year Grant to scale up M4ALL for** 13 additional API for critical global medicines over 5 years.
2018	
Jan – Dec	Expanding personnel, creating the Institute organization, **developing organizational processes and standards** for target selection and project management
2019	
Spring	**Optimized Processes Released** from work on FTC, DTG, TDF, 3TC
June	**AMPAC Fine Chemicals reopens Petersburg manufacturing site**
2020	
April	**GOVirginia awards grant to VCU College of** Engineering to conduct strategic planning process for maximizing impact of M4All on region and state economic development
May	**BARDA** awards **contract valued up to $850 million** to Richmond based **Phlow Corp** and partners, including M4All, AMPAC Fine Chemicals and Civica Rx to secure nation's supply chain of essential medicines
Summer	Phlow creates the **nation's first Strategic API Reserve (SAPIR) in Petersburg** and begins to stock it with medicines essential for the treatment of COVID-19
Summer	**AMPAC Fine Chemicals begins expansion of production lines and jobs** at Petersburg API manufacturing plant for collaboration with M4All and Phlow
Summer	**Phlow begins construction on $100+ million continuous flow advanced manufacturing plant** based on M4All chemistries adjacent to AMPAC
2021	
February	**CivicaRx announces it will build a $124 million injectable drug manufacturing plant and create 185 jobs** beside AMPAC and Phlow to create end-to-end manufacturing cluster
February	**USP** announces strategic alliance with M4All and Phlow to develop industry / FDA standards for continuous processing and **co-locate in Bio+Tech Park**
February	**Virginia General Assembly includes $10 million** in 21/22 budget for infrastructure support to Petersburg to serve AMPAC / Phlow / CivicaRx site
March	Phlow announces **Children's Hospitals Coalition powered by Phlow**, a collaboration to provide essential medicines at risk of shortage and medicines for pediatric rare disease to children's hospitals across the nation

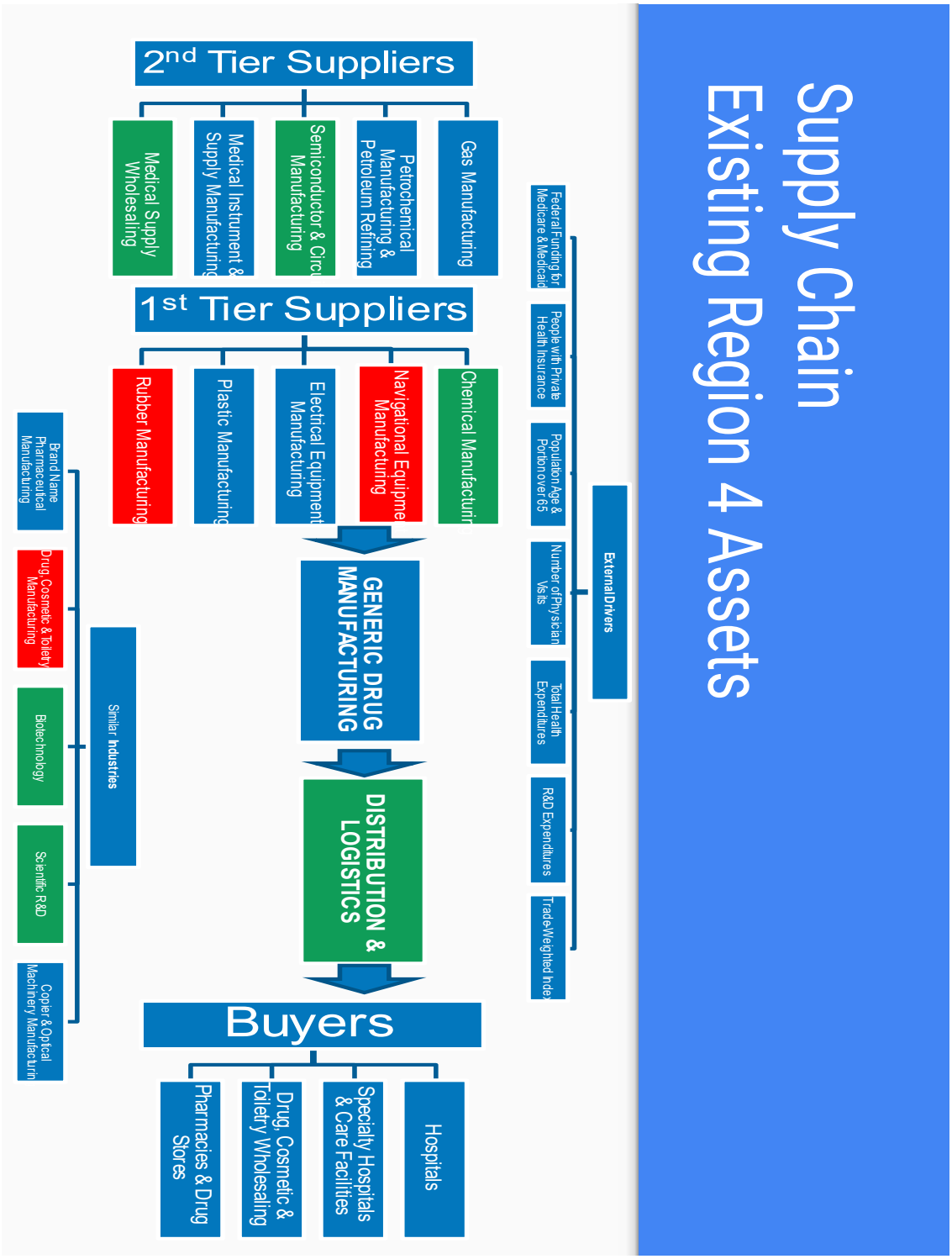
A detailed narrative of the development of the cluster and its major firms and organizations is found in the White Paper, Appendix 2 to the Final Report, at pp 18-26.

Attachment 3 – Summary SWOT analysis - emerging advanced pharmaceutical manufacturing cluster

Strengths • M4All is a global leader in the R&D powering the manufacturing revolution, the major source of technology, attracting national and global companies/research and attention, and its translation to commercial use • Phlow/AMPAC/CivicaRx partnership funded by BARDA is most advanced commercial cluster developing and building new advanced pharma manufacturing, and an end-to-end ecosystem in nation • VCU Engineering a national leader in training the chemists and chemical engineers in this technology, and is growing in numbers and breadth • Ready partners in community colleges and effective state/local programs to find / develop required workforce in time • Excellent VA universities with relevant research and talent • Close to DC, federal funding and regulatory agencies • Superior infrastructure– I-95, I-64, I-85, Virginia Ports, etc. • Region strong in chemical & advanced manufacturing, logistics • Lower cost manufacturing operations and labor, development, construction and real estate • CCAM, CCALS, Activation Capital / Bio+Tech Park have specific expertise, resources and missions to support the firms in the cluster • Twin pillars of cluster in Richmond to Petersburg uniquely unite the region	**Weaknesses** • The region is not organized for to set the vision and strategy, and for effective, coordinated, collaborative action to develop and promote the cluster • Lack of available lab space now • Lack of pilot/scale up facilities and space • Infrastructure issues associated with certain manufacturing sites • Lack of workforce experienced in pharmaceutical manufacturing • Lack of reputation of region as a life science hub historically, and as leader in this emerging technology, industry and cluster • Lack of public understanding of the significance of continuous manufacturing and supply chain innovation for pharmaceuticals • Supply chain for this cluster is limited within the region and state
Opportunities • Best in nation story to tell right now, given prominence and leadership of M4All and Phlow partnership and momentum • Disruptive innovation creates opportunities to attract established players and host new innovators • Technology and industry in development stage, with many needs to meet, gaps to fill, “firsts” at hand • The political, economic, social tide is high now – reshoring advanced manufacturing, securing the medical supply chain for national security, access to health care and affordable high-quality medicines, infrastructure investments, particularly in historically overlooked communities • In line with long term goal of FDA to convert to continuous process and advanced manufacturing platforms • State policy review for focused incentives • Void of thought leadership to public, academia, industry and policymakers	**Threats** • Worldwide competition in developing advanced pharma manufacturing • Capital intensive with longer-term deliverables • Unfair state supported foreign competition (government investment in capital, lesser regulatory compliance, IP theft) • Possible Federal gridlock or change of policy • State political structure, policy and fiscal issues constraining infrastructure support • RTP and Maryland catch up, become alternatives and not compliments to the region • Localism slows or prevents collaboration which would add value and grow cluster

Attachment 4

Conceptual supply chain map: generic pharmaceutical manufacturing



Appendix 5

Market Scan of supply and demand for laboratory space in Richmond / Petersburg Region

ACTIVATION CAPITAL
From start to phenomenal

HR&A Analyze. Advise. Act.

ACTIVATION CAPITAL
THE LIFE SCIENCE ECOSYSTEM OF RICHMOND, VA

Market Scan
March 2021

PRELIMINARY DRAFT

TABLE OF CONTENTS

Executive Summary

HR&A conducted research and interviews regarding the Richmond life sciences market to gain a preliminary understanding of the life sciences ecosystem and the supply of and demand for lab space.

HR&A is an industry-leading consulting firm working at the intersection of the public and private sector. With a focus on equity and inclusive growth, our work supports communities and revitalizes urban environments in the United States and abroad.

Within our Knowledge Economy practice, HR&A provides:

- **Development advisory that unlocks value;** We bring management experience, expert real estate knowledge, and contextual understanding of economic and policy priorities to deliver development plans for modern innovation places that attract talent, business, and investors.
- **Sectoral knowledge that accelerates value creation;** We apply our in-depth understanding of each sector's priorities and resources to structure partnerships, facilitate negotiations, and recommend implementation structures that generate value to diverse stakeholders.
- **Actionable strategic planning that effects change;** We create programs that support adoption and implementation and build local capacity to manage technology and change.

This report was led by **Bob Geolas**, Partner, and former President and CEO of Research Triangle Park. Bob has experience in both established Life Sciences markets like San Diego, Boston, and Raleigh/Durham, as well as in emerging markets like St. Louis, Austin, and Tampa/St. Pete.

Within this report, HR&A completed the following:

- Preliminary analysis of:
  - **Demand**, segmented by tenant type including start-ups, emerging businesses, and large-scale enterprises
  - **Supply**, including preliminary analysis accounting for potential conversion space
  - **Emerging Market Gaps** in the data on supply and demand
- Preliminary **description of alternative programmatic options and operational models** based on national best practices
- Preliminary outline of **recommendation to create a demand analysis system** which could be used to provide potential funders and developers with idea for market appetite and to inform financial forecasting

HR&A completed a market scan, resulting in projected supply and demand for each of the selected use types.

HR&A completed the following tasks to conduct our market scan, resulting in projected supply and demand figures for the selected space and use types.

Step 1: Define Market Areas | Defined study areas to better understand the supply, demand, and gaps in the market.

Step 2: Determine Space and Use Types | Determined the appropriate uses to investigate based on market insights and competitive product.

Step 3: Available Data Sources | Analyzed data utilizing available resources including CoStar, as well as market reports and insights from the Greater Richmond Partnership, Cville BioHub-UVA Weldon Cooper Center, Virginia's Gateway Region, City of Richmond, Virginia Economic Development Partnership, Cushman & Wakefield | Thalhimer, JLL, and others.

Step 4: Interviews with Knowledgeable Market Stakeholders | Interviewed invested stakeholders, including local real estate developers, brokers, and regional economic development partnerships.

Emerging Market Data – Methodology

In addition to HR&A's internal knowledge of other life sciences markets, we compared Richmond markets to other emerging and established markets by collecting insights from the following:

- **CBRE,** 2019 U.S. Life Sciences Clusters: Markets Positioned for "Century of Biology
- **CBRE,** Leading Life Science Clusters: The Bio-Boom Intensifies (2020)
- **JLL,** 2020 Life Sciences Real Estate Outlook
- **Research Triangle Regional Partnership:** Life Sciences
- **Greater Richmond Partnership**, Key Industries Reports – BioScience
- **Costar Group, Inc.,** property reports for the primary and secondary study areas, as well as analytics reports from other markets

Our team conducted interviews with representatives from the following stakeholders:

Jennifer Wakefield, Interim CEO Greater Richmond Partnership

Casey C. Gilchrist, Senior Manager Business Investment & Job Creation, City of Richmond Department of Economic Development

Jane DuFrane, Vice President and Market Lead Highwoods Properties Richmond Division

Daphne Berkowitz, Real Estate Contract Specialist Activation Capital

Emerging Market Data – Findings

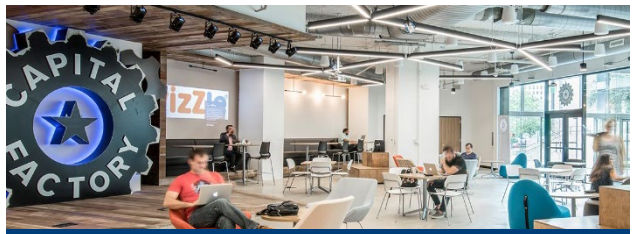
Findings

Richmond is still an emerging life sciences market like those in St. Louis, Austin, and St. Petersburg/Tampa, and data on flex and office space converted into lab space is limited. Firms interested in locating in Richmond are not tracked in a centralized database and the landing locations of those firms unable to find readymade lab space is unknown, hindering the measurement of regional demand.

More mature markets like Boston and Raleigh/Durham track the life sciences activity using metrics such as venture capital investment, NIH/NSF and other federal investment, employment, number and notoriety of companies, retention of companies throughout their life cycle, number of patents, and the number of advanced degrees in related fields.

Data is collected in both periodic and more formal analyses conducted by local governments, governing bodies of local innovation districts, economic development organizations, and other interested parties. More formal analyses of the market include survey data on company size, including square footage and number of employees, anticipated short term space needs, market investment, and building specifications.

Cortex, St. Louis



Capital City Innovation, Austin

The District, St. Petersburg

Demand – Methodology

HR&A collected data and insights from the following sources:

- **Greater Richmond Partnership**, Key Industries Reports – BioScience, Information Tech, and Advanced Manufacturing
- **Cushman & Wakefield Thalhimer,** Marketbeat Richmond – Office (Q4, 2020) and Marketbeat Richmond – Industrial (Q4, 2020)
- **Virginia Economic Development Partnership**, Key Industries – Life Sciences
- **Virginia's Gateway Region,** Location Advantages and Talent Profile – Research and Innovation
- **Cville BioHub-UVA Weldon Cooper Center,** The CvilleBioHub Region: A Report on the Local Biotechnology Industry, Metrics and Economic Impact

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Bob Richards, Executive Vice Chairman Cushman & Wakefield

Brian Berkey, Senior Vice President Cushman & Wakefield

Rett Turner, Broker Cushman & Wakefield Thalhimer

Matt Hamilton, Senior Vice President CBRE

Andrew Ferguson, Senior Vice President CBRE

Demand – Findings

Findings

1. Consistent with other emerging life sciences markets, the primary demand generator in Richmond is mid-sized, emerging businesses. These firms require lab space but often in smaller quantities and tend to lack the resources necessary to rent and fit out higher-cost spaces.
2. Businesses in search of lab space have spread out across the secondary market area, utilizing office and flex industrial spaces.
3. Anchor businesses are not as common and tend to prefer to build out their own spaces. If Activation Capital can secure an anchor tenant for 8L, they are unlikely to prelease more than six months in advance.
4. Due to the lack of data, explicit demand is not quantifiable at this time. Addressing this data gap is critical to understanding and addressing the needs of Richmond's life sciences market and should be a priority for Activation Capital.

Main Demand Generators

	Anchor	Emerging	Startup
Typical footprint	+75k SF	<10K SF	Co-Working/ Shared Spaces
Range of Employees	50+	5-20	<5
Type of Lab Space	Wet Lab, Built to Suit	Lab or Flex, ready made	Shared Lab, ready made
Presence in Richmond	Moderate	Limited	Moderate

Insights from regional stakeholders

Central Virginia offers low cost of living, educational opportunities, highly-rated counties from government management perspective, and great infrastructure because we are a capital city and we're seeing increased density in multifamily, like Raleigh 10 years ago.

Talent is a major factor always mentioned during discussions with site selectors with VCU's engineering (VCU Institute for Engineering and Medicine) and pharmacy programs highlighted.

A lot of lab activity has space requirements around 10,000 SF. These firms are not leasing build to suit spaces but rather is landing in retrofitted flex spaces in the surrounding counties.

