

Overarching Narrative - Advanced Pharmaceutical Manufacturing Tech Hub

Executive Summary

The United States faces an urgent national security crisis – nearly \$260M Americans rely on a vulnerable pharmaceutical supply chain every day.¹ Drug shortages are at the highest levels they have been in over a decade² leading to increased medication costs³, medication errors, treatment delays, and in some cases, rationing of lifesaving treatments.⁴ The White House recognizes that the U.S. government must take steps to address and mitigate this crisis,⁵ which is due to overreliance on foreign manufacturing of active pharmaceutical ingredients (APIs)⁶ and critical drugs.⁷ Over 80% of the world's API supply is manufactured in China and India and 23.6% of all U.S pharmaceutical imports come from China,⁸ putting the supply and quality of medicines at risk.⁹ With Tech Hubs funding, the Advanced Pharmaceutical Manufacturing (APM) Consortium, based in the Richmond Metropolitan Statistical Area (MSA/Region) is poised to rapidly expand production of APIs and pharmaceuticals in the U.S. and create a sustainable, globally competitive APM Tech Hub.

Building on a 2021 strategic plan, the Consortium will leverage this high-growth industry to drive impact and close economic gaps in the Region.¹⁰ It will do this through seven interwoven component projects (CPs) across the Hub's selected core technology area

(biotechnology/advanced manufacturing), that will complement existing regional APM assets, redesign pharmaceutical processes and technologies, address regulatory hurdles, develop talent, and build the organizational infrastructure needed to support reshoring manufacturers. Funding will help the Region overcome an industry sectoral "valley of death"¹¹¹², re-shore manufacturers, and help Americans get the medicines they need.

Vision

Subject to "severe ripple effects" of international economics, geopolitics, and public health crises, ¹³ overseas pharmaceutical manufacturing not only poses a national security risk but has

¹ Pharmacy Times: <u>Americans Love OTC Medications</u> (2019) V.23 I.1

² American Society of Health-System Pharmacists (ASHP): Drug Shortage Statistics

ASPE Report to Congress: Impacts of Drug Shortages on Consumer Costs

⁴ U.S. Senate Committee on Homeland Security and Governmental Affairs: <u>Short Supply - the Health and National</u> Security Risks of Drug Shortages (March 2023) ⁵ FACT SHEET: Biden-Harris Administration Announces Supply Chain Disruptions Task Force to Address Short-

Term Supply Chain Discontinuities

⁶Active Pharmaceutical Ingredient – any substance intended for incorporation into a finished drug product and is intended to furnish pharmacological activity (FDA CFR Title 21)

⁷ FACT SHEET: Biden-Harris Administration Announces Supply Chain Disruptions Task Force to Address Short-Term Supply Chain Discontinuities

⁸ CPA: <u>Skyrocketing Pharmaceutical Imports To The U.S. Endanger National Security</u> (2023)

⁹ Gibson, Rosemary & Singh, Janardan Prasad. China Rx: Exposing the Risks of America's Dependence on China for Medicine. New York: Prometheus Books (2018). Singleton, Marilyn, M.D., J.D. "China Rx: Exposing the Risks of America's Dependence on China for Medicine." Association of American Physicians and Surgeons (June 2019). ¹⁰ A projected compounded annual growth rate (CAGR) of 14.3% through 2028. Frost and Sullivan: Global

Pharmaceutical Continuous Manufacturing Market - Growth Opportunities, Analysis, Forecast, North America, 2023 (February 2023) CAGR calculated for APIs and Finished Dose Formulations (FDFs)

¹¹ The phase between research and successful innovation in the pharmaceutical industry is known as the "Valley of Death["] (NIH)

¹² The Journal of Technology Transfer: <u>Valleys of Death and Darwinian Seas: Financing the Invention to Innovation</u> <u>Transition in the United States (2003)</u> ¹³ Harvard Business Review: <u>The U.S. Needs to Reimagine its Pharma Supply Chain (</u>2020)



also contributed to a 20+ year decline in U.S. manufacturing jobs.¹⁴ For the past five years, Consortium partners have been working to re-shore safe and affordable medicines and create economic growth in the MSA.

