Advanced Pharmaceutical Manufacturing and R&D Cluster in Richmond /Petersburg region

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Alliance for Building Better Medicine
A program of Activation Capital

ALLIANCE FOR BUILDING BETTER MEDICINE

Solving pressing national problems and addressing critical unmet social needs

- U.S. supply chain for quality affordable medicines is at high risk – 80%+ of medicines are sourced from India or China
- Manufacturing of medicines fled overseas in last 30 years due to cost and environmental hurdles
- Chronic shortage of essential medicines in U.S. hospitals
- Uneven and poor quality of imports, and difficult to regulate
- High cost of medicine creates barrier to access to health and wellness, an economic burden on patients and fiscal burden on government

Emerging cluster provides global leading solution to the problems

- World-leading research at VCU College of Engineering Medicines for All Institute at the Virginia Bio+Tech Park reinvents technology of making small molecule medicines
  - -Intensified process and innovative synthetic routes make medicines faster, cheaper, less waste, higher quality
  - -Established with funding from the Bill & Melinda Gates Foundation and funded by philanthropy, global public health organizations and industry
- Innovative curriculum and teaching at VCU produce top talent to fuel this new approach
- NSF CeRCaS
- USP

Emerging cluster provides global leading solution to the problems

Three manufacturing facilities under construction in Petersburg are the nation's largest investment in reshoring the manufacture of medicines and full use of continuous flow manufacturing. Private investment supported by $800M contract from U.S. HSS BARDA

AMPAC Fine Chemicals restart and expansion
Phlow Corp - new continuous and hybrid manufacturing facility
US Strategic Active Pharmaceutical Ingredient Reserve ("SAPIR")
Civica Rx – new finished dosage form manufacturing facility

Defining the emerging cluster

- “Small molecule medicine” manufacturing – 90% of all
- End to end manufacturing – from KSM, API, finished formulation to distribution
- R&D in chemistry, chemical engineering, other fields enabling
- Products and services creating continuous flow pharmaceutical manufacturing

Innovative technology and business models

Technology

- focuses on manufacturing, not drug discovery
- brings many different advances in chemistry, engineering to the intensification of the synthetic chemistry processes by which medicines are made
- less steps, less inputs, less complexity, less waste, faster, cheaper, greener
  - worldwide cost of HIV antivirals
  - the covid antivirals of Merck and Pfizer
- enables advanced manufacturing methods (continuous flow) to be applied to small molecule medicines

Business Models

- BARDA's investment by contract to Phlow (B Corp) and partners (($350M->$850M) to build end to end manufacture campus for API and essential medicines to US
- Civica Rx – hospital and insulin
- Children's Hospital Coalition
- World Patent Pool
- SAPIR

Organizing for success – the regional coalition

- Year long regional strategic planning by VCU College of Engineering funded by GO Virginia in 2020
- Final Report/Recommendations March 31, 2021.
- A permanent regional coalition formed September 2021 with private, public and GO Virginia funding
- Mission: to fast-track the development of the advanced pharmaceutical manufacturing and R&D cluster for the Commonwealth

Strategy:

- Develop in the region the **supply chain** the pioneer firms and the cluster require to be successful.
- Improve **infrastructure** required for near-term success and long-term growth.
- Assure the full range of **workforce** needs are known and met both now and in future.
- Create and coordinate **communications and marketing** necessary to drive cluster growth.
- Develop and support strategic partnerships for transformative initiatives for the cluster and its firms – industry philanthropy, federal and state.

The Coalition

Leadership Board

- Virginia Biotechnology Research Partnership Authority (Activation Capital)
- Virginia Commonwealth University
- Virginia State University
- Community College Workforce Alliance
- Virginia Economic Development Partnership
- Greater Richmond Partnership
- City of Richmond
- Virginia's Gateway Region
- City of Petersburg
- AMPAC Fine Chemicals
- Phlow Corp.
- CivicaRx

Stakeholder Partners

Commonwealth Center for Advanced Manufacturing
Center for Rational Catalyst Synthesis
Chamber RVA
Commonwealth Center for Advanced Logistics Systems
Crater Planning District Commission
Crater Regional Workforce Development Board
GENEDGE
Grow Capital Jobs Foundation (GOVirginia 4)
Greater Washington Partnership
Plan RVA
RVA 757
VBHRC, the Catalyst
VCU Innovation Gateway
Virginia Bio
Virginia Innovation Partnership Authority (VIPA)
Workforce Coalition VA