Supply – Methodology

HR&A collected data and insights from the following sources:

- **Cushman & Wakefield Thalhimer,** Marketbeat Richmond – Office (Q4, 2020) and Marketbeat Richmond – Industrial (Q4, 2020)
- **CoStar Group, Inc.,** Market Analytics and Property Reports for Flex Spaces in the Primary and Secondary Study Areas
- **City of Richmond,** Roster of Shared Office Suites with Support Service
- **City of Richmond,** Richmond 300: A Guide for Growth Master Plan
- **Richmond Times-Dispatch,** various clippings
- **Business Wire**, various clippings

Our team conducted interviews with representatives from the following stakeholders:

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Matt Hamilton, Senior Vice President CBRE

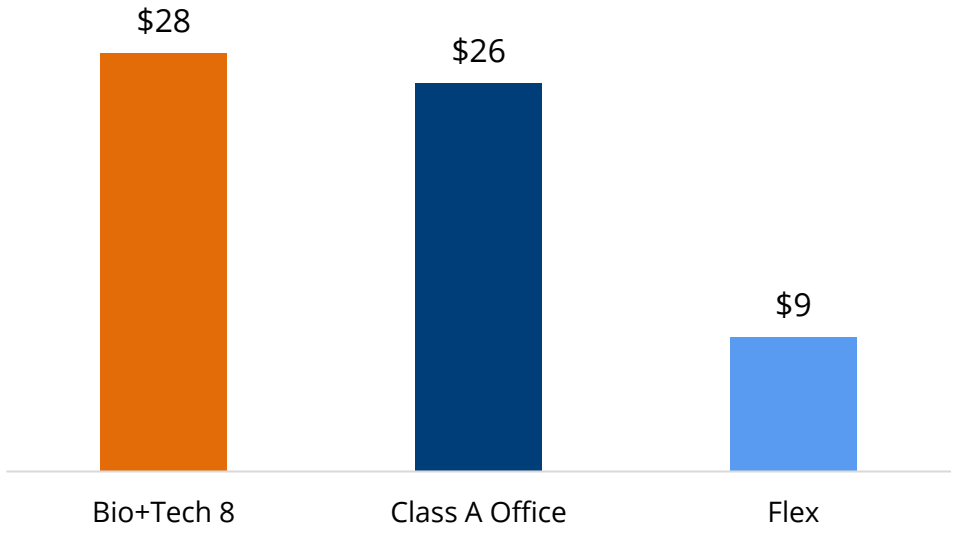
Andrew Ferguson, Senior Vice President CBRE

Supply – Findings

Findings

1. The only readymade lab space in the market seems to be is 48,000 SF available in Bio+Tech 8. Asking rent for Bio+Tech 8 space modestly exceeds asking rent for Class A office space in the market and drastically exceeds the asking rent for flex space, making it inaccessible to all but well-funded anchor tenants.
2. With a lack of readymade lab space, life sciences companies must convert Class A office and flex space to labs. Based on the data, it is difficult to know how much of the Class A office and flex markets have been converted to lab space; given that current Class A office rents are only slightly lower than rent for currently available lab space in Bio+Tech 8, future tenants are unlikely to invest in retrofitting Class A office unless all lab space has been fully absorbed and flex spaces do not fit their needs.
3. The pipeline of flex development consists of approximately 2.3M SF. However, even at the high level of conversion (10%) seen in mature markets, the pipeline would only constitute 230K SF in new flex space competitive with 8L over the next 10 years.
4. If life sciences businesses continue to outfit and occupy office and flex spaces, the emerging life sciences market will be thinned and struggle to stabilize around a concentrated hub.

BIO+TECH 8 AND PRIMARY STUDY AREA RENT PER SQUARE FOOT, 2020



Insights from regional stakeholders

Bio+Tech 8 is relatively expensive, and available spaces are larger than most firms can take on.

In very strong life sciences markets, pre-leasing rarely happens more than a year in advance. It's vital to design space that is very flexible to go after multiple tenants

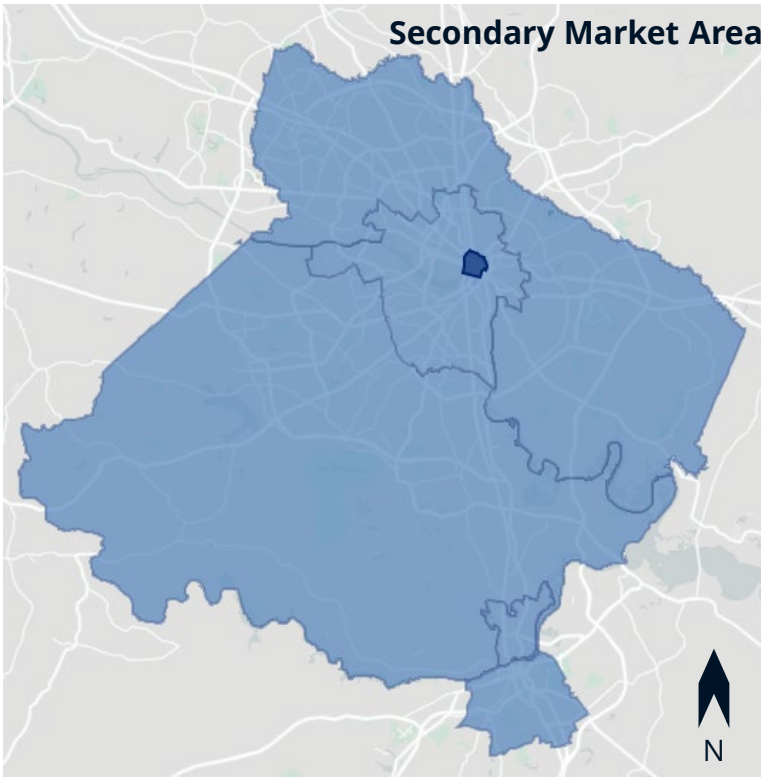
Executive Summary – Conclusions

Conclusions

1. **Richmond is a growing but still not yet mature life sciences market** requiring space and programming to ensure long-term success.
2. The market **is anchored by a few large players** in the life sciences field **but is being fueled by small- to mid-sized companies** with a demand for equipped and programmed space.
3. **Supply for such equipped and programmed space is non-existent**, requiring such companies to settle for retrofitting office or flex space, diluting the ecosystem, leading to data gaps in the life sciences market, and potentially stunting the prospect for the growth.

Market Report

Study Areas | This analysis focused on the CBD and the VA Bio+Tech Park area but included adjacent suburban submarkets to augment our understanding of the Greater Richmond market.



The primary market area consists of Richmond's CBD, the North Broad submarket, which includes the VA Bio+Tech Park, and the adjacent Monroe Ward area, and it is bounded by I-64 and I-95 to the north and east, the James River to the south, and U.S. 31 (Belvedere Street) to the west. The secondary market area includes Henrico and Chesterfield counties, as well as the cities of Colonial Heights and Petersburg.

The Life Sciences Ecosystem | The Richmond area is an emerging hub of life science activity. The market is dominated by small- and medium-sized companies, averaging about 8 employees per business. There are comparatively few large, anchor companies.

650
Bioscience companies in the region

5,800+
Bioscience workers in the region

$300M
Invested by bioscience firms since 2010

Key companies include

Phlow PPD envera VCU Health McKESSON

An established life science hub like Research Triangle Park in Raleigh, NC is home to upwards of 24,000 life science employees across 569 companies. While not yet stabilized, Richmond is an emerging market and home to a growing life sciences cluster. Benefitting from proximity to VCU's engineering department, and regional proximity to key federal agencies including NIH, DARPA, FDA, and NSF, the VA Bio+Tech Park is the center of the Richmond life sciences ecosystem. The park has nine buildings on 34 acres and hosts more than 70 companies, research institutes, and state and federal laboratories.

Source: Greater Richmond Partnership, Research Triangle Regional Partnership

The Life Sciences Ecosystem | The Richmond life sciences market is comprised of three distinct types of businesses defined by the size of space they occupy.

The Richmond life science market is comprised of three distinct types of businesses, start ups, emergent businesses, and anchor firms, represent the different stages of a company's path to stabilization. These three levels vary in size and stability, and as such require different sized spaces.

Start Ups:

Start-ups are small organizations, typically consisting of a couple employees. These organizations are just getting off the ground and require minimal square footage. They typically do not have funds for equipment and rely on incubators and accelerators to begin to commercialize their products. Start ups tend to occupy space in life-science coworking outfits, incubators, or accelerators. These organizations are new the ecosystem and typically require less than 1K SF.

Emergent Business:

Emergent companies are organizations that have outgrown incubator, accelerator, or coworking space and are looking for new space to lease. These companies are not yet matured enough to be anchor tenants, and likely do not have a 10-year runway. Emergent companies will either succeed or succumb over the next 5-10 years. These companies tend to look for spaces under 10k SF and are often left out of the development of the lab market.

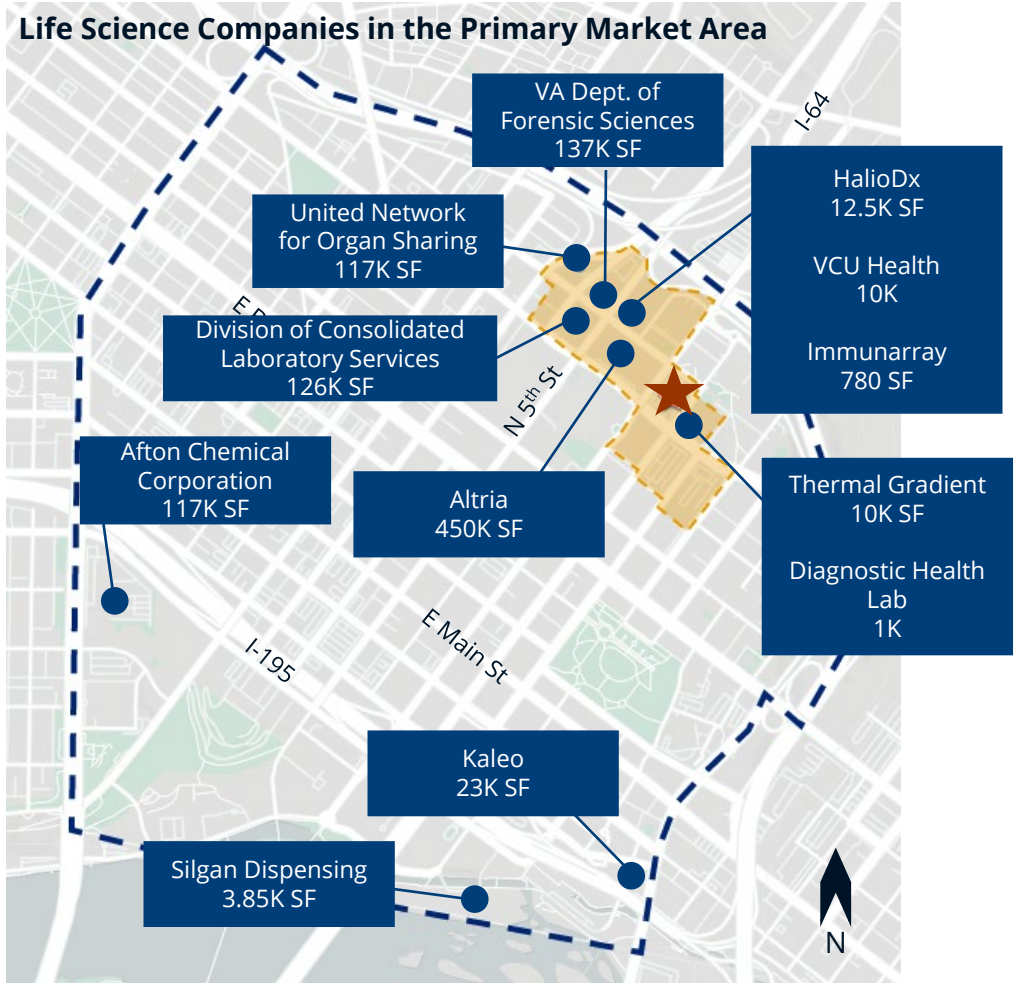
Anchor Firms:

Anchor firms are large scale organizations that utilize both office and lab space. These businesses are looking for larger spaces, upwards of 75K SF, and are usually willing to prelease space to have a say in designing spaces to meet their needs. Anchor firms are limited in number in emerging life sciences markets like Richmond

The Life Sciences Ecosystem | Anchor life sciences businesses have capital to develop or design larger footprints to meet their needs. Within the primary market area, the majority of these life sciences businesses are located in the VA Bio+Tech park.

Within the primary market area, **the VA Bio+Tech park is the heart of the life sciences ecosystem** for anchor businesses. Of the 13 designated life science and biotech buildings in the primary market area, six are located within VA Bio+Tech. These six companies occupy almost 1 million SF, but it is unclear how much of that is lab space versus office.

Anchor businesses occupy larger spaces, 75k-100k SF, and are usually willing to prelease space 6 months to a year in advance to have a say in designing spaces to meet their needs.



Legend

- VA Bio+Tech Park
- Primary Study Area
- Life Science Company
- Proposed Site

Source: CoStar, Stakeholder Interviews

The Life Sciences Ecosystem | Emergent businesses represent the bulk of the demand for new lab space in Richmond. These businesses are looking for smaller footprints and have limited funding for upfront capital investments.

Life science firms that consider locating in Greater Richmond need space that is easily adaptable and available on short notice. **There is high demand for wet lab space that has outpaced the market in Richmond.**

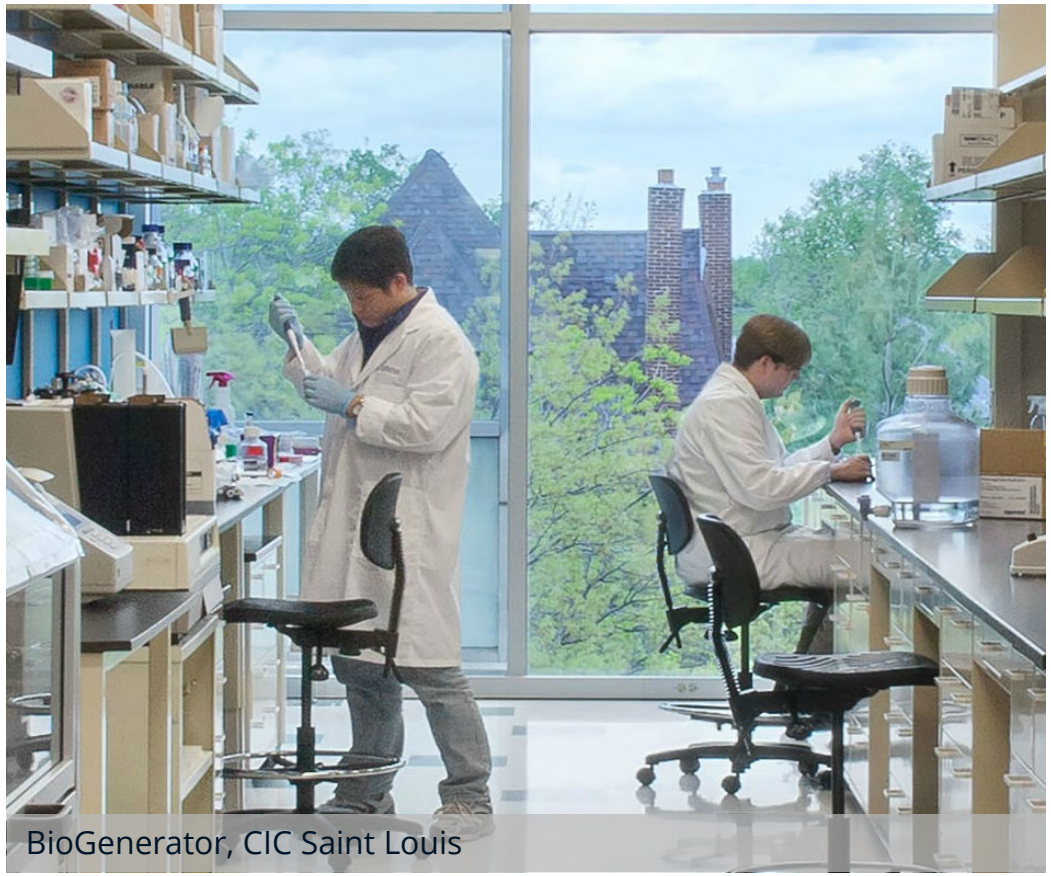
According to the Greater Richmond Partnership, **the demand for lab space is high, particularly for emerging life sciences businesses**. According to their data, these businesses are seeking smaller lab spaces, usually under 10,000 SF, and have limited capital for upfront investment, approximately $200,000.

Source: Greater Richmond Partnership

The Life Sciences Ecosystem | Coworking spaces offer flexible and affordable working options for smaller, start-up life sciences businesses.

Coworking facilities offer spaces that cater to a variety of professional needs, offering makerspace, private offices, and communal hubs. Of the 7 co-working outfits in the primary market area, Pinq Co-Working, 1717 Innovation, and IMPACT Studio serve Richmond exclusively, while Gather serves the region and Novel the nation. While there is more coworking space in the city outside of the primary market area, the market is still relatively limited, with no brand name outfits in or outside of the primary market area.

Bioscience coworking requires a different set up than creative coworking given the proprietary nature of the work. The coworking market of Richmond almost exclusively caters to creative coworking, with the exception of the 28,000 SF 1717 Innovation. Other markets have developed successful bioscience coworking outfits like CIC St. Louis and the University of Utah's Center for Medical Innovation. **These outfits provide private wet, prep chemical, and biological lab space with access to core lab equipment.** These labs tend to range from 100-1,000SF and accommodate teams up to 10 people. These outfits provide much needed space for life-science start ups while still providing access to broader coworking networks.