This effort builds significant prior work including more than a decade of globally recognized work from <u>Virginia Commonwealth University's (VCU) Medicines-for-All Institute (M4All)</u>. From 2010 to 2019, our Region's pharmaceutical industry experienced a 3.3% annual growth rate, more than double the U.S. average.¹⁵ Since then, investments in APM have totaled more than \$964M. As a result, academia-industry partnerships have nearly doubled, allowing the Region to emerge as a leader in innovative hybrid and continuous manufacturing (CM) ¹⁶, an FDA recognized emerging technology.

While many of the processes and products underpinning our Consortium are well into the latter stages of the <u>technology readiness level</u> (TRL) spectrum¹⁷, the TRL maturity that makes up the interconnected Hub is at a critical inflection point. The APM Consortium is ready for acceleration from proof of concept (TRL 3) out of the Valley of Death for end-to-end production of safe and affordable APIs and pharmaceuticals needed to secure a U.S. medicine supply chain. This valley "crossing" has been shown to necessitate the type of strong government engagement and investment that Tech Hubs funding would provide and has the potential to deliver jobs and production outcomes at 2-3xs faster than the current rate.¹⁸ With Tech Hub funding, the Consortium will establish an accelerated pipeline for CM and other emerging APM technologies, deliver a comprehensive industry-led APM workforce development platform, and drive international thought leadership, allowing the Region to grow a globally competitive APM Tech Hub within the next decade.



¹⁴ Economic Policy Institute: <u>Botched policy responses to globalization have decimated manufacturing employment</u> with often overlooked costs for Black, Brown, and other workers of color (2022)

¹⁵ U.S. Cluster Mapping Project, regional data set

¹⁶ <u>Continuous Manufacturing</u> - A manufacturing method in which the materials (dry bulk or fluids) that are being processed are continuously in motion, undergoing mechanical, thermal, and/or chemical treatment.

 $^{^{17}}$ A TRL framework is a nine-point scale used to measure the progress of a particular technology from basic science to operational application (<u>via EDA</u>)

¹⁸ <u>Virginia Economic Development Partnership (VEDP) Analysis</u>



This includes five institutions of higher education; three state/local governments and political subdivisions; fifteen industry groups/firms; eight economic development organizations (EDOs), and four labor organizations or workforce training organizations. Of these members, seven are CP leads and 21 are sub-recipients – more than half of all Consortium partners. For a full list of partners please see graphic. For more information, please see Letters of Commitment (LOCs).

Component Projects

The APM Consortium will undertake seven interconnected CPs:

- 1. **Governance:** <u>The Strategic Governance and Sustainability Project (CCAM)</u> will create a sustainable and flexible governance structure while nurturing collaboration among partners, tracking Hub-wide metrics, and fostering a culture of diversity, equity, inclusion, accessibility (DEIA), learning and innovation across the Hub.
- 2. Commercialization: The Acceleration of APM Product and Process Technologies into Commercialization (USP) Project will create an APM-specific "Accelerator" through an ecosystem of organizations with the knowledge and expertise to quicken drug product commercialization through new manufacturing technologies and quality testing systems.
- 3. **Digital Tools:** <u>The Digital Readiness Transformation Project (Phlow)</u> will expedite the integration of digital technologies (e.g. <u>Industry 4.0</u>) into APM by establishing a <u>cyber-physical</u> testbed that will 1) enable industrial scale, technology assessment and standardization; 2) in tandem with the Accelerator, support rapid technology maturation; and 3) boost the technical competency of the Region's growing APM workforce.
- 4. **Global Leadership:** <u>The Global Competitiveness Development Project (GRP)</u> will fill an APM industry and talent perception gap of the Region by raising its value proposition through market-driven design and aligned industry partner attraction. This includes the annual APM Conference, further cementing the Region as a global APM leader.
- 5. Infrastructure: <u>The Water and Wastewater Infrastructure Development Project</u> (<u>Petersburg</u>) will build on the BBBRC-funded system wide capacity improvements to add 856.3 acres of industrial shovel-ready sites¹⁹ within/around the Petersburg Industrial Park (PIP), the country's end-to-end APM campus securing the U.S. medicine supply.
- 6. Infrastructure/Workforce Development Training: <u>The Pharmaceutical Training Facility Project (Civica Foundation)</u> will outfit 3,500 square feet in the Scale-Up Development Center as a dual-purpose pharmaceutical training facility for emerging APM technologies for 1) expansion of <u>BCC's Pharmaceutical Manufacturing Career Studies Certificate (CSC) program</u>, and 2) shared training space for the Consortium.
- Workforce Development Career Paths: Supported by an AI-powered career mapping tool, <u>the End-to-End Workforce Project (RCC)</u> will leverage existing workforce assets to resource a robust workforce for the high-growth, technology-centric APM industry.