Build Back Better Regional Challenge of the US Economic Development Administration

- Historically ambitious program goal – transformative investments in 30 regions with emerging high tech industrial clusters to grow jobs
- We had a plan, relationships and a team - led by Activation Capital
- Phase 1 competition: for $0.5 M and a chance to apply for the big prize. From 559 applicants Richmond/Petersburg was one of 60 selected
- Phase 2 competition: on March 14 we submitted application asking for $77M federal support for 6 projects costing $99M projects; we will learn in May, and grant will begin Oct 1

Six Component Projects

1. Sewer and water infrastructure in Petersburg serving current and future manufacturing sites
2. Expanded laboratory facilities at VA Bio+Tech Park near Medicines for All Institute
3. Scale up facility and Development Center to accelerate lab discoveries to commercial use
4. Advanced Pharmaceutical Manufacturing workforce programs, including technician certificate
5. VCU and VSU collaboration on pharmaceutical engineering education, training, R&D and industry support
6. Supply chain development needed to support cluster growth

Sewer and water infrastructure in the City of Petersburg critical to serve the manufacturing cluster

- City sewer and water systems lines and pumping stations serving the Poor Creek Service Area in which manufacturing cluster is located are at capacity and in need repair and upgrade to provide the volume, pressure and reliability required for industry to succeed and expand in the area.
- The City of Petersburg is one of Virginia's most fiscally challenged, with limited funds and funding capacity for needed maintenance, repairs, replacement.
- Poor Creek Service area covers 1/3 of city and its residents, and current limitations impede commercial, industrial and residential development.

Sewer and water infrastructure in the City of Petersburg serving the cluster

Sewer

- Replace, increase capacity and reroute sections of Force Main
- Upgrade Poor Creek Pump Station

Water

- Create new high pressure zone within Poor Creek Service Area
- Line maintenance and upgrade
- Pumping station
- Pressure relief units

Additional lab space VA Bio+Tech Park in Richmond

- Firms are seeking space to locate near the Medicines for All Institute and VCU to be at the epicenter of R&D driving the cluster, but there is no readily available lab space near M4All's location in the Virginia Bio+Tech Park.

- The Park will construct **a new building to provide laboratory space immediately adjacent to M4All to serve firms wishing to enter the region and cluster.**

- The building will house Activation Capital's **Innovation Center**, entrepreneurship/innovation support services for startups, spinoffs.

Additional lab space VA Bio+Tech Park in Richmond

Scale up Facility and Development Center

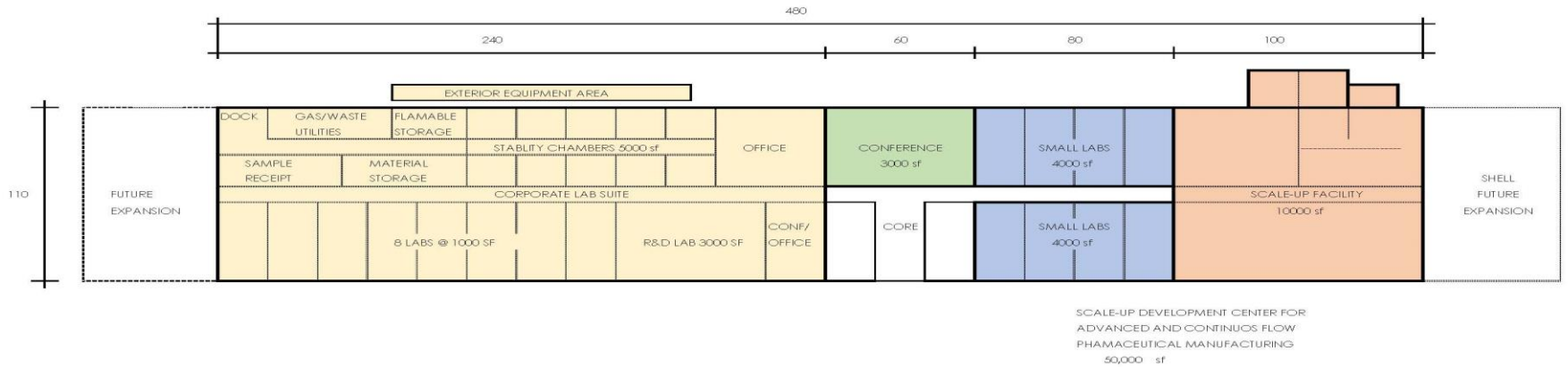
- First of its kind facility closing gap between lab bench scale innovations and commercial scale, offering specialized scale up equipment, laboratories, instrumentation, and office space for industry and researchers to co-locate and collaborate on innovative products and services.