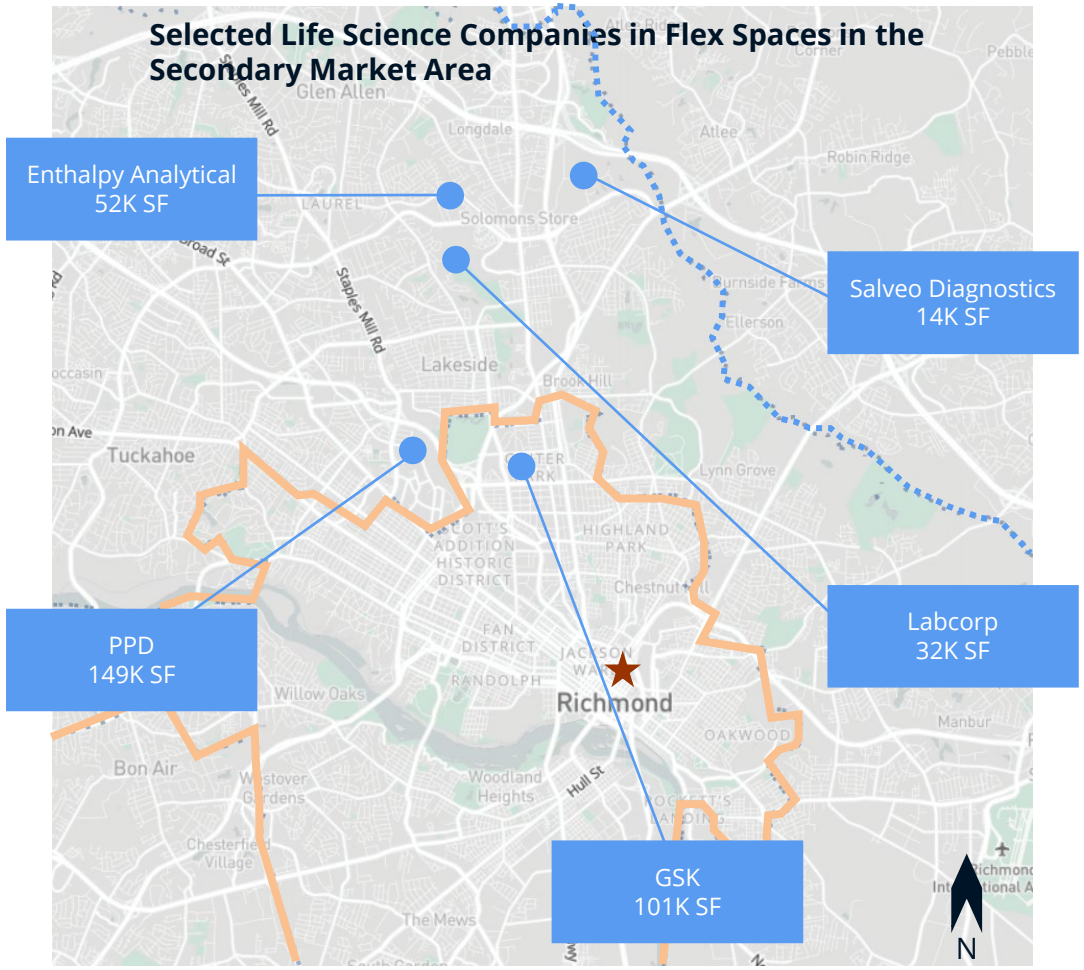
BioGenerator, CIC Saint Louis

Source: CoStar, Property Websites, CIC, University of Utah Center for Medical Innovation

Market Overview| Life sciences businesses in Richmond that can make upfront capital investments tend to locate in flex and Class A office spaces. In some cases, a lack of readily available lab space has pushed life sciences businesses out of the market.

A lack of existing lab space has made it difficult to expand and stabilize the life sciences ecosystem in Richmond, pushing anchor and emergent life sciences businesses to office and flex uses, oftentimes further from the CBD and VA Bio+Tech Park. **The upfront costs to adapt office and flex spaces is substantial** and indicate a willingness by these businesses to afford higher rents for lab space that is readymade or more easily adaptable for their use.

Coworking spaces and incubators tend to locate in office spaces, accounting for the smaller life science businesses, accelerators, and incubators that might utilize lab space.



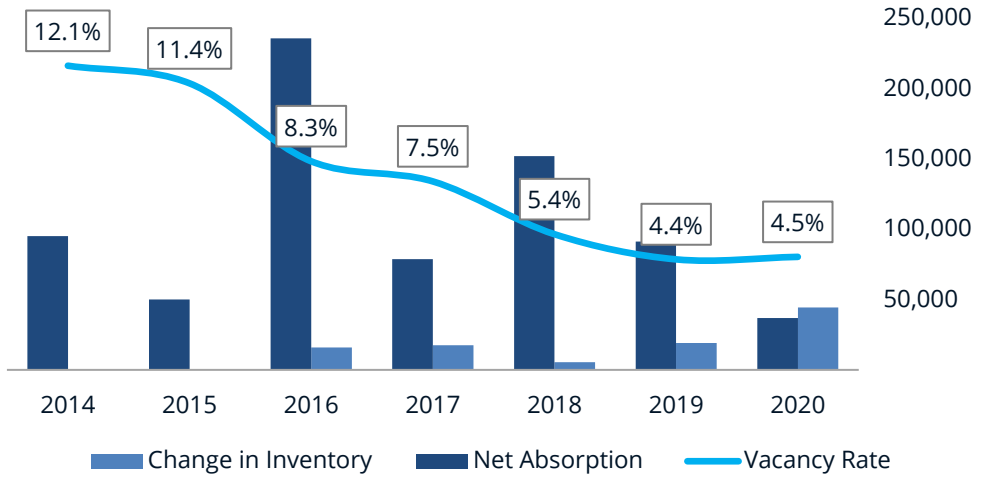
Legend

- Secondary Market Area
- City of Richmond
- Proposed Site

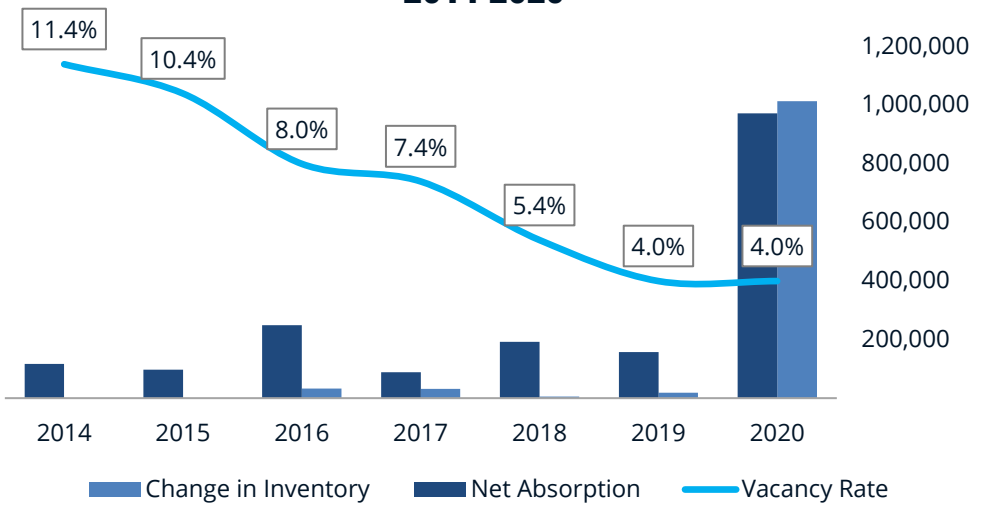
Source: CoStar, The Greater Richmond Partnership, Stakeholder Interviews

Market Overview | Steady absorption of flex space has lowered vacancy in both the primary and secondary market areas. Moreover, the secondary market absorbed nearly all the 1M SF delivered in 2020.

DOWNTOWN RICHMOND FLEX SPACE TRENDS, 2014-2020



GREATER RICHMOND FLEX SPACE TRENDS, 2014-2020

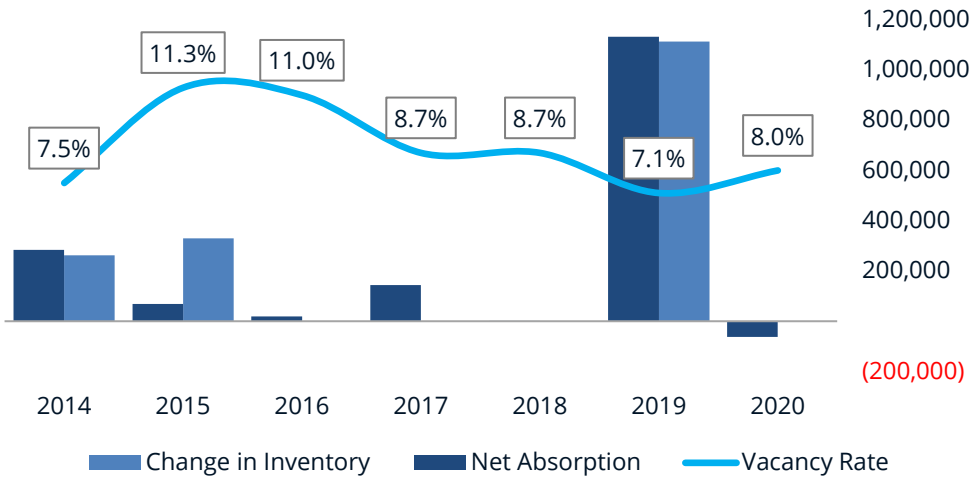


Despite low levels of new deliveries prior to 2020, steady absorption of flex space in the primary and secondary market areas has brought vacancy rates down from post-recession highs to below 5%. In 2020, Facebook opened a 950k SF data center in the secondary market area, in Henrico County, but even prior to the opening of that data center, vacancy in the secondary market area had fallen to 4%. Leasing activity in the secondary market and stakeholder discussions suggest some of the demand for flex space is being filled by life sciences firms that are having difficulty finding space downtown: PPD, Pfizer, and Labcorp are all leasing space that, depending on their needs, may have been absorbed in the primary market area if such lab space had been available. In addition, smaller life sciences startups may be seeking out less expensive space in the suburbs as they look to gain a foothold in the industry.

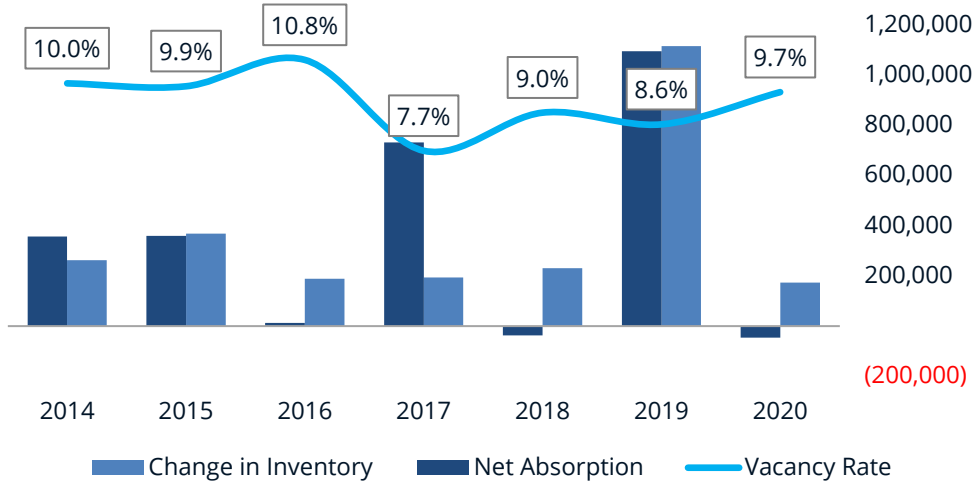
Source: Costar, Stakeholder Interviews

Market Overview | Absorption of new Class A office space has kept pace with development in both the primary and secondary market areas. However, the vacancy rate in both market areas has remained high since 2014.

DOWNTOWN RICHMOND CLASS A OFFICE TRENDS, 2014-2020



GREATER RICHMOND CLASS A OFFICE TRENDS, 2014-2020

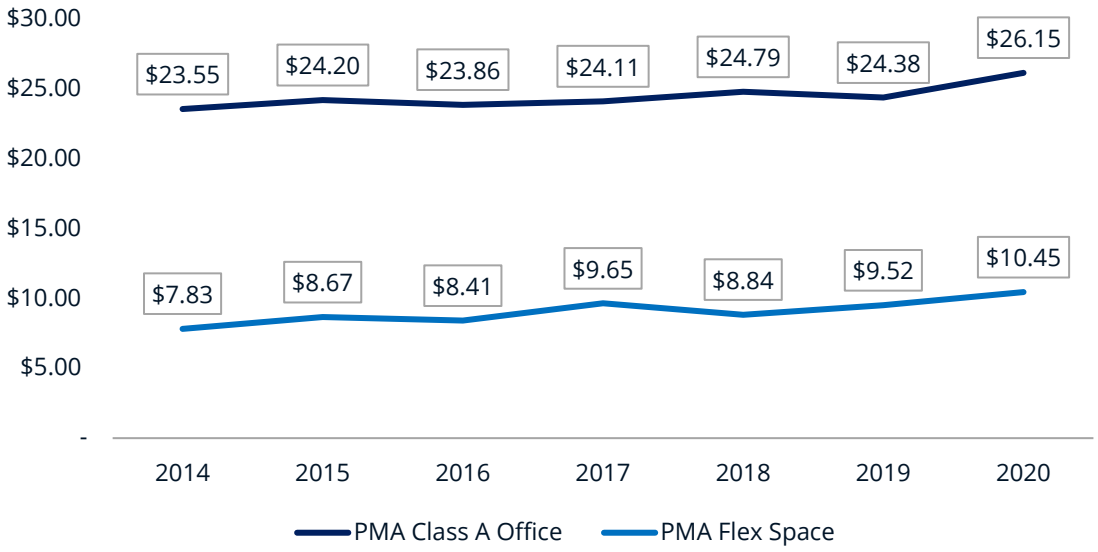


Up until 2020, new office deliveries of Class A office space were quickly absorbed in both the primary and secondary market area, however, vacancy rates never dropped below 7% in either market area. A recent rise in vacancies in both the primary and secondary market areas is likely attributable to the market response to the COVID-19 pandemic. The availability of office space in the primary and secondary market areas could present opportunities for life sciences businesses interested in locating in office space. Given market saturation and the slow pace of the pandemic recovery, absorption of new office space may be slow in coming years.

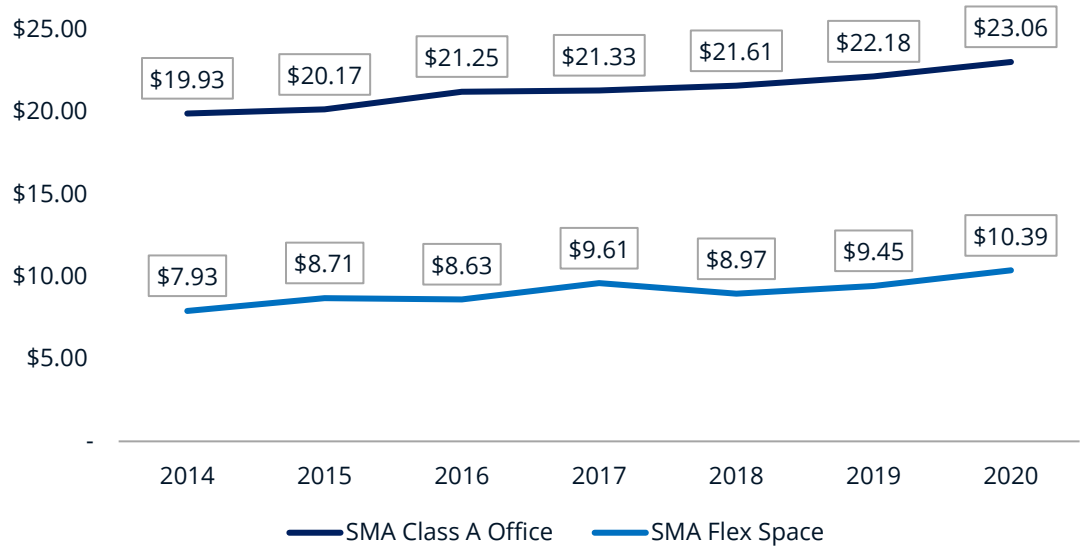
Source: Costar

Market Overview | Rent for Class A office, as well as available space in the Bio+Tech Park, is considerably higher than rent for flex space rendering Class A office space attainable only for established anchor businesses, which are limited in the emerging Richmond market.

PRIMARY MARKET AREA OFFICE AND FLEX PER SQUARE FOOT RENT, 2014-2020



SECONDARY MARKET AREA OFFICE AND FLEX PER SQUARE FOOT RENT, 2014-2020



Source: Costar

Class A office rent far exceeds flex rent in both the primary and secondary market areas. This creates an affordability hurdle for life sciences companies interested in locating in Class A office space. The asking rent for available space in Bio+Tech 8, the only readymade lab space in the market, is around $28.00 per square foot, higher than the average rent per square foot for Class A office in the rest of the primary market area. Well designed lab space, such as the space in the VA Bio+Tech Park, comes at a premium and may only be feasible for anchor life sciences businesses, which are limited in the Richmond market.

Market Overview| There is over 6 million SF of Class A office and flex space in the development pipeline in the primary and secondary market areas. This represents a competitive product to 8L.

Real Estate Type	Inventory	Vacancy Rate	Average Asking Rent	Pipeline
Primary Market Area Class A Office	7.5 Million SF	8.00%	$26	1 Million SF
Secondary Market Area Class A Office	19.5 Million SF	9.70%	$23	3 Million SF
Primary Market Area Flex Space	7.3 Million SF	4.50%	$9	0 SF
Secondary Market Area Flex Space	10.5 Million SF	3.99%	$9	2.3 Million SF
VA Bio+Tech Park Class A Office	1 Million SF	4.64%	$28	N/A

Source: Costar

With most life science companies locating in Class A office and flex spaces, new office and flex developments represent a competitive product to Activation Capital's development, and potentially a more affordable product. Asking rent for 8L should be calibrated to remain competitive while also serving as a revenue generator for Activation Capital. This can be determined through a financial feasibility analysis.

ACTIVATION CAPITAL
From start to phenomenal

HR&A Analyze. Advise. Act.

ACTIVATION CAPITAL
THE LIFE SCIENCE ECOSYSTEM OF RICHMOND, VA

Market Scan
March 2021

PRELIMINARY DRAFT

Report of the Workforce Work Group

Executive Summary

The Work Group was formed to describe the existing state of the workforce to support pharmaceutical advanced manufacturing, guide the decisions of the Study on how to meet short- and long-term needs, and form a working network of informed experts from key stakeholders who are equipped, enthused and ready to work together to support cluster growth in the months and years ahead. The Work Group's twelve members come from private industry, university, community college and economic development. In these positions, many of them have been working daily for months learning and building workforce solutions for the core cluster firms. **(Attachment 1)**

The Richmond / Petersburg region is home to an emerging core cluster of pharmaceutical advanced manufacturing and R&D. Focusing on understanding and addressing the cluster's workforce needs, both today and tomorrow, is key to unlocking its potential to grow.

The workforce of the advanced pharmaceutical manufacturing industry includes positions which require PhD, graduate and undergraduate degrees, and technical and production positions which typically do not require post-secondary education but rather require a high school diploma plus certification, experience or a less than four-year degree.