These CPs will build on/complement the foundational work a \$52.9M investment by the <u>Build</u> <u>Back Better Regional Challenge (BBBRC)</u>, and an invited \$1M grant from the <u>National Science</u> <u>Foundation (NSF) for the Regional Innovation Engines (RIE)</u>. A graphic displaying the interaction of all CPs is available <u>here</u> and discussed in "Global Competitiveness."

Commitments

The APM Consortium will leverage a staggering \$118M+ in committed and proposed investment from public and private sources as well as an estimated \$285M in projected investment (\$403M

¹⁹ Petersburg Comprehensive Plan, 2014



total) as part of its overall strategy to grow a globally competitive Tech Hub. Notable investments and policy commitments include:

- <u>Virginia's Research Triangle (\$100M)</u> Gov. Glenn Youngkin and the Virginia General Assembly have proposed funding to create a network between the University of Virginia (UVA), VCU and Virginia Tech to build collaboration in biotechnology, life sciences and pharmaceutical manufacturing. This includes up to \$55 million for Consortium partner's UVA's Manning Institute for Biotechnology and up to \$15 million for M4All.
- <u>VIPC</u> has committed \$5M in match to USP's Accelerator CP for APM-focused investments coming out of Virginia's Research Triangle institutions. Historically, VIPC funding has resulted in the generation of additional funds between 21X and 37X an estimated potential impact of \$105M \$185M for the APM Consortium. In addition, VIPC has committed \$1M to the Governance CP for Hub sustainability activities.
- <u>Virginia's Naloxone Investment (\$16M)</u> Virginia's General Assembly has <u>proposed</u> <u>bills</u> for an end-to-end opioid overdose reversal agent nasal spray development program at the PIP to provide a new FDA-approved generic opioid overdose reversal agent.
- <u>AMPAC Fine Chemicals (AFC) (\$400,000)</u>– AFC will utilize USP's Accelerator to build an innovative regulatory pathway for its modular CM system design.
- <u>USP Policy Assessment and White Paper (\$186,617.38)</u>: As part of the Global Competitiveness CP, USP commits to create Hub policy recommendations, published in a regularly updated White Paper (WP), first released at the Hub's 2025 APM Conference.

In addition, partners will make an aggregated match of nearly \$29M towards Hub CPs.

Global Competitiveness

Investments in the APM Consortium to date have centered on building out the needed physical infrastructure (\$447M+) for advanced manufacturing. Bolstering these assets (infrastructure CPs) while developing the integrated, cross-organizational activities to drive industry maturation and reshoring including 1) a strong pipeline for accelerated technology maturation (tech maturation CPs), 2) a responsive and agile industry-led workforce development program (End-to-End Workforce), and 3) international thought leadership attraction (Global Competitiveness CP). Along with thoughtful efforts to build shared strategy and a sustainable Hub (Governance CP), the proposed CPs address this path to global competitiveness while driving equitable job growth.

Climate Impacts and Environmental Responsibility

Recent events have highlighted the climate-related risks to the pharmaceutical supply chain. In the past year alone tornado damage to a North Carolina manufacturing facility resulted in a subset of 65 products potentially experiencing "continued or new disruptions."²⁰ The Consortium is taking active steps to assess and prepare infrastructure for disruptive weather events. This includes initial risk mitigation assessments for the two infrastructure CPs. In addition, USP will leverage its <u>Medicine Supply Map</u> to inform strategic choices for future investments.