- A public private partnership anchored by VCU College of Engineering and CivicaRx.

- The Center will support training of students in the community college workforce programs, the VSU/VCU educational collaboration, and existing workers from industry in specialized advanced manufacturing techniques needed on the job.

Scale up Facility and Development Center

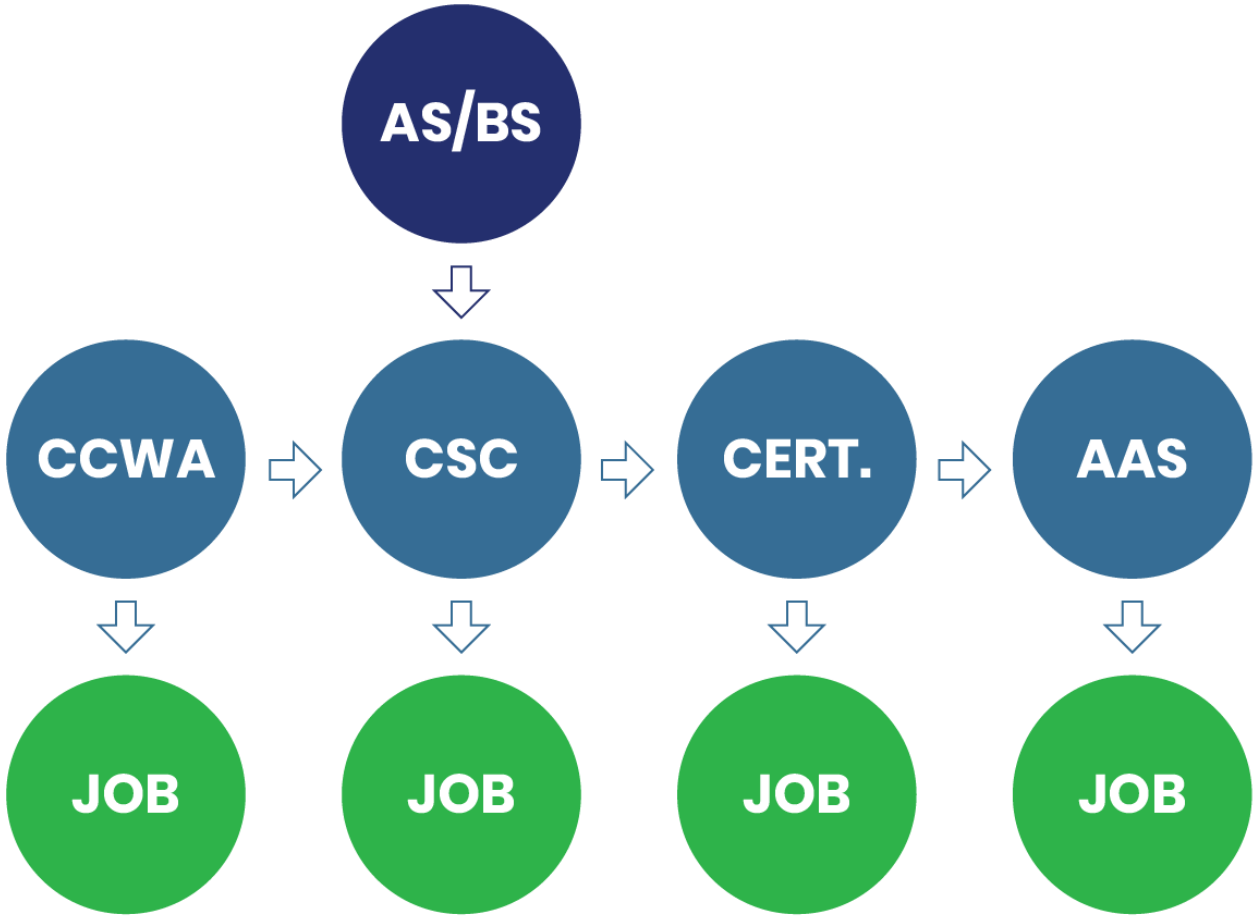
- Industrial zoning
- Scale up facility (non GMP) for shared use
- Laboratories - GMP and non GMP
- Training space and equipment
- Ancillary office space
- Space for expansion