Anchored by Virginia Commonwealth University College of Engineering the region is well positioned to supply top talent at *the BS, MS and PhD* level. VCU College of Engineering is a national leader in the development of the enabling technology related to pharmaceutical manufacturing and also in the education and training of students in the innovative approaches that give birth to the technology. The M4ALL Institute in the College assures a strong flow of well-educated and trained graduate, post graduate and post docs in the Richmond region. The close connection between M4ALL and the region's core cluster employers structured into the contract from the Biomedical Advanced Research and Development Authority (BARDA) assures unparalleled experiential learning opportunities, and placements with relevant experience. Virginia offers, in this region at VCU, Virginia State University (VSU) and other universities across the state many excellent engineering and chemistry programs which assure a rich and diverse supply of talent to employers in the region now and in the future. A growing and evolving technology innovation cluster like this will require more highly trained talent and richer relationships between higher education and industry, but again anchored by M4ALL and its existing pipeline of support, this can be accomplished. The College will need to grow enrollment in its programs and allow its programs to evolve into areas the cluster will push, such as scale up, adaptation of technologies and extension of continuous processing and manufacturing. Furthermore, the College must expand ties with industry to create experiential learning opportunities in an ever-widening cluster effort. Pathways to talent at other Virginia colleges and universities will need to be built.

The required *technical and production talent* is well within reach, given the startup time until operation of the core cluster companies and the responsiveness and skills of local community colleges and industry collaboratives who already are at work creating workforce solutions. VEDP's Virginia's Talent Accelerator program, in close collaboration with the community colleges, is working closely with AMPAC and Civica Rx to provide tailored workforce training for immediate needs. Community College Workforce Alliance (CCWA), the workforce division of John Tyler and Reynolds Community Colleges, is working with AMPAC

and Civica Rx to research, plan and build an appropriate sustainable onboarding workforce training program for the industry in the region. While advanced pharmaceutical manufacturing requires many of the same skills and training as other advanced manufacturing industries which operate in highly regulated industries, unique critical needs must be met as well (e.g., core competencies in quality control and assurance, recordkeeping, clean and cGMP environments, safety.) This can be built on core capacities at JTCC, shaped to the needs of the Core Companies, and modeled in part on successful programs which have been identified in Virginia and North Carolina. Generally, this will establish on ongoing program tailored to the industry that includes stackable workforce credentials in manufacturing as well as learning modules custom tailored to industry needs. Any pharmaceutical manufacturing workforce training or education program offered by John Tyler Community College's academic or CCWA divisions could be supported by the Commonwealth's new "Get Skilled, Get a Job, Give Back" (G3) $36 million statewide initiative that is set to become law July 1, 2021. Manufacturing is one of the "in demand" industry clusters for which G3 funds can be used to fiscally support student tuition for related workforce training or occupational/technical college certificate programs. Separately, CCAM and higher education collaborators are launching a comprehensive program built on a successful national model (FAME) to recruit and train workers for manufacturing maintenance and support. The FAME program has received support from GO Virginia support, and the CCWA/JTCC specialized on-ramp certificate program will be a strong candidate for such support as well.

This review shows that present supply and programs, augmented by programs which are in planning by the region's strong ecosystem of talent providers, will meet the estimated workforce needs of AMPAC Fine Chemicals, Phlow and Civica Rx as these companies build their initial local workforces in over the next 24 months. However, as the firms in the emerging cluster grow and new firms enter, significant investments will be required to expand the pool of talented workers available so that the region's workforce powers, not hinders, the growth of the cluster. Finally, despite these significant workforce strengths the region faces a relative lack at all levels and occupations of workers with significant experience *in pharmaceutical manufacturing*. This issue is inherent in the startup of a new cluster where there has been none. Focused and creative attention must be paid to address this while the cluster matures, and a local community of experienced workers naturally forms.

Introduction

This Work Group was formed to accomplish several goals: (i) to create a working team of collaborators from key stakeholders to bring immediate attention and support to the firms in the cluster during the pendency of the Study; (ii) to study certain issues to inform the Final Report and Recommendations; and (iii) to continue as the core network of relationships moving forward to understand, plan for and address the workforce needs of the emerging cluster and its firms.

The Work Group's twelve members are in private industry, university, community college and economic development, and many of them are responsible for building solutions for the firms in the cluster. The membership reflects the belief that building this workforce requires vision, structure, communication and collaborative relationships from all corners of industry, high schools, community colleges and universities, and local / regional / state economic development entities.

Over the past six months, these individuals and their organizations have leapt into action in support of immediate workforce needs as well as working on long term solutions. These practical efforts are briefly

described below and have uncovered important recommendations and allowed us to look further ahead on the horizon

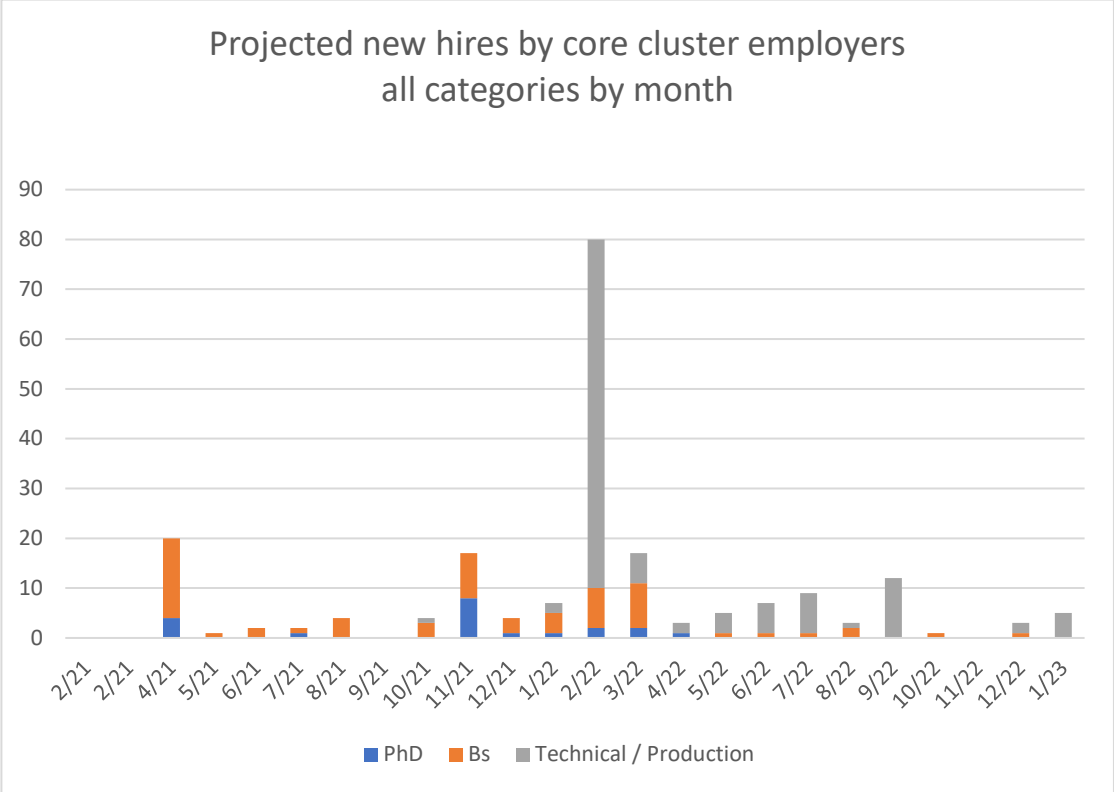
Research and Findings

The work group was asked to look at several foundational issues, drawing on existing information sources and focused in particular on the real needs and opportunities of core members of the cluster. We were not asked to and did not do new labor market studies or market research.

Demand**.** This emerging cluster with its ambitious R&D, advanced manufacturing technologies and reimagined supply chain requires a wide and diverse community of talent. This includes career-experienced workers and newly matriculated graduate and undergraduate technical degree holders, and a strong backbone of middle-skill level technicians. The constituent firms in the cluster will need large numbers of technical and production personnel who won't require a four-year degree. The cluster is in its growth phase and has to fill today's needs and establish a robust workforce pipeline for the future.

Two distinctive features of this advanced manufacturing cluster must be noted because they will present unusual workforce needs. First, the advanced pharmaceutical industry – particularly continuous flow, is itself in the throes of development, and therefore highly dependent on innovative and developing technology, and on top science and engineering to adapt and extend enabling technologies. This work focuses on advances in manufacturing, not drug discovery. Nevertheless, an outsized amount of R&D is required to translate and scale up the chemistry and chemical engineering innovations on which the new industry stands. It is on these very areas that VCU Engineering offers the best education and training in the nation. But even more may be required. Second, another essential and distinctive element of this emerging cluster is the use of advanced manufacturing breakthroughs to reinvent the supply chain of essential medicines in the US and globally. The nation's first Strategic API Reserve has been funded and is being built out in Petersburg. Nearby ground has been broken for a logistics center for the supply of essential medicines to the nation's largest coalition of hospital systems. Recently many of the nation's leading children's hospitals and Phlow announced the formation of a coalition to address challenges face in the supply of essential medicines and medicines for pediatric rare diseases. More innovations in supply chain are undoubtedly ahead. The talent to plan and execute advanced logistics systems to overcome besetting issues in access to medicine will be a significant element of the cluster.

At our request, the core employers of cluster at this moment - Phlow, AMPAC Fine Chemicals and Civica Rx, gathered estimates of projected new hiring (not accounting for attrition) by category and timing for 24 months following February 2021. The data is provided in the charts below and in **Attachment 2**. These numbers provide important guidance for serving their short and midterm needs, and a foundation for understanding future needs in the cluster. The first chart shows the number of new hires per month by category for all three core employers, and the second the cumulative number of new hires to date. It is notable that these estimates conform to the widely circulated assessment that 70% of the nation's jobs in advanced manufacturing are and will be Technical / Production.


Projected new hires by core cluster employers
all categories by month
90
80
70
60
50
40
30
20
10
0
2/21
2/21
4/21
5/21
6/21
7/21
8/21
9/21
10/21
11/21
12/21
1/22
2/22
3/22
4/22
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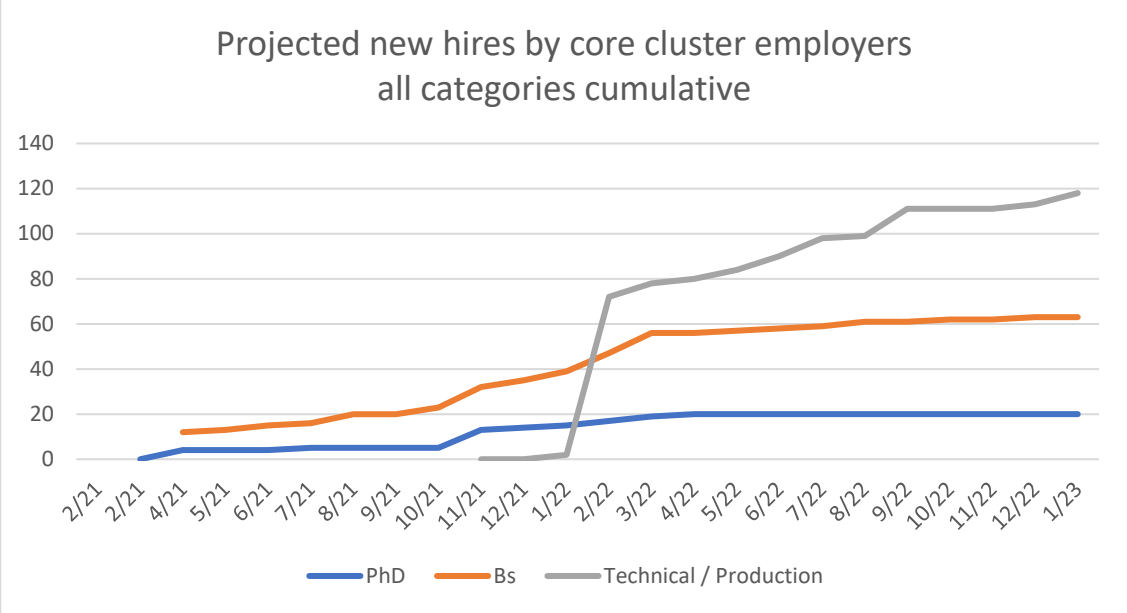
8/22
9/22
10/22
11/22
12/22
1/23
PhD
Bs
Technical / Production


Projected new hires by core cluster employers
all categories cumulative
140
120
100
80
60
40
20
0
2/21
2/21
4/21
5/21
6/21
7/21
8/21
9/21
10/21
11/21
12/21
1/22
2/22
3/22
4/22
5/22
6/22
7/22
8/22
9/22
10/22
11/22
12/22
1/23
PhD
Bs
Technical / Production

Supply**.** A review of labor market data for the Richmond Metropolitan Statistical Area (MSA) (which also includes the cities of Petersburg, Hopewell and Colonial Heights and adjacent counties) provides broad insights on the region's capacity to satisfy the workforce needs of the emerging advanced pharmaceutical manufacturing cluster. The picture that emerges is that of a region which is producing, and has the ability to quickly increase production of, large numbers of the range of educated and trained talent for the occupations the cluster requires. However, because pharmaceutical manufacturing is not a legacy industry in the region, currently there is relatively low employment in life science manufacturing and a relatively small pool of workers with significant work experience in life science manufacturing.

As seen in Attachment 3, of the 22 occupations most commonly tied to life sciences manufacturing, Richmond has a very high concentration in 9 of 22 of them. However, even in those target occupations in which Richmond has an abundance of people, only approximately 5 - 10% of them currently work in life sciences. Note that hospital systems are top employers for these occupations. The region has an excellent pipeline of highly specialized life sciences talent. The region produces an exceptional amount of highly specialized life sciences talent on account of VCU and other educational institutions; but the region does not have an above average concentration of workers in these occupations. By contrast, the talent pipeline for production workers such as industrial technicians appears relatively weaker. These workers represent a significant portion of talent needed by life sciences manufacturers. Other regional industries such as chemical manufacturing, will seek compete for these workers. For most of these 22 occupations, a very high percentage of educational attainment of workers is high school diploma or some college / Associates only.

BS, MS and Ph.D.

Ph.D. and master's degree talent is required to spearhead the innovative chemistry and chemical engineering that powers this cluster and will translate and develop it into competitive advanced manufacturing facilities. The supply for both BS and PhD scientists is met by the existing educational infrastructure. Looking beyond the College of Engineering and M4All, VCU and the region and state's universities matriculate ample PHD and master's students in what could be called pharma-ready degrees. When the state's other universities and colleges offering MS and BS degrees in relevant fields are included, there is a wealth of potential talent. Because this large sudden spike of demand will disrupt established pathways, it will be important to do great recruiting, and for general communications, to students and the universities supplying talent to this emerging cluster, about the sustained and exciting career opportunities it will present.

VCU College of Engineering is perhaps the leading producer of talent in this field in the world. In the classes and labs, chemists and chemical engineers learn and work side by side. They are trained in the unique framework of M4ALL. VCU's Ph.D. program in pharmaceutical engineering is the only one of its kind in the country. VCU is home to the interdisciplinary Center for Pharmaceutical Engineering and Sciences, a collaboration between the VCU School of Pharmacy and VCU Engineering – one of only a few such centers in the country. VCU Engineering organizes its undergraduate programs in this field differently from other schools, and it has proven amazingly effective. Students are offered the ability to study for both a chemistry and chemical engineering undergraduate degree. This option is so popular that 70% of VCU chemical engineering students graduate with double majors. The BARDA initiative provides significant financial support for VCU M4ALL to educate and train these specialized students in close collaboration with Phlow and its strategic partners, the firms building the emerging cluster. M4ALL also uses a large number of postdocs. This strengthens VCU's focus and excellence in educating the

talent for the new chemistries and processes which are foundational to advanced pharmaceutical manufacturing and the manufacturing processes and products of Phlow and its collaborators. Recently VCU Engineering was funded for workforce, training and research in cybersecurity of advanced manufacturing.

Complementing VCU's unique strengths are chemistry and engineering programs at the many and diverse *colleges and universities across Virginia.*[1] These include the College of Engineering and Technology and the College of Natural and Health Sciences at Virginia State University, whose campus lies just a few miles from AMPAC's Petersburg manufacturing site. VSU offers the state's only bachelor's degree program in Manufacturing Engineering and Information Logistics Technology. These and other colleges and universities in far flung corners of the state also have the talented graduates who may be valuable students in the VCU / M4ALL graduate level programs specialized in this field.

Further complementing these strengths, Virginia also hosts two university-industry statewide consortia with foundational expertise for this emerging cluster. Both are located in this region. Both provide ready collaborators with specialized research, development and technical support, and link undergraduate and graduates specializing in the field with employers in experiential learning placements. The Commonwealth Center for Advanced Logistics Systems (CCALS) is a consortium of five Virginia universities with focus in advanced logistics systems. CCALS provides research-intensive, project-based consulting work to private industry and public organizations through professor-led teams of students. While serving the needs of industry, graduate and specializing undergraduate students receive valuable experience, mentoring, exposure to industry practices and norms, and establish relationships with firms in their chosen field. The Commonwealth Center for Advanced Manufacturing (CCAM) is a public-private, industry-university collaborative research center that undertakes research critical to advanced manufacturing industries tailored to the region's needs.

Production and technical workforce

Production and technical workers will be the majority of jobs at the advanced pharmaceutical manufacturers in the cluster. Virginia's Community College System has long embraced industry partnerships to design and implement programs that benefit students and the Commonwealth's employers and is well equipped to meet this need. **(See Attachment 4)** In the *Community College Workforce Alliance (CCWA),* the region has a unique asset. CCWA is an industry-facing workforce initiative conceived and supported by two of the region's community colleges — *John Tyler Community College and Reynolds Community College*. CCWA aligns its efforts and pools its deep experience in meeting the workforce needs of the region's industries and potential workers.