Furthermore, the Consortium is driving environmentally responsible industry best-practices through the use of <u>green chemistry</u> and CM processes based on the global leadership of M4All. CM processes have been cited as one of the most effective ways of reducing carbon emissions associated with drug production as have biomanufacturing methods,²¹ both core aspects of the Consortium's innovation and commercialization strategy. The Consortium will continue its leadership in green chemistry through the Accelerator, where APM products and processes will

²⁰ USP: <u>Pfizer's Rocky Mount Facility Tornado Damage: Impact on Pharmaceutical Supply Chain</u>

²¹ Pharmaceutical Technology: <u>Cutting the carbon footprint of pharma's supply chain (2022)</u>



minimize hazards and pollution while transforming resource efficiency in synthesis and manufacturing techniques.²² See Problems Slowing Technology Advancement for more.

Equitable Growth and Inclusive Innovation Economies

The Region has a non-White population of 41% compared to the national non-White population of 32%.²³ Black and Hispanic populations are disproportionately impacted by income disparities, poverty, and unemployment.²⁴ In addition, more than 13% of high school graduates in the Region live below the poverty line – a figure that is nearly three percentage points higher than the Region's overall number.²⁵ Those with lower incomes are often uninsured,²⁶ and less likely to take medications due to cost - this not only impacts individuals in the Region, but across the U.S ²⁷ as drug shortages have led to an average increased medication price of 16.6%.²⁸

The Consortium is committed to continuing its equity-driven mission to lower drug costs and embed DEIA across the Tech Hub, including the Region's rural footprint (20%²⁹). As part of BBBRC, the Alliance developed an <u>Equity Action Plan</u> to drive the creation of long-term DEIA policies and programs. With support from <u>JMI</u>, regional Workforce Development Boards (WDBs) and others, the Consortium will operationalize this plan across all CPs. Up to 6,850 jobs for underserved and underrepresented individuals are projected as a result of similar recent APM investment³⁰ - Tech Hub CPs could nearly double this figure within 10-years. Please see the "Equitable Benefits" section, CP narratives and LOCs for more specific DEIA information.

Outcome Tracking and Metrics

Tech Hubs investment is collectively expected to create 5,500 jobs and increase the Region's compounded annual growth rate (CAGR) by up to 7.1% in 10 years. ³¹ In addition, it is anticipated to grow Hub partnerships by at least 50% in five years. All CPs will track metrics through a Hub-wide metrics dashboard and circulated in quarterly newsletters and an annual "State of the Hub" Impact Report. While all CPs will track metrics differently, through the Governance CP, the Hub overall will track:

- <u>Capital Growth</u> tracks investment, venture capital investment growth, and new companies added through the Global Competitiveness CP.
- <u>Product Development</u> tracks the maturation of new technologies and time to market.
- Job Growth and Unemployment Rates measures initial, direct, indirect, and induced number of jobs and unemployment rates in distressed census tracts as well as workers/jobs retained in the Region and new companies.
- <u>Educational Achievement</u> measures individual enrolled and completed programs.
- <u>Equity and Inclusion Benefits</u> tracks jobs created for underserved populations, including minorities, women, and low-to-moderate-income (LMI) individuals. It also tracks educational achievement and supplier diversity within infrastructure CPs.

²² ACS Publications: <u>Green Chemistry in the Synthesis of Pharmaceuticals</u> (2021)

²³ American Community Survey (ACS) 2022 1-Year Estimates - DP05 (Richmond VA) Metro)

²⁴ American Community Survey 2022 5-Year Estimates

²⁵ ACS 2022 1-Year Estimates – S1501 (Richmond VA Metro)

²⁶ Healthy People 2030: <u>Access to Health services</u>

²⁷ National Center for Health Statistics: <u>Characteristics of Adults Aged 18–64 Who Did Not Take Medication as</u> <u>Prescribed to Reduce Costs: United States, 2021</u> (2023)

²⁸ <u>ASPE Report to Congress: Impacts of Drug Shortages on Consumer Costs</u>

²⁹ U.S. Census Bureau (2010)

³⁰ Impact projections derived using data from Economic Modeling Specialists International based on BBBRC investments.