Workforce Development: Advanced Pharmaceutical Manufacturing Technician training and education

- Brightpoint Community College in close collaboration with industry partners, state, regional, local EDOs and local philanthropy
- Foundational program: 16 course **certificate program for advanced manufacturing technician under development** with GOVirginia funding
- In BBBRC we will ask for support for a **best in nation comprehensive pathways** to employment approach, with CSC, Cert, AAS, employee training
- "**Bridge" programs** will reach out to and open up these opportunities to individuals from historically excluded communities

Pathways to Employment



Education, training and research collaboration between VCU and VSU

Virginia State University

- HBCU and anchor institution in Petersburg; 4,500 students, 95% undergraduate
- College of Engineering and Technology with strong programs in manufacturing and mechanical, but not chemical or pharmaceutical
- Undergraduate programs seek and enroll students from historically disadvantaged communities who do not readily qualify under traditional Engineering School admissions criteria

Virginia Commonwealth University

- Carnegie designations as “R1 Doctoral University – Highest Research Activity” and “Community Engagement”.
- Anchor institution in downtown Richmond; 29,000 students, 80% undergraduate
- College of Engineering offers nationally leading or unique programs in Pharmaceutical Engineering; its Medicines for All Institute is the nation’s leading source of innovation underlying the advanced pharmaceuticals manufacturing of small molecule API and medicines and their continuous flow manufacture.

Education, training and research collaboration between VCU and VSU

- **Easy on ramp for VSU College of Engineering and technology students** to undergraduate, undergraduate dual degree in chemistry and chemical engineering, and master's degrees
- **Joint research relationships** between faculty and students
- **Build up at VSU of fundamental equipment and instrumentation** equipment and instrumentation to support teaching and research in advanced pharmaceutical manufacturing and R&D, and complimentary equipment to extend VCU capabilities
- **Collaborative experiential learning programs** with one another and with industry cluster in the region
- **Joint research projects with industry**, funded under Virginia Biomedical Health Research Corporation grant program
- Matriculation and training **linkages with range of workforce training programs of** by Community College Workforce Alliance and Brightpoint Community College