CCWA has a flourishing *Fast Forward* program with particular bench strength in manufacturing, logistics and trades. CCWA offers the Virginia Manufacturers Association's Manufacturing Technician I (or MT1) credential prepares workers to operate precision machinery, systems and processes. JTCC offers a variety of current curricula and courses that help fill the employment need for a pharmaceutical manufacturing workforce. JTCC offers careers studies certificates (CSC) that range from 9 – 29 credits.

[1] Other higher education institutions in Virginia offering engineering programs are Christopher Newport University, George Mason University, Hampton University, James Madison University, Liberty University, Norfolk State University, Old Dominion University, Sweet Briar College, the University of Virginia, Virginia Military Institute, Virginia State University, Virginia Tech and Washington and Lee.

These shorter-term programs are designed to give students skills to get an entry-level job in a particular industry. JTCC also offers Certificates which is a set of technical coursework that ranges from 30-50 credits. The Associate of Applied Science (AAS) degree is a two-year degree that contains the technical courses required by industry but also classes related to general education including math, English, social science, and humanities. A full list of career and technical program related to advanced manufacturing, construction and skilled Trades offered by JTCC is seen in **Attachment 4, Table 1,** with those best suited to the pharmaceutical industry are highlighted in bold. The Advanced Manufacturing Management CSC contains coursework in supply chain management, quality assurance, world class manufacturing, and basic computer integrated manufacturing. The Advanced Manufacturing AAS degrees contains additional coursework in applied technology, industrial safety, and materials and processes of industry. JTCC Career and Technical Programs related to related to advanced manufacturing are: Advanced Manufacturing Management, CSC; Advanced Manufacturing Technology, AAS; Mechanical Engineering Technology, AAS; Mechanical Maintenance, CSC; Technical Studies, AA. JTCC also offers the customizable AAS Technical Studies degree and an Associate of Science in Science.

While the programs in place can produce workers to fill many of the technical needs related to the expansion of the pharmaceutical industry, there is not, however, an established dedicated pharmaceutical or even biotechnology manufacturing technician program in the area. The Work Group researched best practices and found several programs in Virginia, in North Carolina and across the United States that do so. Northern Virginia Community College offers a CSC, Biotechnology Lab Technician and an AAS in Biotechnology. Blue Ridge Community College offers an AAS degree in Advanced Manufacturing Technology with a specialization in Manufacturing Biotechnology. These students help meet the workforce needs of the large Merck biomanufacturing facility in Elkton, VA. North Carolina community colleges offer an outstanding program that prepares high school students for a career as a process technician for a biotechnology, pharmaceutical, or chemical manufacturing company. Students who complete the program are eligible to take more non-credit courses and obtain the BioNetwork Capstone Certificate in Biomanufacturing at Wake Tech and several other community colleges.

Armed with this research, CCWA and JTCC have been working with AMPAC Fine Chemicals and Civica Rx in planning tailored workforce training programs for the specific needs of pharmaceutical manufacturers in this emerging cluster. Two distinct, though complimentary, approaches are under discussion. One approach is to modify CCWA's successful MT1 program by adding curricular elements to provide appropriate preparation for entry level production occupations in the pharmaceutical manufacturing industry. The other approach is to create a more extensive and intensive John Tyler CC certificate program or CCWA workforce training program in advanced pharmaceutical manufacturing modeled on the highly regarded program at Wake Tech CC. Research with cluster firms has not revealed a need at this time for an AAS in Pharmaceutical or Bio manufacturing or Biotechnology. While a final course has still not been set, whatever curriculum CCWA and John Tyler CC, in coordination with AMPAC, Phlow and Civica, decide to create, it will be designed to qualify as a new state approved Fast Forward and G3 program. This will ensure tuition support for job seekers and incumbent workers and help ensure a steady stream of applicants who have received foundational training and assessment.

A robust workforce also addresses workforce readiness of a pool of talent with the right technical and soft skills to maintain and repair the highly specialized processes and equipment on which advanced manufacturing relies. CCAM, which also works with the region's industries and higher ed to create and operate innovative and needed workforce training programs, identified that the region has a relative

shortage of these skill sets. To address this, CCAM in partnership with Richard Bland College of William and Mary (RBC) and other higher ed institutions is establishing a regional chapter of the Federation of Advanced Manufacturing Education (FAME) program to recruit, educate and train entry-level employees to support and maintain the advanced equipment which are used in these fields. The FAME program produces graduates with a strong foundation in industrial system integration and troubleshooting of complex manufacturing equipment. Formal education is augmented with multi-skill training in industrial electricity, Programmable Logic Controllers (PLCs) for manufacturing environments, industrial robotics, industrial automation, fluid power, mechanics, and fabrication. Just a five-minute drive from the AMPAC/Phlow/Civica Rx site in Petersburg, CCAM's 62,000-sq. ft. Manufacturing Research Center features computational and engineering research labs, high bay production space for commercial scale equipment and tools required for research in manufacturing systems.

Finally, supplementing the workforce efforts of higher education **are local, regional and state-level public policies and programs. VEDP offers two outstanding** workforce incentive programs: One offers new or expanding companies grants to reimburse a large portion of recruitment and training costs, and the other, the Virginia Talent Accelerator, offers a wide range of tailored workforce solutions services at no cost to employers in the program. **Attachment 5** describes these and other state workforce programs in detail.

Virginia Talent Accelerator staff have been working closely with AMPAC and Civica Rx for months to plan and implement tailored solutions for their immediate workforce needs and coordinating with regional and local workforce professionals and with CCWA to design the training programs of the future. The Virginia Talent Accelerator will be a key resource to assure that the workforce needs of new companies entering and growing in the cluster are successfully met.

Experienced workforce

Despite these significant strengths in producing the variety of talent required by the cluster, the region has a relative lack of workers in all occupations with significant work **experience in pharmaceutical manufacturing**. This issue is inherent in the startup of a new cluster. However, focused and creative attention must be paid to address this while the cluster matures, and a local community of experienced workers naturally forms. The Region has a strong base of advanced manufacturing, some in chemicals and highly regulated industries. These sectors can be sources of talent and cross training programs can be designed. The Virginia Talent Accelerator can help companies recruit. A strong branding and communications campaign by the cluster can help attract talent from across the and nearby regions with experienced talent such as North Carolina and Maryland/DC.

Recommendations of the Workforce Work Group

1. **Organize to effectively and quickly deliver workforce assistance and develop programs to meet anticipated needs and provide a foundation for collaborative workforce efforts for the cluster**

    a. Establish a sustainable organization of stakeholders with the responsibility to coordinate regional action in support of development of the cluster and implementation of the Recommendations of the Final Report, including these workforce development matters. Without this little progress will be made.

b. Continue and expand the network of public sector, academic and private sector workforce specialists and cluster firms focused on this opportunity that has formed as a work group in the strategic planning process. This group will work collaboratively to implement these recommendations and other workforce development initiatives which are identified and prioritized in the future. This networking has accelerated delivering assistance and creating collaborations to date and will continue to do so in the future.

c. Set the goal for the region and cluster to provide best in class workforce and workforce development for an advanced pharmaceutical manufacturing cluster using continuous flow and creating innovative end to end supply chain solutions.

d. Support a coordinated communications campaign by the cluster and its key stakeholders to tell the story of the cluster, its compelling mission, strong economic future and the essential role of workforce. Include among targeted audiences and messages recruitment of students, transitioning worker, and experienced workers in other advanced manufacturing industries or from out of state to the labor pool and to workforce development initiatives here.

e. Encourage collaboration among stakeholders with congruent regional assets which can support or lead workforce development initiatives in areas of specialized expertise important to the cluster, including CCAM and CCALS, and help them develop and source funding for innovative and effective experiential learning, workforce training and career enrichment programs.

f. Find and develop opportunities for close industry – academic/student relationships. Look for creative collaborations, and relationships with nontraditional partners and underserved communities.

g. Support VCU in the relentless pursuit of global leadership in educating and training the chemists and engineers who will lead the creation, scale up and commercial development of the innovative technology on which the new industry is built. Support VCU College of Engineering / M4ALL efforts to recruit and train students, including special outreach to students from the region and state, to establish training and experiential learning opportunities with industry, to extend their efforts into scientific and technical stages of the new industry still under development, and to create a national center of excellence.

h. Seek public and philanthropic funding opportunities to support these recommendations, paying particular attention to federal funding opportunities given the confluence of urgent and important national interests advanced by the cluster and this unique opportunity to bring jobs of the future to historically disadvantaged communities.

2. Deliver immediate assistance as needed to the firms in or coming to the cluster

a. Give all-hands focus to help core cluster companies here meet their hiring needs for the present scale up and start-up phase over the next 1-24 months. Support the efforts of

VEDP's Virginia Talent Accelerator, Community College Workforce Alliance (CCWA) and John Tyler Community College (JTCC), regional and local economic development organization and private firms alone and in collaboration.

b. Find near-term steps to reach workers with direct experience in this industry**. Virginia Talent Accelerator** provides help directly, and private sector recruiting, and human resource companies are here and ready to help. Develop and support efforts to recruit and offer cross-training to workers with experience in other advanced and regulated manufacturing industries.

c. Provide support from the cluster core companies, community colleges and higher education to local, regional and state economic development organizations as they attract and growing companies in the cluster by meeting with potential candidates and other means.

3. Build a stronger pipeline to unlock future growth by preparing our workforce to meet the needs ahead. (3,4,7)

a. Develop a new permanent accredited manufacturing technician program specifically for advanced pharmaceutical manufacturing to meet the needs of cluster core companies and others which will come. Support the efforts now underway by CCWA, JTCC, AMPAC Fine Chemicals and Civica Rx to launch a program based on national models adapted to the needs of cluster firms. Incorporate VEDP industry knowledge and experience and support and build toward integration with complimentary VEDP workforce programs and plans. Take advantage of Fast Forward, the new state workforce funding program and "Get Skilled, Get a Job, Give Back" (G3), both delivered through community colleges, as primary sources of tuition support and access GO Virginia as key sources of additional support.

b. Support the CCAM/FAME recruitment and training program for entry-level advanced manufacturing service and support workers to widen the pipeline of young and transitioning workers into the advanced pharmaceutical manufacturing industry. This program already enjoys GO Virginia support.

c. In collaboration with other Virginia engineering schools, universities and colleges, develop a strategy and system to inform, expose and recruit students and graduates in targeted majors to the cluster. Collaborate with the Virginia-Bio Connect statewide network newly formed with GO Virginia funding, with its strong university relationships. Engage VSU in a lead role.

d. Explore potential mechanisms of state incentives to increase supply of experienced pharma manufacturing workers in Virginia.

Attachment 1

Members of the Workforce Work Group

Elizabeth Creamer, Community College Workforce Alliance, Co-lead

Anita H Taylor, VCU College of Engineering, Co-lead

William DuBay, AMPAC Fine Chemicals

Omar Faison, Virginia State University

Mike Grundmann, Virginia Economic Development Partnership (VEDP)

Pam Harder, Virginia Economic Development Partnership (VEDP)

John Milton-Benoit, Commonwealth Center for Advanced Manufacturing (CCAM)

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Thomas D Roper, VCU College of Engineering, Pharmaceutical Engineering

Lorin Sodell, Commonwealth Center for Advanced Manufacturing (CCAM)

Matt Stallings, Apex Solutions

Johanna Weiss, John Tyler Community College

Attachment 2
Data on projected hiring by core cluster firms next 24 months

Projections of New hiring by core cluster and other firms in advanced pharmaceutical manufacturing in Petersburg

New Hires by month for 24 months beginning Feb 21 (does not include replacement hires)

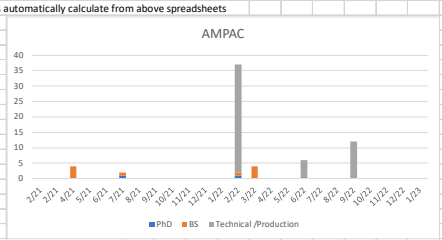
by employer | by category | data input cells | **Spreadsheet A**

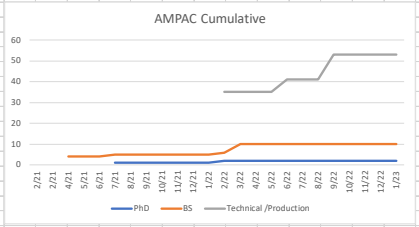
		2/21	3/21	4/21	5/21	6/21	7/21	8/21	9/21	10/21	11/21	12/21	1/22	2/22	3/22	4/22	5/22	6/22	7/22	8/22	9/22	10/22	11/22	12/22	1/23	Total
AMPAC	PhD						1							1												2
	BS			4			1							1	4											10
	Technical /Production													35				6			12					53
Phlow	PhD			4							7				1											12
	BS			8							7			4	1											20
	Technical /Production													35		2				8						45
Civica Rx	PhD										1	1	1	1	1	1										6
	BS			4	1	2	0	4	0	3	2	3	4	3	4		1	1	1	2		1		1		37
	Technical /Production									1			2		6		4			1				2	5	21
Others	PhD	0																								0
	BS	0																								0
	Technical /Production	0																								0
All	PhD	0	0	4	0	0	1	0	0	0	8	1	1	2	2	1	0	0	0	0	0	0	0	0	0	20
	Bs	0	0	16	1	2	1	4	0	3	9	3	4	8	9	0	1	1	1	2	0	1	0	1	0	67
	Technical / Production	0	0	0	0	0	0	0	0	1	0	0	2	70	6	2	4	6	8	1	12	0	0	2	5	119

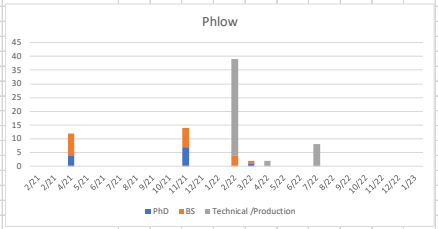
Cumulative hires projected next 24 months | by employer | by category | calculated automatically from above | **Spreadsheet B**

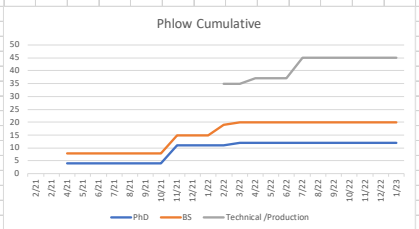
		2/21	3/21	4/21	5/21	6/21	7/21	8/21	9/21	10/21	11/21	12/21	1/22	2/22	3/22	4/22	5/22	6/22	7/22	8/22	9/22	10/22	11/22	12/22	1/23
AMPAC	PhD						1	1	1	1	1	1	1	2	2	2	2	2	2	2	2	2	2	2	2
	BS			4	4	4	5	5	5	5	5	5	5	6	10	10	10	10	10	10	10	10	10	10	10
	Technical /Production													35	35	35	35	41	41	41	53	53	53	53	53
Phlow	PhD			4	4	4	4	4	4	4	11	11	11	11	12	12	12	12	12	12	12	12	12	12	12
	BS			8	8	8	8	8	8	8	15	15	15	19	20	20	20	20	20	20	20	20	20	20	20
	Technical /Production													35	35	37	37	37	45	45	45	45	45	45	45
Civica Rx	PhD		0	0	0	0	0	0	0	0	1	2	3	4	5	6	6	6	6	6	6	6	6	6	6
	BS				1	3	3	7	7	10	12	15	19	22	26	26	27	28	29	31	31	32	32	33	33
	Technical /Production										0	0	2	2	8	8	12	12	12	13	13	13	13	15	20
Others	PhD																								
	BS																								
	Technical /Production																								
All	PhD		0	4	4	4	5	5	5	5	13	14	15	17	19	20	20	20	20	20	20	20	20	20	20
	Bs			12	13	15	16	20	20	23	32	35	39	47	56	56	57	58	59	61	61	62	62	63	63
	Technical / Production										0	0	2	72	78	80	84	90	98	99	111	111	111	113	118

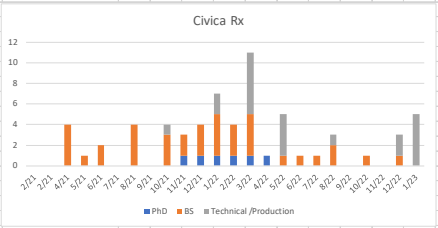
All Charts automatically calculate from above spreadsheets