³¹ VEDP Analysis



• <u>Risk Mitigation</u> – measures incidents reported, and mitigation activities undertaken. *Timeline for APM Tech Hub Implementation*

		Pre-Award			Year 1				Year 2				Year 3				Year 4				Ye	-> Year 10		
Activity	2024			2025			2026			2027			2028			2029			2034					
Nedhadde (982)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	
Strategic Governance and Sustainability Project				R	amp Up							mpleme	ntation								Sunse	t / Closed	ut	Self- Sustaining
Acceleration of APM Product and Process Technologies into Commercialization					1	Phased R	amp Up				Implem	entation				1	1		1 1	Phased	i Sunset / (Closeout	1	Self- Sustaining
Digital Readiness Transformation Project				Ra	l Imp Up	1 1			1		Imp	lementa	tion		1		1		Sui		1	Self-Su	staining	
Global Competitiveness Development Project				Ri	amp Up				1		1	mplemer	ntation							Su Clo	nset / iseout		Self-Sus	aining
Water and Wastewater Infrastructure				Ramp Up Constru				uction	ion Project Complete - Available to Support Cross-CP Activities, esp. Global Competitiveness															
Pharmaceutical Training Facility				Co	l onstructi	on		Project Complete - Available to Support Cross-CP Activities, esp. Global Competitiveness																
End-to-End Workforce Project						Ramp Up					Implem	entation							Sunset / Closeout			Self-Su	staining	
Phas app c	e 2 Si lue fi	tate bud	get Pha	ase 2 P ard d	hase 2 g	rant I	•		•			Annual H	ub-wide	I Meeting:	s s	1	•	1	•	Projects self-sust	become taining	Fede use o	ral fundir deadline	Programs continue throug planned self- sustaining resources

A larger timeline view is available <u>here</u>.

Problems Slowing Technology Advancement

Pharmaceutical manufacturers primarily rely on outdated methods like "batch manufacturing", a multi-step process which involves capital intensive, large-scale equipment across distributed, specialized sites.³² This approach limits the number of drugs produced in a certain period, produces substantial waste and has negative environmental consequences.³³³⁴ These outdated methods coupled with lack of market incentives, regulatory challenges, and the need for large factory sites often deter manufacturers from innovating in manufacturing methods and operating in the U.S.³⁵³⁶ In addition, unlike China³⁷, U.S. industry, government, and academia remain disconnected around advanced production technologies.³⁸ A "system redesign" linking innovation to production is required to incentivize and ensure adoption of these practices.³⁹

The APM Consortium seeks to mitigate these complex problems and address the nation's drug shortage by developing a frictionless pathway to increasing adoption of innovative APM technologies like CM and digital technologies that drive industry efficiencies and competitive advantages. The innovations and programs outlined in this proposal will enhance flexibility and efficiency in manufacturing, lower production costs, cut environmental footprints, accelerate production and scale-up in response to emergencies, and reduce quality issues.⁴⁰

No single Consortium partner can address these complex problems alone. A comprehensive marketing strategy is needed to boost the visibility of the Region's assets and capabilities and attract expanding companies. Shovel ready infrastructure at a cost competitive rate is needed to support manufacturers and industry partners. An industry-led, competency-based workforce is

 ³² IQVIA <u>Orphan Drugs in the United States (Part One): Growth Trends in Rare Disease Treatments</u> (2018).
³³ FDA: <u>Safeguarding Pharmaceutical Supply Chains in a Global Economy</u> (2019)

³⁴ FDA: <u>Modernizing the Way Drugs Are Made: A Transition to Continuous Manufacturing</u> (2017)

³⁵IQVIA Orphan Drugs in the United States (Part One): Growth Trends in Rare Disease Treatments.(2018).

³⁶ U.S. Food and Drug Administration: <u>Safeguarding Pharmaceutical Supply Chains in a Global Economy (</u>2019)

³⁷U.S. China Economic and Security Review Commission: <u>Potential Health & Safety Impacts from Pharmaceuticals</u> and <u>Supplements Containing Chinese-Sourced Raw Ingredients (2010)</u>

 ³⁸ American Affairs: <u>America's Advanced Manufacturing Problem – and How to Fix It.</u> Fall 2023 V.7 N.3.
³⁹ Ibid

⁴⁰ <u>USP Workshop on Identifying and Addressing Barriers to Continuous Manufacturing Adoption (2023)</u>



also needed. Finally, a strategy to sustain long-term collaboration is critical to the Hub. Only a collaborative and expanding Consortium comprised of diverse entities with different skillsets and expertise can holistically tackle this problem and address the nation's drug shortage crisis.