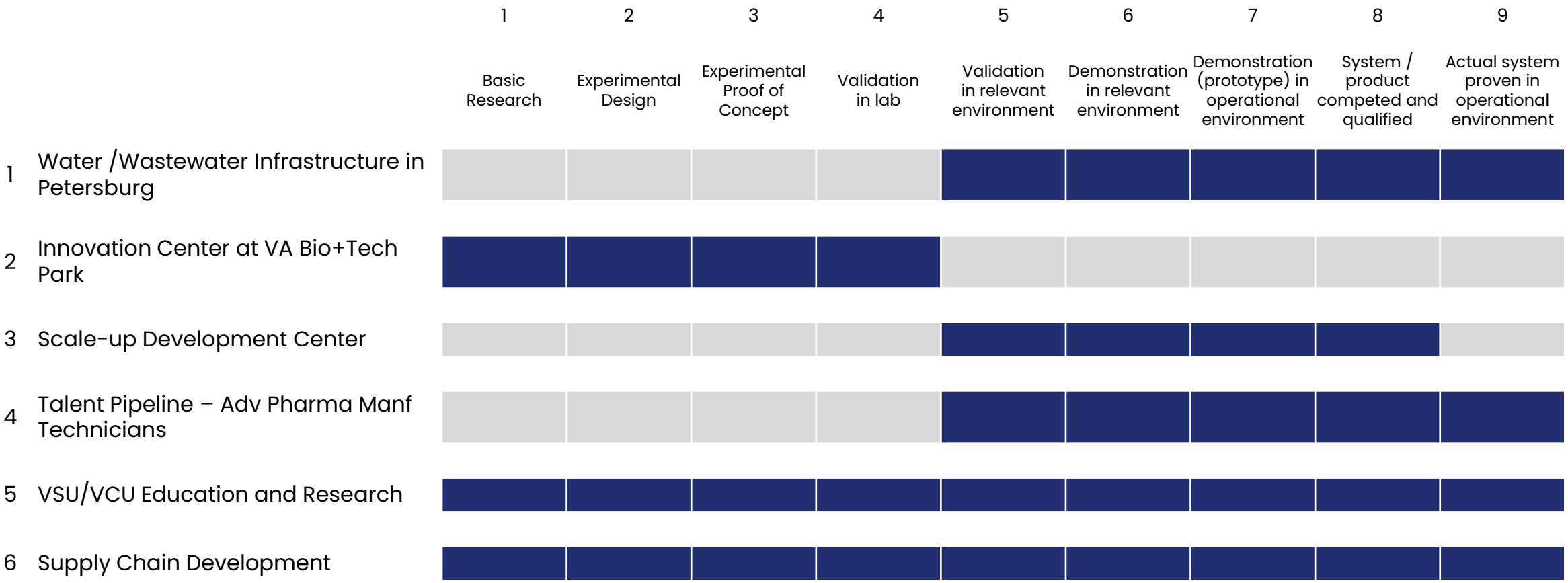
Supply Chain Development

- Rapid growth and the development of a novel manufacturing platform (continuous flow) create a challenge for supply chain to the cluster.

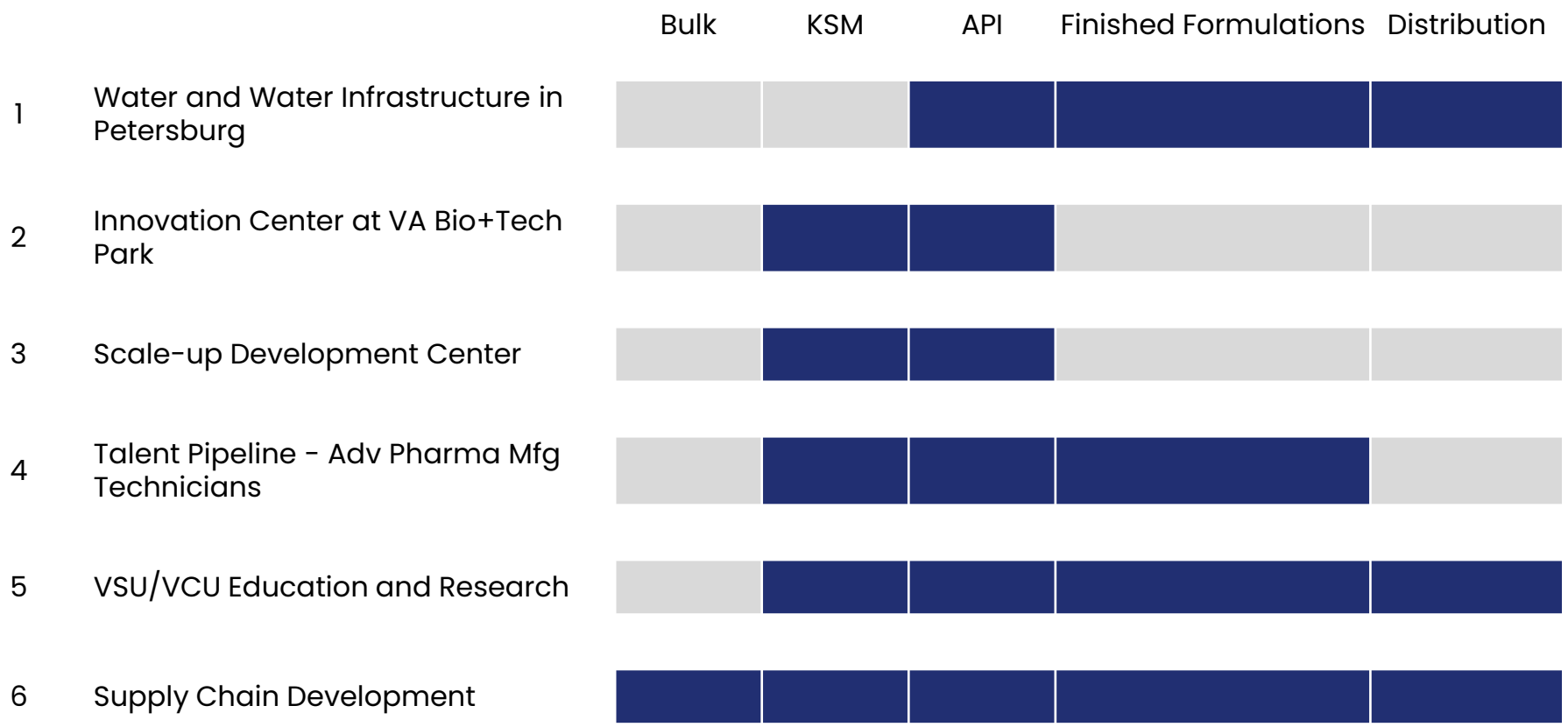
- The region will undertake a strategic study to **map the gaps** to identify specific gaps that are barriers to growth and how to strengthen.