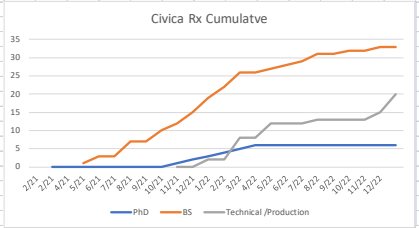


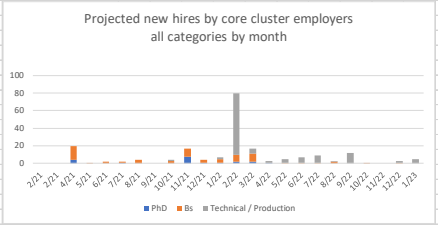


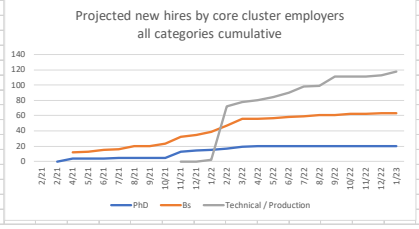








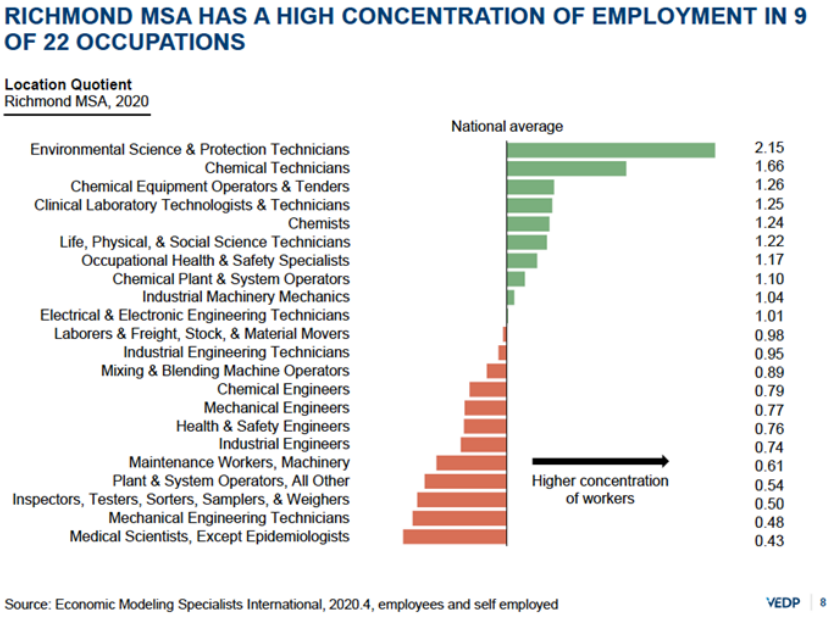




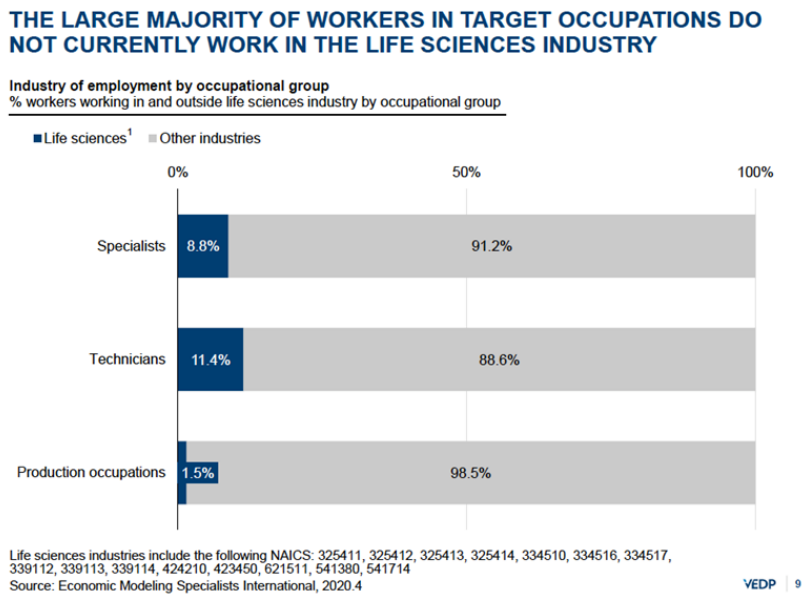
Attachment 3

Insights from regional labor market data

1. **Of the 22 occupations most commonly tied to life sciences, Richmond has a very high concentration in nine.**
2.



2. **Richmond produces an exceptional amount of highly specialized life sciences talent on account of VCU and other educational institutions; currently the supply greatly exceeds demand such that there's no shortage of this talent now and can be reasonably expected.**



3. **Richmond also has an abundance of people working in the target occupations listed below. Currently the life sciences employ a small fraction of this large and experienced talent pool.**

HIGHEST AND LOWEST DEMAND OCCUPATIONS IN LAST 12 MONTHS[1] IN THE RICHMOND MSA

Highest demand occupations

- Industrial Engineers / Technicians
- Medical Scientists
- Health & Safety Engineers
- Occupational Health and Safety Specialists
- Lab / Clinical Technicians
- Electrical And Electronics Engineering Technicians
- Mechanical Engineers / Technicians

Lowest demand occupations

- Mixing and Blending Machine Operators
- Industrial Machinery Mechanics / Maintenance
- Chemical Technicians
- Chemical Equipment Operators
- Plant / Systems Operators

[1] Among 22 occupations studied
Source: Labor Insight, Burning Glass Technologies; Economic Modeling Specialists International, 2020.4; VEDP analysis

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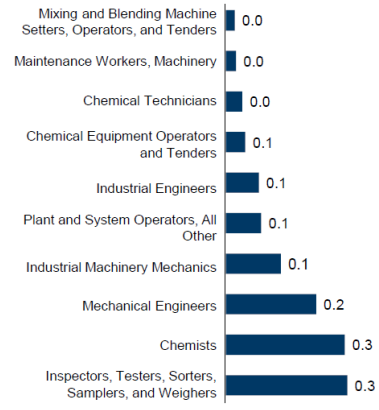
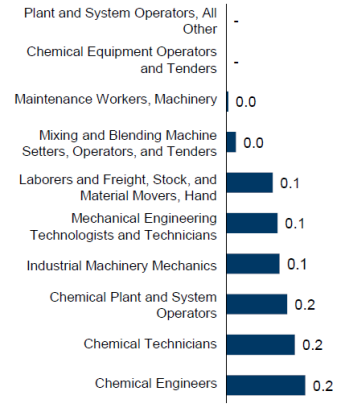
4. **Richmond has an excellent pipeline of highly specialized life sciences talent. The talent pipeline for production workers such as industrial technicians is less strong. These workers represent a significant portion of talent needed by life sciences manufacturers. Other regional industries such as chemical manufacturing of course are in competition for these workers.**

LOWEST DEMAND OCCUPATIONS AMONG 22 SELECTED OCCUPATIONS

Burning Glass lowest demand occupations
Job postings per job, Richmond MSA, past 12 months



Emsi lowest demand occupations
Job postings per job, Richmond MSA, past 12 months



Source: Labor Insight, Burning Glass Technologies; Economic Modeling Specialists International, 2020.4

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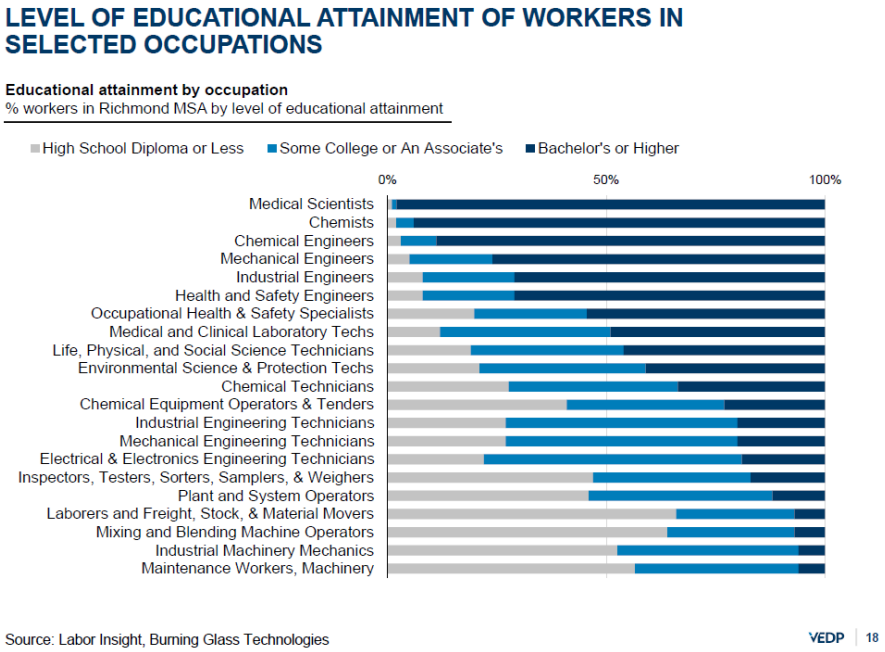
5. A very high percentage of educational attainment of workers in these 22 occupations is "high school diploma" or "some college / Associate's" (gray and light blue bars):



Attachment 4

Technical and production Workforce

CCWA, JTCC, and CCAM provide a continuum of training, education, and credentialing for technical and production workforce.

Community College Workforce Alliance (CCWA). CCWA is the shared workforce development division of John Tyler and Reynolds Community Colleges. As such, CCWA's primary mission is to work with its community colleges and regional education and workforce development providers to create and sustain talent pipelines for technician and trades occupations in industry sectors such as manufacturing, logistics, trades, transportation, information technology, and health care. Specifically, CCWA aims to expand the region's technical and production workforce in key industry sectors through industry sector strategies, occupational training and workforce credentialing, apprenticeship related instruction, career coaching, and customized business training. Serving more than 7500 regional residents a year, CCWA programs and services are targeted to providing job preparation and workforce credentials, such as industry certifications and occupational licenses, to those seeking entry level positions that do not necessarily require a baccalaureate degree but, instead, technical and employability (or "soft") skills as well as a contextual knowledge of the selected industry and occupation. CCWA is thus a starting point for a career pathway that can continue through a community college degree program or a registered apprenticeship. Additionally, CCWA has extensive experience in working with regional industries to provide pre-employment and incumbent worker training, including apprenticeship related instruction.

The Commonwealth of Virginia's signature initiative to ensure a ready workforce of technician and trades workers is called the **Fast Forward Workforce Credential Grant**, which provides tuition support for all Virginians regardless of income level if they enroll and complete a workforce training program to prepare them for an in-demand production or technical occupation so identified by the Governor's Workforce Board. CCWA has a flourishing Fast Forward program with particular bench strength in manufacturing, logistics and trades. The Virginia Manufacturers Association's Manufacturing Technician I (or MT1) credential provides foundational knowledge and skills that, with some additional curricular elements, AMPAC has indicated would be appropriate preparation for entry level production occupations in the pharmaceutical manufacturing industry. CCWA is pursuing this concept but is also working directly with Civica at present to research with the idea of adopting and adapting a more extensive and intensive non-credit or college certificate workforce training curriculum.

Whatever curriculum CCWA, in coordination with AMPACT, Phlow, and Civica, decides to adopt as a result of current research and development efforts currently taking place, the goal will be to create new state approved Fast Forward and G3 programs thus ensuring continued tuition support for job seekers and incumbent workers and a steady stream of applicants who have received foundational training and assessment. CCWA's Fast Forward programs already serve a wide swatch of regional residents through high school industry certification "boot camps" for graduating seniors to military to manufacturing programs to transition active-duty service members to a civilian technical and production workforce to "rapid response" programs designed to quickly reemploy dislocated workers with technical experience to regionally available, related jobs.

CCWA has dedicated classrooms and industrial labs at two Reynolds and two John Tyler Community College campuses including a new 25,503 square foot Workforce Development Center at John Tyler's

Chester Campus. CCWA's instructional resources also include a mobile manufacturing lab that introduces technical career fields to high school students throughout the region.

JTCC Credit Courses and Curricula. Current curricula and courses offered by JTCC that may help fill the employment need for a pharmaceutical manufacturing workforce. JTCC offers careers studies certificates (CSC) that range from 9 – 29 credits. These shorter-term programs are designed to give students skills to get an entry-level job in a particular industry. JTCC also offers Certificates which is a set of technical coursework that ranges from 30-50 credits. The Associate of Applied Science (AAS) degree is a two-year degree that contains the technical courses required by industry but also classes related to general education including math, English, social science, and humanities.

A full list of career and technical program related to advanced manufacturing, construction and skilled Trades offered by JTCC is seen in Table 1. Those best suited to the pharmaceutical industry are highlighted in bold. The Advanced Manufacturing Management CSC contains coursework in supply chain management, quality assurance, world class manufacturing, and basic computer integrated manufacturing. In addition to these courses, the Advanced Manufacturing AAS degrees contains coursework in applied technology, industrial safety, and materials and processes of industry.

Table 1: JTCC Career and Technical Programs related to related to advanced manufacturing, construction and skilled trades (source: JTCC.edu)

• **Advanced Manufacturing Management, CSC**	• **Advanced Manufacturing Technology, AAS**
• **Mechanical Engineering Technology, AAS**	• **Mechanical Maintenance, CSC**
• **Technical Studies, AAS**	• Building Construction Certificate
• Basic Precision Machining Technology, CSC	• Computer-Aided Drafting and Modeling, CSC
• Precision Machining Technology Certificate	• Heating and Air Conditioning, CSC
• Computer Numerical Control, CSC	• Electricity, CSC
• Electrical Engineering Technology, AAS	• Residential Electricity, CSC
• Energy Technology, CSC	• Industrial Electricity, CSC
• Welding Certificate	• Mechanical Engineering Technology, Mechatronics Specialization, AAS
• Welding CSC	

The AAS Technical Studies degree is a customizable degree where a student can combine 1-2 CSCs with other workforce-related and general education coursework. This degree may be a venue for combining manufacturing coursework with courses in science and lab skills.

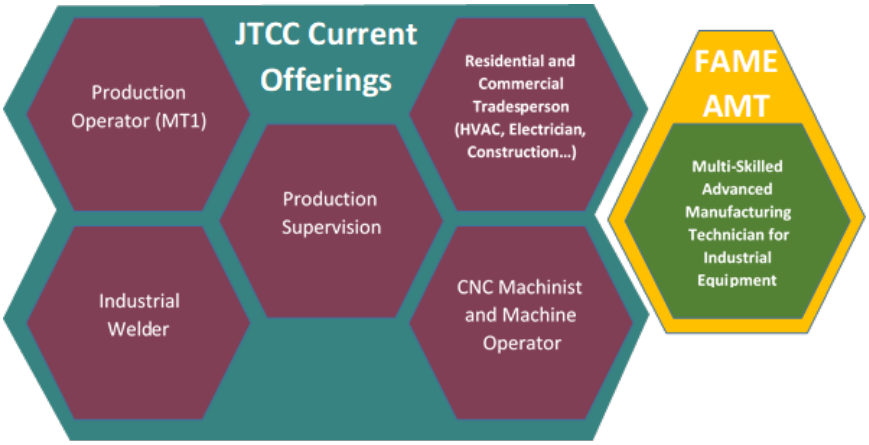
JTCC also offers an Associate of Science in Science. This transfer program is designed to serve as the first two years of a B.S. degree in Biology, Chemistry, Physics, Environmental Science, etc. Courses include math (through at least Precalculus II), two semesters of general biology, two semesters of chemistry, two semesters of physics, and the general education required by transfer institutions. Though not intended to prepare students to enter the Biotechnician workforce, students who take coursework in and/or obtain the AS in Science have a strong scientific and technical background that would lend itself well toward the entry and completion of a short-term non-credit biomanufacturing training program (see below).

The FAME model at RBC and CCAM. In addition to the programs for training technical and production workers via John Tyler Community College and CCWA, another key area of workforce readiness that must be addressed is the population of workers with the right technical and soft skills to support and maintain the highly technical manufacturing equipment that will be the backbone of the Ampac/Phlow/Civica processes, and for any other partners who collaborate in this venture. To address the overall shortage of these skill sets in the region, a partnership of Richard Bland College of William and Mary (RBC) and the Commonwealth Center for Advanced Manufacturing (CCAM) has proposed to establish a regional chapter of the Federation of Advanced Manufacturing Education (FAME) program to recruit, educate and train entry-level employees to support these fields. CCAM/ RBC have attracted support from a broad region of companies and industries across the region. In addition to the Core Members, the Chapter will include at least twelve public school divisions as "Associate Members" whose students will fuel the workforce pipeline. To tie everything together, the Chapter will include input and support from sixteen of the Region's public sector organizations that provide economic development, workforce training, industry advocacy, and educational support. These "Supporting Members" will help to ensure that the Chapter's goals remain aligned with the overall needs and capabilities / capacities of the Region.

Over five semesters and a weekly schedule of three days at work paired with two days in a shop-floor emulation at CCAM and at RBC, students earn a paycheck to help defray (or even offset) associated tuition and fees as they earn an associate degree and learn technical and personal skills to greatly accelerate their careers. As a result of the previous pilot programs, Region 4 now has fully functional training facilities in dedicated labs at CCAM to certify and train mechatronics students. This training equipment is not available at other community colleges or programs in the Region. The FAME program will take advantage of this existing equipment and directly build on it to fully-satisfy the program's objectives.

CCAM and RBC have closely studied the existing educational and career skill offerings by Community Colleges in Region 4 to ensure that the FAME program complements, rather than duplicates or cannibalizes existing programs. CCAM already collaborates with JTCC, the CCWA, and SVCC to support their programs and curricula. While JTCC offers many degree and certificate programs to support technical career paths (see Table 1 and Figure 1), manufacturers in the region have recognized that the AMT profile fills a gap not addressed by the current programs.

Figure 1: Targeted Job Types for the FAME Advanced Manufacturing Technician vs. current offerings



The FAME program focuses on graduates having a strong foundation in industrial system integration and troubleshooting of complex manufacturing equipment. Formal education will be augmented with multi-skill training in industrial electricity, Programmable Logic Controllers (PLCs) for manufacturing environments, industrial robotics, industrial automation, fluid power, mechanics, and fabrication. RBC will deliver the non-technical and general education requirements.

The principal difference between FAME's AMT program and the Maintenance Technician 1 "MT1" certification offered by the CCWA is that the AMT is focused on support and repair of highly specialized processes and equipment, whereas an MT1 "operates precision machinery, systems and processes" (source: ManufacturingSkillsInstitute.org). The purpose of the MT1 certification is to document individuals' mastery of the critical competencies required for modern manufacturing production and production-related occupations. The program includes 64 hours of training over 8 weeks. Sample MT1 Job Titles include: "Operator, Production Operator, Production Technician, Technician, Chemical Equipment Operator, Chemical Operator, Fixers, CNC Technician Manufacturing Technician and Production Manufacturing Specialist" (source: ManufacturingSkillsInstitute.org).
Since the FAME program is a 24-month program focused on support and repair of processes and equipment, rather equipment operation, the FAME will *complement* workers with the MT1 certification rather than conflict with them.