Tech Hubs Nexus

The Region's investments in biotechnology and advanced manufacturing directly correlate to the United States's national priority to make more essential medicines in America, mitigate drug shortages, and invest in domestic manufacturing – all of which have been deemed by the Administration as "essential" to national defense.⁴¹ Investment in the APM Tech Hub not only addresses national security concerns, but also increases the economic competitiveness of the U.S and the Region. Within the next decade, the APM Consortium estimates it will have the capacity to produce 245 metric tons of APIs through APM methods, capturing 12.8% of this growing market.⁴² This ability is bolstered by the Hubs public and private assets including:

- <u>M4All</u>: Since 2014 M4All has received <u>nearly \$70 million</u> from the Gates Foundation to use APM to maximize the impact of novel development processes for lifesaving drugs.
- <u>Civica Rx:</u> A nonprofit drug manufacturer for 1/3 of U.S. hospitals working to prevent drug shortages through conversion of APIs into finished dose formulations (FDFs), has invested in facilities for <u>injectable drug manufacturing in Petersburg</u> (where affordable insulin will be manufactured at <u>market-shaping lower costs</u>), a BBBRC-funded <u>Good</u> <u>Manufacturing Practice</u> testing facility and <u>Scale-Up Center</u> in Chesterfield County
- Virginia Bio+Technology Research Park (Park): A life science and tech community home to nearly 70 private firms, nonprofits, research institutes, and labs in Richmond.

Private assets are discussed below. A list of over 100 regional assets is available here.

Private Sector Participation

The APM Consortium has 16 private members. Both technology maturation CPs will be led by the private sector (USP and Phlow) to ensure the Tech Hub builds on and integrates existing assets into all Hub work. CCAM and Civica Foundation will also lead CPs and an additional 11 private sector members will be sub-awardees. Together, they represent a \$311.6M+ investment in the Region including, but not limited to:

- <u>Phlow Facilities</u>: Phlow received a <u>\$354M from Health and Human Services (HHS)</u> <u>Biomedical Advanced Research and Development Authority (BARDA), contract which</u> supports development of Phlow's regional advanced manufacturing <u>facilities</u>.
- USP Advanced Manufacturing Technologies Lab: Develops methods and standards for APIs and Key Starting Materials (KSMs) made using APM technologies. In addition, USP will identify/recruit 10 new companies entering the Accelerator within five years.
- <u>AFC Plant:</u> AFC is currently expanding its <u>Petersburg facility</u> which manufactures APIs used for cancer and HIV treatment medications among others.
- <u>CCAM</u>: A \$17M facility dedicated to maturation of advanced manufacturing technologies with more than \$85M invested in equipment/development/implementation.

Commitments and Investments

Pending and committed investments from state/local governments, philanthropy, and nonprofits total \$190M. This includes efforts by the Commonwealth such as the Virginia Research Triangle,

⁴¹ <u>FACT SHEET: President Biden Announces New Actions to Strengthen America's Supply Chains, Lower Costs for</u> <u>Families, and Secure Key Sectors</u>

⁴² <u>Alliance Market Sizing Data</u>



a KSM pilot project investment, and a naloxone program investment, as well as the \$1M NSF RIE grant, and UVA investments in a biotechnology park. For more information, please see the "Commitments" sub-section on page 4.

Sustainability

Each CP is designed to continue operations long after the initial funding period. The Tech Hub is expected to become sustainable by Year 5 through an overarching sustainability plan:

- <u>Maintain long-term leadership</u> Hub leadership will meet at least quarterly. Members will set benchmarks for achieving goals including equity and member recruitment goals.
- <u>Ongoing partner engagement and attraction</u> continue efforts to recruit expanding companies and talent through the Consortium's EDOs. The Hub will also target new partners to fill identified gaps, with a goal of increasing partnerships by 50% by Y5.
- <u>Develop additional long-term value and reduce long-term costs</u> continue technology maturation activities and develop new, green technology and products focused on reducing environmental impacts and costs through the Accelerator.
- <u>Build workforce pipeline</u> continue workforce development activities, many of which are expected to be sustainable by Year 4 through enrollment and tuition costs.
- <u>Funding pursuits</u> work collaboratively to pursue additional federal/state/private funds.