ESTABLISHING NEW WORKFORCE PROGRAMS TO FILL GAPS IN PRODUCTION OF TECHNICAL WORKFORCE

Programs at CCWA, JTCC, and RBC/CCAM that can produce workers to fill some of the technical needs related to the expansion of the pharmaceutical industry in the metropolitan Richmond area. However, there is not an established biotechnology or pharmaceutical manufacturing technician program in the area, and in-depth discussions with the core cluster companies suggest this would be very beneficial. There are several programs in Virginia and in United States that could serve as models to establish a regional program, and CCWA and JTCC are in study, planning and discussions with employers to determine what curriculum and what form – workforce training, certificate program, AA degree program, would be optimal, and are ready to begin to implement such a program.

Several models of biotechnology/pharmaceutical manufacturing programs. Within the Virginia Community College System (VCCS), two community colleges have established new programs in biotechnology/biomanufacturing over the past 5 – 10 years. The first program emerged at Northern Virginia Community College where they now offer two paths: a CSC, Biotechnology Lab Technician and an AAS in Biotechnology (Biotechnology Program - Northern Virginia Community College (nvcc.edu)). Because there is not a dominant biotechnology sector such as biomanufacturing in northern Virginia, this program was designed to instruct students on basic lab techniques and includes coursework in biology, chemistry, microbiology, biotechnology concepts, biotechnology methods, protein application in biotechnology, nucleic acid methods. There is additional coursework in regulatory and quality environments and business of biotechnology.

Blue Ridge Community College developed an AAS degree in Advanced Manufacturing Technology with a specialization in Manufacturing Biotechnology (Advanced Manufacturing Technology: Manufacturing Biotechnology <Blue Ridge Community College (brcc.edu)). The curriculum combines biology and operational technology includes basic mechanical and electrical skills with a focus on bioprocessing methods and technologies plus process improvement. The goal of the program is to prepare graduate

for employment one for the pharmaceutical, food processing industries and healthcare facilities and related fabrication and service operations. Potential jobs include vaccine operator/technician, quality control technician and cleanroom/contamination control technician. They also have CSCs in Applied Mechatronics I, Mechatronics II, Applied Manufacturing Biotechnology, Manufacturing Biotechnology Technician I, and Manufacturing Biotechnology Technician II.

There are several biotechnology/biomanufacturing programs in North Carolina. BioWork, offered at most community colleges, is a 136-hour non-credit certificate course (Workforce Continuing Education) (BioWork | NCBioNetwork.org) which gains high marks from the experiences of one of the Core Cluster companies . Topics include:

- Biotechnology Industry and Job Overview
- Working Safely
- Current Good Manufacturing Practices (cGMP)
- Measurements, Metrics, and Math
- Chemistry for Process Manufacturing
- Process Flows, Technology, and Equipment
- Controlling the Process and Maintaining Quality
- Aseptic Processing
- Fermentation and Cell Growth
- Job Search, Resumes, and Interviews

This program is geared toward students who have a high school diploma and prepares students for a career as a process technician for a biotechnology, pharmaceutical, or chemical manufacturing company. Students who complete this are eligible to take more non-credit courses and obtain the BioNetwork Capstone Certificate in Biomanufacturing at Wake Tech and several other community colleges (BioNetwork Capstone Certificate in Biomanufacturing | Wake Technical Community College). Several other institutions throughout the United States offer courses and curricula in biotechnology and biomanufacturing. Examples include Wake Tech also offer an Associate degree in Biopharmaceutical Technology APPLIED ENGINEERING & TECHNOLOGIES (waketech.edu). Quincy College offers both an associate degree and certificate in Biotechnology & Good Manufacturing Practice (Biotechnology and Good Manufacturing Practice | Quincy College). Kansas City Kansas Community College offers a 16-credit certificate in Biomanufacturing (Biomanufacturing - Certificate | KCKCC). A complete list of credit biotechnology and biomanufacturing programs can be found at the National Biotechnology Education Center (The InnovATEBIO Network | InnovATEBIO (bio-link.org)).

Development of short-and long-term training at CCWA and JTCC. In order to fill the increasing demand for workers training in biomanufacturing and biotechnology, CCWA and JTCC are determined to partner to create both short-term and long-term training programs. They already have sketched a work plan and are proceeding through it working on research and Set-up, Communications and Recruitment, Convening businesses, Program Design and Fundraising. Current plans call to begin to pilot a short-term (one semester) non-credit program in Fall 2021 or Spring 2022. Concurrent with this, they will complete plans, obtain funding and design a comprehensive onboarding program. This may be simply select additions specific to the pharmaceutical industry to the current successful MT1 program, or a new comprehensive CSC program for pharmaceutical technicians similar to NVCC, BRCC or North Carolina's popular program. Whatever the components and order of roll out, they will endeavor that the short-term non-credit training will stack into the new CSC and perhaps ultimately an AAS in Pharmaceutical Manufacturing and Biotechnology.

Attachment 5

Leveraging state workforce development incentives to expand the cluster

To attract new biopharma employers to the cluster and encourage existing employers to expand, the Commonwealth and localities offer a variety of grants and tax incentives. The primary state-level incentives are offered through and administered by the Virginia Economic Development Partnership (VEDP). Two of these incentives are focused on recruitment and workforce development:

- The Virginia Jobs Investment Program (VJIP) reduces a company's talent development costs through grant funds supplemented by consulting, and coordination with regional partners to streamline company recruitment and training.

- The Virginia Talent Accelerator Program delivers direct recruitment and training services that are fully customized to a company's unique operations, requirements, standards and culture. All program services are provided at no cost to qualified companies as an incentive for job creation.

Eligible employers have the option to choose the VEDP talent incentive option that best fits their needs. Eligibility for both programs is primarily based on an employer's net new job creation and requires that the company be considering multiple states for the project (i.e., the project is competitive). Major bio-pharma product manufacturers who meet eligibility requirements are generally eligible for both programs if they plan to create at least new 25 jobs. The VJIP program can also support eligible smaller companies (under 250 company-wide employees) which are creating at least five new positions.

If VJIP is selected, the funds may be used to fund training support delivered by a college or university. VEDP's team of Regional Talent Solutions Managers will work to initiate introductions and facilitate the development of relevant programs. However, there is no requirement that employers use VJIP grants to fund training provided by a College. The grant funds are often used to offset the expense of leveraging internal resources for recruiting and training.

Support for Teleworking Employees

While most bio-pharma cluster jobs require on site work at a production or lab facility, there is an increasing number of data analytics jobs in the field which may be done remotely. Recognizing the growing number of jobs like this, the Commonwealth of Virginia has adopted new statutory language that enables VEDP to take telework positions, held by Virginia residents, into account when offering performance-based economic development incentives for new, competitive site-selection projects. Therefore, these jobs can generally be included as part of a VJIP, or Virginia Talent Accelerator supported project.

Virginia Talent Accelerator Program Overview

If the Virginia Talent Accelerator Program is selected, all services are delivered in collaboration with the appropriate higher education partners, with the primary partner being the nearest Community College, to ensure that the program's recruiting and training support for the facility start-up is coordinated with the long-term workforce development support provided by the Colleges.

Community Colleges and Universities operate programs that provide opportunities for the workforce at large and for graduating high school students to gain credentials that elevate their qualifications for jobs in the bio-pharma cluster. Benchmarking work is currently underway to identify the specific opportunities to enhance and expand existing programs or create new ones that more closely align courses of study with the needs of bio-pharma employers. The objective is to supply qualified workers for the sector's known job growth and present a highly visible bio-pharma workforce pipeline to help Virginia compete against other states in attracting new bio-pharma employers.

Winning multi-state competitions for expansions of existing firms, as well as attracting new competitive projects to Virginia, is what the Virginia Talent Accelerator Program was created to do. While College and University programs provide individuals with opportunities to gain relevant skillsets, once hired they still need to learn how to apply the skills, they bring from either from a college program or previous work experience to the new employer's unique processes and procedures. This "last mile" of training, generally delivered within the first few days or weeks on the job, is where Virginia Talent Accelerator services are focused. The program also provides a robust suite of recruitment services to ensure that eligible employers attract job candidates to new positions at all levels of their organizations. The scope of Virginia Talent Accelerator Program Services encompasses:

Talent Attraction

Recruitment services include job advertising media development, in-depth talent pool research, and media buys to generate applications from the highest quality candidates. Localized recruiting web pages, applicant tracking, job fair support, and professional search services are also available.

Talent Screening

Components of the training services can be delivered prior to an employment offer. Customized pre-hire training provides an opportunity for companies to observe job candidates' work habits, detail orientation, and team skills as they perform representative tasks – prior to final employment offers. It likewise provides candidates with the opportunity to opt out of the selection process if they decide the work is not a good fit. Most of the customized job-specific technical training is typically conducted post-employment to protect the confidentiality of company processes.

Job-Specific Training with Highly Customized Media Development

Customized job-specific training is focused on a production facility's equipment operators and technician level positions. It is delivered using methodologies and media determined to be most effective for accelerating learning in given topic. These feature broadcast-quality videos, hands-on simulations, instructor-led classroom sessions, illustrated work instructions, animations and e-learning modules**.**

Organizational Development

In addition to recruiting and job-specific training services, the Virginia Talent Accelerator Program offers a robust suite of organizational development and operational excellence training and consulting services. These services help companies establish a collaborative culture and optimize individual performance.

Support Beyond Individual Bio-pharma Employers

It is anticipated that most eligible bio-pharma employers will choose the service-based Virginia Talent Accelerator option. It bears repeating that this and the VJIP program are only available to companies planning significant job creation and considering multiple states for their new operations. Therefore, the programs do not directly serve the employment needs of the entire cluster; rather they serve to expand the cluster's employment base by enabling Virginia to attract major new bio-pharma employers, namely by enabling the rapid re-skilling of an area's workforce.

That said, the Virginia Talent Accelerator program can *contribute* to Community College programs that enable individuals seeking credentials to qualify for employment in the cluster. While all customized employer-specific materials developed during the project become the property of the company to protect proprietary information, an employer is free to release all or select portions of these high quality training materials to a college to enhance a public open enrollment program, or to enable the college to continue delivering proprietary training to the employer on a cost-recovery basis once the Virginia Talent Accelerator's commitments to support the start-up have been fulfilled.

Specialized Equipment and Facilities

If a prospective new employer is large enough, VEDP may be able to rapidly secure funding for specialized bio-pharma equipment and/or facilities through the Major Employment and Investment (MEI) commission as part of the incentive package deemed necessary to win the competition with other states and land the jobs in Virginia. Initially, these assets would be deployed to provide just-in-time Virginia Talent Accelerator proprietary job-specific training for the first waves of employees hired with the requisite work experience. In parallel, the Virginia Talent Accelerator team will collaborate with area colleges and universities to leverage the assets for use in non-proprietary open enrollment programs that would generate a pipeline of pre-qualified workers. These workers will form the talent pool for the employer's subsequent hiring waves. Once the Virginia Talent Accelerator program's commitments are fulfilled, the training assets could be turned over to the college primarily for use in non-proprietary open enrollment programs that would generate a pipeline of pre-qualified workers to support the ongoing workforce needs of all cluster employers.

Federally Funded Workforce Support and Assistance

In addition to the state-funded programs outlined above, there are a number programs partially or wholly supported by federal funding which can serve to further advance workforce development in the bio-pharma cluster. Below is a synopsis of each.

Workforce Innovation and Opportunity Act

The Workforce Innovation and Opportunity Act (WIOA) provides federal funding for employment and training activities to enhance productivity and competitiveness. Through statewide and local workforce investment systems, WIOA attempts to increase employment, retention, skill levels, credential attainment, and earnings. In Virginia, the WIOA is administered at the state level by the Virginia Community College System. At the local level, workforce boards appointed by local elected officials

oversee the program. Through the one-stop service delivery network established by WIOA, available employment and training services include:
For Employers:

- Assistance in finding qualified workers, including interview facilities
- Information on and referral to business start-up, retention, and expansion services
- Information and access to a variety of training-related resources to provide for a skilled workforce
- Information on labor markets, workplace accommodations, and tax credits for new hires

Some of the specific training options of value to employers funded by WIOA include:

- On-the-job training (OJT), which allows the employer to be reimbursed for up to 75% of the participant's wage rate to compensate for employer costs during training depending on Local Workforce Development Board Policy
- Customized training, which allows up to 75% of an employer's training costs to be covered by WIOA funds for training designed to meet the needs of an employer, or group of employers, if there is a commitment to employ or retain individuals at the completion of training depending on Local Workforce Development Board Policy
- Incumbent worker training, providing the opportunity to upgrade skills of the existing workforce

For Individuals:

- Job, career, and skill self-assessment tools and assessment services
- Information about and access to a variety of educational and training resources to enhance skill levels and make individuals either work-ready or provide opportunities for advancement along their career pathway
- Information about and access to other supportive services that can help guarantee success while in educational or training programs

The majority of WIOA funding is passed directly to 15 local workforce development areas for direct service delivery. In addition, WIOA funds at the state level can assist businesses with layoff aversion strategies and fund rapid-response services to workers affected by plant closings and other dislocations. For more information: www.vccs.edu/workforce

Registered Apprenticeship Program

The Virginia Registered Apprenticeship Program partially reimburses eligible sponsors (employers) for certain costs of related instruction. The incentive funding is available to private industry sponsors in the specific fields of professional and business services, information technology, and cybersecurity.

State and local government entities have access to the incentive reimbursements for related instruction in any occupation. The Registered Apprenticeship Program benefits these entities by allowing them to better recruit, retain, and strengthen the skills of workers beginning their public service careers.

The Registered Apprenticeship Program is administered by the Virginia Department of Labor and Industry's (DOLI) Registered Apprenticeship Division. DOLI may reimburse the sponsor, up to a maximum of $1,000 annually, per apprentice, for a maximum of 10 apprentices. Reimbursement is not guaranteed and is subject to available funding on a first-come, first-serve annual basis after the

apprentice has successfully completed the coursework. For more information, visit: www.DOLI.virginia.gov/apprenticeship/brochure

Report of the Communications Work Group

"This is not just about chemistry, it's about vision and the right players. We are not just bringing molecules together; we're bringing people together to solve a problem." Dr. Frank Gupton

The Work Group's six members are highly experienced communications specialists from Virginia Commonwealth University's College of Engineering as well as local, regional and state economic development authorities, the private sector and CCAM. **(Attachment 1)** In their positions, many have been following and communicating the developments in this emerging cluster.

The mission of the work group was to listen for the facts and shape the story of the cluster in a clear, coherent and comprehensive way for the region's stakeholders; to suggest how communications could support the growth of the cluster, success of its firms and prosperity of the region; to guide the recommendations of the Study; and to form a working network of informed experts from key stakeholders who would be equipped to work in support cluster growth in the years ahead. Members were asked to take the point of view of the region as well as their own organizations in their participation.

The key role of communication and branding in economic development of a region and cluster is well recognized. Indeed, the Grow Capital Jobs Economic Growth and Diversification Plan (2017), which laid the foundation for this strategic planning effort, remarked "Communicating and branding the region's appeal will be essential to enhancing our competitive position." A strong and unified communications effort - unlike anything that exists now, will be essential for this cluster to thrive.

Gathering the story

The efforts of the Work Group to listen for and gather the facts and ideas that shape an account of the emerging cluster culminated in the production of the White Paper which appears **as Appendix 1 of the Final Report.** The White Paper is intended to be a resource for those who wish to know what this cluster is all about, and a reference for regional stakeholders to draw on time and again. It will be a foundational resource for cluster communications. Several points jump out of great significance to efforts in cluster communications.

First, the breadth and significance of the facts are enormous, so it's critical to start with a clear focused definition of the cluster. This is not a "life sciences" cluster or even a pharma cluster; defined so broadly the region has little distinction or competitive advantage. Rather, it's a cluster of advanced pharmaceutical manufacturing of small molecule medicines, pioneering continuous flow and reinventing medicine supply chains. Defined in this way, the players in this region are in fact leading the nation now, the cluster has strong momentum, it's propelled by the winds of economics and pressing national interests and the opportunity is large. Defined in this way, it's clear the emerging cluster is not simply the newest shiny thing, but rather the intersection of the three broader clusters which this region has identified as its greatest strengths and top priorities for the future - life sciences, advanced manufacturing and logistics.

Second, this is indeed an extraordinary story. The emerging cluster uniquely addresses a confluence of many urgent and important national interests and critical unmet social needs. The potential impact of the cluster will be to:

- Create a secure, resilient domestic supply of essential medicines for the U.S.
- Bring manufacturing back to the U.S.
- Create great jobs of the future in a high-tech high-growth industry for people across our entire region and from all our communities
- Lower the cost of medicines to increase access to healthcare in the U.S.
- Provide more lifesaving medicines to the world's poorest people and deter global pandemics
- Ensure that generic medicines in the U.S. and world are high-quality, effective and safe
- Protect the environment
- Transition U.S. pharmaceutical manufacturing to continuous processing to improve quality and regulatory transparency

The many benefits mean the cluster will appeal to many different audiences for many different reasons. Tailoring messages will be of great importance. As will communicating the bigger-than-life aspect of this cluster that can be a unifying endeavor for the Commonwealth in a fractious age.

Third, the technology, the industry and the cluster are newly formed and in development stage with pressing needs and opportunities. Effective strategic communications stands ready to help in many ways, including to: articulate a clear cluster identity and brand; gather and gain the support of regional stakeholders for essential infrastructure and collaborative undertakings, create a common vision around which action can align; enhance the interrelatedness of actors in the cluster; create synergies; amplify the voices of thought leaders; reveal to firms and talent across the region and state new opportunities for growth; recruit outsiders to fill supply chain gaps; entice investment; open markets; reach strategic partners and funders such as national philanthropy and federal sources; inspire and attract innovators, researchers and entrepreneurs to engage the technical and business challenges ahead; lure key employees, talent and inspire the next generation. Communications are poised to make tactical and strategic contributions to cluster growth.

Fourth, this opportunity perfectly embodies the promise – and the challenges, which GO Virginia was created to address. Faced with transformative growth opportunities taking shape as a regional cluster across local boundaries, how do we organize ourselves as a region to lift all boats rather than let those transformative opportunities slip by while we mind our own business? It is uncharted territory to consider using communications in support of a regional cluster where neither the cluster nor the region has a recognized and formalized organization or other unifying interests or efforts. We need to find a voice and a message that creates an identity and story for the regional cluster. But this must be integrated with and not in conflict with its parts. We are encouraged by the dynamics that developed over the 6 months that work groups toiled, and multiple zooms for the benefit of different public audiences were produced. Hundreds of stakeholders in the region for the first time heard the coherent story of the cluster, its technology and players, and this message generated enthusiasm, interest and sense of common purpose and mutual benefit.

Shaping the messaging for different purposes and audiences – illustrations

To illustrate the interplay of need, message and audience, we drew on the work of other Work Groups and identified two priority messaging needs for the cluster at this stage of development. The following are sketches and suggestions and not finished product, which would be well beyond the reach of a small volunteer work group.

To gain participation and financial support from policymakers and leaders within the Richmond / Petersburg region.

Successful cluster building is inherently a region-wide public/private effort. Public investment for infrastructure may be required, public policies may provide important incentives and competitive advantages. The private and public players in the region must commit time and effort to find new ways to work together effectively. It starts with leading individuals and stakeholders in the community agreeing to form and committing to support a leadership organization which will drive and coordinate collaborative action. A precondition is that policymakers and influencer understand the issues and opportunities, that the private sector is informed and engaged, and that the community itself understands the significance of the cluster to help us achieve our hopes and dreams. Key messages:

- It's a high-wage, high-tech, high-value, high-growth sector
- A diversity of jobs will be created – 70% of advanced manufacturing jobs do not require formal education beyond a high school diploma, and most jobs are likely to be located in one of the region's most economically challenged communities
- It commercializes research and draws on talent from Virginia's public universities
- This uniquely draws on our strengths – the intersection of our three priority growth clusters – life sciences, advanced manufacturing and logistics
- High growth global markets for products and services will attract capital and trade
- Success of the cluster will break down barriers of access to healthcare and relieve fiscal burden by lowering cost of quality medicines

Key messages also would include words of admonition and challenges, but ones that can be overcome if faced, understood and confronted together:

- Reshoring pharmaceutical manufacturing will happen. The question is not if, but where.
- This region now has the lead. We need collective, purposeful, swift action to maintain it.
- To grow something new, different and significant like this cluster will require acting in significantly new and different ways – in effective public/private partnership and as a region, not simply each on our own.

To recruit to the region businesses and organizations to participate in the emerging cluster.

Virtually every week over the last several months, companies have contacted the region to investigate a move or expansion here. The more successful we are at recruiting these firms, more quickly the cluster will grow and succeed, and the more jobs and economic benefits will accrue to the region. Key messages:

- There are gaps in technologies and supply chain that are in need now and will become pillars of the new industry going forward to those who act now
- The region is access to the R&D leading this revolution at Medicines for All.
- Top talent combined with an ample and ready workforce, higher education institutions, and the region's workforce partner with the community colleges and Virginia Economic Development Partnership (VEDP).
- This is a top priority cluster for the state and localities, and willing economic development offices understand your needs and ready to serve you.

- In the BARDA, Phlow and its strategic partners is the one federally sponsored private strategic partnership to create end-to-end advanced manufacturing of essential medicines and reinvent the supply chain and create a national reserve.
- The cluster has a small geographic footprint, and the players have a high degree of interconnectedness.
- Great momentum.

Implementing an effective communications strategy to support the growth of the regional cluster

A strong and unified communications effort, unlike anything that exists now, is essential to grow this cluster. This requires a system of regional communication where none currently exists. This will take a structure -- a center of intelligence and activity -- plus a regional stakeholder network of informed and committed communications professionals, a process and a campaign.

The effort calls for a champion in charge who thinks and acts through the lens of the region and cluster and provides a center to everything. The center sustains and convenes the network of communications professionals from stakeholders, gathers information and assesses needs, keeps all players informed, engages the experts to plan the campaign, holds those responsible for implementation accountable, maintains a central source of information, and guides all the local and disparate voices into aligned action, supports the organizations who actively market the region.

An effective communications effort also will require an informed and active network of communication professionals from the major private and public stakeholders. They'll share needs, developments, learnings, resources and help shape the purposes and content of the cluster's communications and help implement it. To do this effectively, the organizations' leaders will have to authorize and empower them to participate for the benefit of the region and their own organization.

With this in place, a professional strategic communications campaign should be planned and implemented. It will start with a brand that stands on its own for the regional cluster and can be integrated with the communications strategies of various stakeholders. The campaign also will encompass digital presence, media relations, paid and earned media, video storytelling, and relations and internal communication among stakeholders. It will require research and active collaboration among stakeholders, and fortunately that road has been paved by the efforts of the Work Groups during this strategic planning process. A basic outline of such a campaign is **Attachment 2.**

Resources can be put in place to support these efforts. To help keep the many stakeholders informed of developments and equipped, a shared communications assets resource can be established. The resource will gather, hold and make readily available articles, photos, videos, publications and other communications about the cluster and its firms from any and all sources. A starting trove of articles on the cluster which were used or encountered during the preparation of the White Paper is set out in **Attachment 3**. Another essential resource will be a contact list of leaders within and outside the region, including communications professionals, who support this collective effort to grow the cluster. Fortunately, there's no need to start from scratch. Creating such a network was one of the purposes of this strategic planning process. An enormous amount of familiarity, accurate understanding and enthusiasm for the cluster story now as compared to a year ago, and yielded a great and proven starting contact list, also in **Attachment 3.**

Recommendations

1. As a region, **organize** a structure to assure successful development and execution of a communications plan deployed by multiple stakeholders on behalf of the cluster to multiple priority audiences. Enlist all the major public and private stakeholders in the cluster participate.

2. Evolve this Communications Work Group into a **network of communications specialists** who share and work with one another in support of and guidance to the cluster's communications needs. Each of them must have the support of their organization in assisting the region in this way. Expand the network moving forward.

3. Plan, invest in and undertake a dynamic **communications campaign** to priority internal and external audiences. Involve all key stakeholders in developing key messaging which supports the cluster and complements their messaging. Start with a few key objectives, e.g.: earning the support of regional stakeholders for a sustained collaborative effort to support the cluster; recruiting select companies to the cluster; recruiting select talent to the cluster; and, supporting a role for the region as thought leader.

4. Create, maintain and make available a shared set of communications assets for stakeholders: brand resources, articles, key messages, photos, video library, contacts, up-to-date information

Attachment 1

Members of the Work Group

Kendra Gerlach, VCU College of Engineering, co-lead

Michael Ivey, Greater Richmond Partnership

Kevin Miller, Virginia Economic Development Partnership

Betsey Odell, Commonwealth Center for Advanced Manufacturing

Kemi Osoba, City of Petersburg

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Special thanks to the team at VCU College of Engineering Marketing and Communications for prodigious editing and layout of the White Paper:

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Attachment 2

Outline of a professional communications campaign for the cluster

Advanced Pharmaceutical Cluster Communications Needs: Moving beyond the GO Virginia Report

Why Does the Cluster Need a Professional Communications Campaign?

This is a unique opportunity that requires and can support a distinctive message. To do that effectively, a well planned and executed campaign is especially necessary. The opportunity is distinctive because:

1. This is not the life science or biotech industry broadly, but a segment of it **- advanced pharmaceutical manufacturing**. We cannot go out publicly with a message saying we are one of the great biotech sectors, but we are in fact the national/global leader in this specific arena, which is unique and topical for many deep enduring reasons.

2. There is something new, emerging, and dynamic about the technology and the industry sector, and knowledge and appreciation of it is not well known.

3. We are at the early stage in the growth cycle of the sector, and there is a steep growth slope; there is a disproportionate number of decisions being made on whether, how and where firms will play in the new industry sector and ride the tide of these big trends. Clear, actionable information that is quickly delivered will have impact.

4. This is a powerful but subtle with a new message and brand. If the messages are unclear or confusing or self-conflicting, they will harm our efforts to grow the cluster. At this moment when we are establishing the brand and spreading the first messages around the globe, thus we need to be clear and consistent.

Use a Best Practices Public Relations Approach

Kick off the project using the four pillars of a successful PR campaign, as defined by the Public Relations Society of America: Research, Planning, Implementation, Evaluation.

Research

Align the PR goals to overarching goal: build a global cluster of advanced pharmaceutical manufacturing and R&D in Richmond/Petersburg, while improving access to safe, effective, and affordable medicines. The great work performed by the work groups will serve as valid research.

Planning

Next, define target audiences and effective strategies for the campaign. Our work group recommends the following strategies at a minimum:

- Branding - does the effort need an internal and/or external brand or name? Logo?
- Digital Presence/Website - build a hub for all stakeholders to access important assets such as photography, approved messaging, maps, graphics, etc. Decide if an external site is needed.
- Media Relations - pitch local, state, national, international media on success stories and efforts around the cluster; positioning the region as the forerunner re: API manufacturing.
- Paid Advertising - targeted to key audiences using print and digital channels (example- scientific startup publications, advanced manufacturing websites).
- Video Storytelling - show how and why this cluster is important through expert interviews and b-roll footage to use across channels and with target audiences.
- Printed Collateral Materials - to share with key groups to promote the cluster.
- Stakeholder Relations - regularly assemble leaders from across the Commonwealth and in the scientific and manufacturing communities to hear first-hand about the cluster potential and success stories.
- Internal Communications - keep lead organizations informed and educated about the campaign and ask that they provide support as needed.

Implementation

Add specific tactics to support the above strategies and launch the campaign.

Define Measurements of Success

Specific objectives outlined at the start of the process will be measured during and after the campaign. Examples of criteria include percentage of awareness change, earned media placements, new company announcements, etc.

Set a Timeline for the Work

The time is now to begin communicating in a professional and organized manner. A timeline of July 2021 through June 2024 could be proposed, with a one-year contract awarded and available for renewal.

Allocate Budget

We believe this effort needs its own dedicated budget in the range of $50,000 to $75,000 per year for professional services and project management (monthly investment of $4,000 to $6,250).

An additional budget should be set aside for out-of-pocket costs such as photography, brand development, printing, web development, videos, etc. We estimate another $150,000 over three years.

This is a project that may be able to leverage the talents within the various cluster organizations if they are willing to provide in-kind services. Examples include graphic design and video production. Perhaps the VCU Brandcenter could be a partner on the overarching branding and messaging development. These budget-saving tactics will only be successful if the PR campaign lead has a clear-cut structure and time commitment from such organizations.

Structure is Essential for Success

A successful communications effort for the cluster needs a Champion in Charge. This could be a contractor or a PR agency, or an individual within one of the key stakeholder organizations. Our group agrees that the last option is the least preferred, simply because work demands for primary employers will always come first. The Champion in Charge will need a vast network of in-house or subcontracted resources to coordinate all the moving parts needed throughout the campaign.

Just as important, this campaign team needs a leader to report to and be accountable to. This leader could be housed within a larger GO Virginia project or within one of the key organizations involved in the cluster. It will be important for the leader to approach the project with an objective lens, not favoring one organization or activity over another, but communicating about the cluster for the greater good of the region and Commonwealth.

Attachment 3

Starting set for a shared resource: Informational resources and contact list

I. Articles, websites and other Informational Resources

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Virginia State University College of Engineering and Technology's Manufacturing Engineering Program. https://www.vsu.edu/cet/departments/engineering/programs/manufacturing-engineering/index.php

Community College Workforce Alliance. http://ccwatraining.org/

John Tyler Community College. https://jtcc.edu/

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Appendix 6

The Planning Process

Overview of the Process, Players and Purpose

The performance of the ECB Grant was designed to: (i) run a social process that informs, equips and energizes stakeholders; (ii) provide timely incisive actionable strategic analysis and recommendations to the College of Engineering, the region and state in a final report by March 31, 2021; and (iii) form networks of people and organizations who will work together for these common goals now and in years to come.

The intended outcome of this effort was to: (i) equip players in region and state to act effectively to support , market, attract; (ii) increase and accelerate R&D of the technology and talent development in the region; (iii) support and maximize successful commercialization by Virginia and recruited companies; (iv) build a global cluster of R&D and advanced pharma manufacturing, creating high-paying high-tech jobs; and ultimately (v) expand dependable access to less expensive high-quality medicines, for the health of the nation and world

The Work Groups

We formed and conducted much of the work of the planning process in four work groups: Communications, Workforce, Cluster Development and Leadership. The Leadership Work group brought together leaders of key stakeholders to provide their observations, insights, reactions to findings of the work group, directional input, and ultimately test commitment to recommendations. The other three focused on foundational elements of cluster economic development. Each undertook research and evaluation, prepared findings and recommendations in a report to the Leadership work group and consultant team. These reports are appendices to the Final Report and the Final Report draws heavily from them. The Communications Work Group also took on the formidable challenge of researching and preparing a White Paper describing in accurate and comprehensive detail the story and significance of the cluster, and this is presented as Appendix 2 to the Final Report. As hoped, work groups did grow into networks of people and organizations prepared and motivated to work together to implement the Recommendations. As it happened during the course of the study on multiple occasions work group members jumped into action on an issue or opportunity as soon as it became apparent. The members of the various work groups are set forth in attachments to the work group report included in the Final Report. The members of the Leadership Work Group are set forth in **Attachment 1** to this document.

The Series of Virtual Summits by Zoom

While the original plan of work called for an all-day Summit, the pandemic made such an in person meeting impossible and a series of three large public zooms over the course of six months accomplished what was intended for the Summit, and more. The zooms enhanced and advanced the efforts of the work groups.

Zoom 1 - The intended audience were leaders of major stakeholders in the region and state. Over 50 attended, and heard presentations from study lead Jeff Gallagher, Frank Gupton, Eric Edwards, Robby Demeria and William DuBay. Goals of this zoom were to:

- meet, see and hear from the key players
- understand
  - the core innovations at the College of Engineering, including Medicines for All, and the many different opportunities to impact health, reinvent pharmaceutical manufacturing and transform the region's economy
  - the recent BARDA contract to Phlow Corp – the players, scope, stages and places
  - the vision of a global cluster of advanced pharma manufacturing and R&D in our region
  - the significance and urgency of the opportunity; the need to work together in new ways
- identify and connect with others in the community who are eager to help
- understand the goals of this strategic planning process by the College of Engineering / GO Virginia, its structure and timeline and how to participate

Zoom 2 - The intended audience were the collective membership of the study work groups and other key stakeholders. Forty attended. Co-leaders from three work groups presented, and attendees were divided into eight breakout rooms to discuss and share reactions. The goals were to:

- Bring everyone up to date on our work to date and goals
- Share ideas, questions, findings and interact across work groups
- Solicit reactions and feedback from leaders outside work groups
- Make clear the plan to finish this planning process and report
- Remind one another of the importance of working together in real time now

Zoom 3 - The intended audience were companies, researchers and innovators in Virginia, and the organizations which represent and support them. Over 150 individuals from over 100 organizations registered, and over 100 individuals participated on the zoom. They heard presentations from Frank Gupton, Eric Edwards, Bill DuBay and Justin Neal, COO of BrightSpec, a Virginia company already successfully collaborating with Medicines for All in developing new products for sale into the new industry. After the zoom conference, attendees were solicited for feedback on what additional information and additional steps would be helpful for therm. The goals of the zoom were to:

- meet, see and hear from the key players, and
- learn
  - the core technology / processes pioneered by VCU College of Engineering/Medicines for All and how it's making a difference in global health and opening up opportunities for this region
  - the work of Phlow Corp and its collaborators AMPAC Fine Chemicals and CivicaRx under the recent BARDA contract to establish a national strategic stockpile of essential medicines and API and to reshore the production of medicine to the US using advanced manufacturing
  - current needs and future opportunities to develop and supply the firms in the emerging cluster

The event was publicized widely by a host of sponsors including lead sponsors Activation Capital, the Center for Innovative Technologies, Greater Richmond Partnership, Virginia BIO, Virginia Bioscience Health Research Corporation (the Catalyst), Virginia's Gateway Region and VCU Innovation Gateway,

and Supporting Sponsors CCALS - Commonwealth Center for Advanced Logistics Systems, CCAM – Commonwealth Center for Advanced Manufacturing, GENedge and Henrico County Economic Development Authority. Immediately following Zoom 3 a questionnaire was sent to attendees for feedback. 21 Responses (20%) were returned substantially complete and reviewed for further direction for the study.

Additional elements, collaborations and contributions

DecideSmart was engaged to develop the Final Report in collaboration with lead consultant. Activation Capital was engaged to perform a study of demand and supply for laboratory, related space and pilot space facilities across Region 4. This had not been done before. The engaged a national expert, and worked in collaboration with VEDP, GRP and VGR.

During the study, the study lead made presentations to foster awareness and cooperation to various community and business groups. Further attention was drawn to the effort when an Op Ed appeared in the Richmond Times-Dispatch on the Cluster and the GO Virginia ECB Grant Planning Process authored by Todd Haymore.

Delivery of Final Report and dissemination

The Final Report was delivered to Go Virginia on March 31, 2021. It will be posted to the public on the website of the VCU College of Engineering and GoVirginia Region 4. On April 7, a summary presentation of the Final Report will be made to the GO Virginia Region 4 Board at a regularly scheduled and public meeting. On Monday April 12, 2021, a zoom presentation summarizing the Final Report will be made to all study participants and key stakeholders.

Attachment 1
Members of the Leadership Work Group

Bob Beckler, Senior Advisor, RKB Consulting

Keith Boswell, CEO, Virginia's Gateway Region Economic Development Organization

Chandra Briggman, CEO, Activation Capital / Virginia Bio+Tech Research Park

William DuBay, Vice President Research and Development, AMPAC Fine Chemicals

Eric Edwards, Founder and CEO, Phlow Corp.

Lara Fritts, CEO, Greater Richmond Partnership (first 3 months only)

Frank Gupton, Co-founder and CEO, Medicines for All Institute of VCU College of Engineering

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