Labor and Economic Benefits

The Consortium will ensure that all CPs incorporate strong labor standards, prioritize supplier diversity, promote fair wages and benefits, and work to create equitable job access. While labor unions have limited reach in Virginia, the Consortium will place no restrictions on partners and their employee's ability to join a labor union and respects all employee's choice to ask questions regarding unionization. The Consortium will work closely with the WDBs to:

- Align partners through Consortium wide memorandums of understanding (MOUs) through the Governance CP to support:
 - Fair and equitable wages.
 - Policies and procedures which support fair hiring and management processes such as whistle blower protection policies, anti-harassment policies, and equal opportunity employer policies.
 - Creation of clear job descriptions for all partner supported positions.
- Identify, hire, and support underrepresented vendors, including those that are Black, female, and veteran owned.
- Engage community and recruiting entities to increase access to APM jobs in underserved and underrepresented populations.
- Prioritize community colleges and HBCU recruitment (including RCC, BCC and VSU).

Equitable Benefits

The Hub will build upon a BBBRC <u>Equity Plan</u> and ensure benefits flow to the Region's underrepresented and underserved individuals including those considered LMI, minority, veteran, and rural. Specific DEIA initiatives that will target these individuals include but are not limited to:

• Biannual community engagement meetings in disadvantaged/rural communities though Year 4, engaging 20,000 individuals run by JMI through the Governance CP.



- Infrastructure CP commitments to supplier diversity and ultimately job creation and increased wages for underserved individuals (2,534 jobs are anticipated)⁴³.
- Workforce training for 10,629 individuals from middle school through to professional development programs, outreach to 600 LMI individuals for recruitment into the APM industry, engagement with 300 rurally based individuals through a mobile lab and expanded wraparound services for 375 underserved individuals by 2028.
- Global Competitiveness CP activities including a Strategic Plan informed by four employer equity surveys by the <u>Center for Economic Inclusion (CEI)</u>, generating diversity impact measurements, and equitable talent attraction by <u>Chamber-RVA</u>.
- As part of the USP Accelerator, VIPC will provide a portion of funding through its <u>Virginia Venture Partner equity investment program</u> focused on funding for demographically and geographically underrepresented founders.

The Hub is anticipated to serve 10,629 individuals and raise the average annual wage for pharmaceutical manufacturing in distressed areas by up to 55%.⁴⁴ CP activities will train a diverse workforce and create pathways for underserved individuals to access good paying jobs.

Outcomes

The table below gives a summary of the top goals, outputs, and outcomes expected:

Component Project Goals	Outputs	Outcomes/Impacts					
Strategic Governance and	Collaborative working structures	-Hub-wide portfolio strategy and					
Sustainability Project – put in place	solidified, aimed at growing	sustainable business model created					
infrastructure to create an inclusive and	Consortium and increasing	-Grow partnerships by 50% by Y5					
sustainable Hub	equity						
Acceleration of APM Product and	Creation of an APM Accelerator	-Pipeline of 20 projects and 10					
Process Technologies into	program leading to development	new companies entering the					
Commercialization – create an	of support systems and pipeline	Accelerator network by project end					
ecosystem of companies with expertise	of new projects, products, and	-Four commercialization projects					
to accelerate commercialization of	companies.	completed, including biocatalysis					
pharmaceutical products		of KSMs, sterile injectable drug in					
		shortage, novel spectroscopy tech.					
Digital Readiness Transformation	Creation of a tailored digital	-Three new technologies matured					
Project - expedite development and	technology maturation	- 20% tech readiness level increase					
adoption of advanced digital tech.	framework for the APM						
	industry.						
Global Competitiveness	Marketing and business	50 new jobs and \$35M new					
Development Project – fill asset gaps	attraction activities including	investment per year over four years					
and attract new industry to the Region.	APM Conference	(200 jobs/\$140M total).					
Pharmaceutical Training Facility	Outfit 3,500 square feet within	Capacity to train up to 56 students					
Buildout Project – create	the Scale-Up Development	per class (up from the ability to					
pharmaceutical training space for BCC	Center for BCC and Consortium	train 16 students per class in its					
and the Hub's shared use.	members shared use.	current shared lab space).					
Water and Wastewater	Improve wastewater	Anticipated creation of 2,534 jobs					
Infrastructure Development -	infrastructure to create capacity	(direct, indirect, and induced) and					
enhance PIPs ability to attract/retain	for 856.3 "shovel ready"	average wage differential of					
industry manufacturers	industrial sites.	\$50,500					
End-to-End Workforce Project –	Train 10,629 individuals,	Industry-led, competency-based,					
create an integrated and responsive	provide 168 work-based learning	robust workforce development at					
end-to-end APM workforce	experiences and serve 375 with	all levels ready to serve existing					
	wraparound services.	and future Tech Hub needs.					

⁴³ VEDP Analysis

⁴⁴ VEDP Analysis



Housing Demand Growth

The Hub recognizes that while funding can increase wages, and lower unemployment, it can also create tight housing markets and decrease housing supply, negatively impacting low-income residents.⁴⁵ The Hub will work to mitigate these risks across the Region, with a focus in the City of Petersburg, an EDA persistent poverty county equivalent,⁴⁶ which has approximately 20,000 individuals on public assistance⁴⁷ and lower homeownership rates when compared to the surrounding areas.⁴⁸ To prevent displacement and ensure affordable housing units are available to low-income individuals, Petersburg commits to examining its housing policies, including local land use laws and zoning regulations, which can limit where, and how densely, housing can be built. ⁴⁹ These efforts aim to address potential unintended effects including perpetuation of segregation patterns, decreased job access, and increased energy costs and climate risks.⁵⁰

In addition, the Hub's WDB's will coordinate with <u>Southside Community Development and</u> <u>Housing Corporation (SCDHC)</u> to provide homeownership education to low-income families throughout the Region. SCHDC's work will come at no cost to the Project and be intertwined with the Workforce CPs wraparound services. Finally, the Hub will solicit community feedback on available housing supply and needs as part of its biannual community engagement meetings (through Y4) and follow up surveys that will be held in primarily disadvantaged and rural areas.

Relevant Activities from Phase 1

The APM Consortium has maintained its vision since Phase 1 Designation – its focus remains on addressing the national security priority to reshore manufacturers, create a resilient U.S. based pharmaceutical supply chain, and ultimately reduce nationwide drug shortages. To support its strong and sustained vision, the Consortium has received additional funding since Phase 1:

- <u>\$1M RIE Planning Grant</u> this will allow the Consortium to build a Strategic Implementation Plan, create a recruitment/management strategy, craft a workforce development plan, and strengthen DEIA in the Region. The proposed Governance and Sustainability CP has been designed to complement and accelerate this work.
- <u>Phlow HHS funding</u> Since Designation, Phlow has received an additional \$50.6M through its Health and Human Services contract. The funds will be used to continue manufacturing APIs of generic essential medications in importance to the health of the population and on the essential medication drug shortage list.

Since December 2023, the \$100M Research Triangle investment proposal was announced, and BCC received a <u>GoVirginia</u> Talent Pathways Initiative grant with \$125,000 dedicated solely to understanding APM talent gaps. Updated LOCs from partners are included as an attachment.

The lead applicant for the Consortium has not changed.

⁴⁵ PD&R EDGE: <u>Boom Town Effects of New Oil and Gas Exploration on Local Housing Markets</u>

⁴⁶ FY 2023 Persistent Poverty County List

⁴⁷ The Progress Index: <u>Is there a need for more Section 8 housing? The mayor doesn't think so</u>. (2023)

⁴⁸ City of Petersburg Comprehensive Plan 2040

⁴⁹ White House: <u>Biden-Harris Administration Announces Actions to Lower Housing Costs and Boost Supply</u> ⁵⁰ Ibid