- State, regional and local economic development organizations will **work collaboratively with added resources**, and working with industry, to implement strategies and solutions to develop the supply chain from within and recruiting expansions to the region.

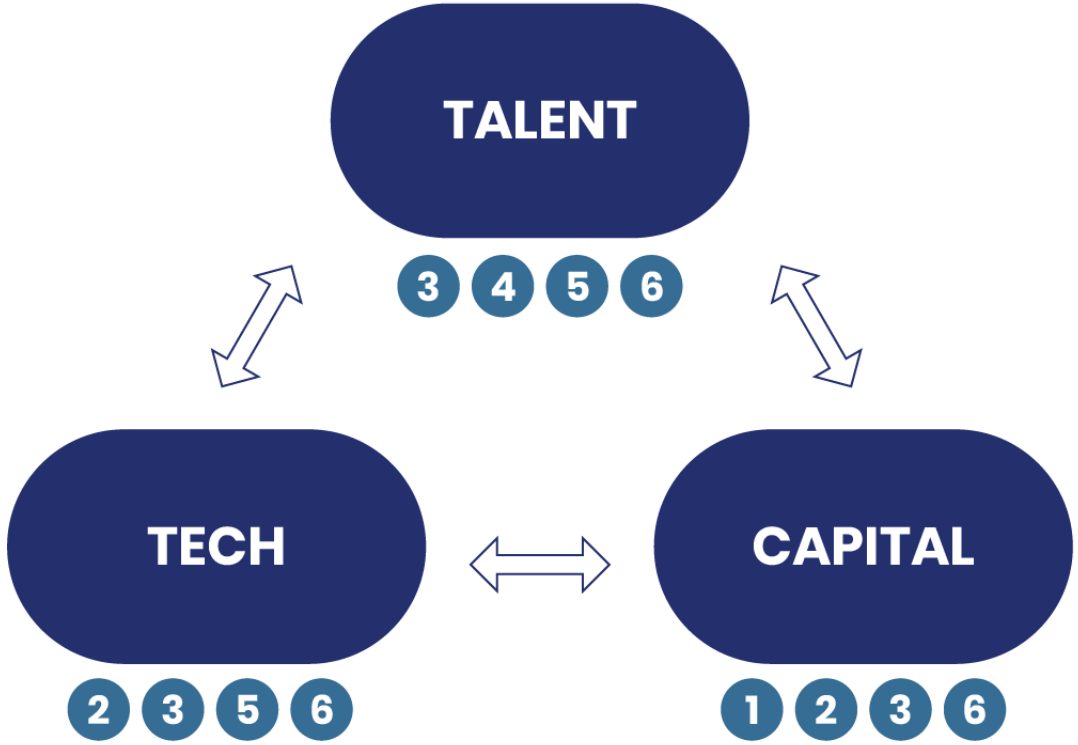
Strategic Focus and Impact of the Projects: Technology Readiness Levels



Strategic Focus and Impact of the Projects: End-to-End Pharmaceutical Manufacturing



Strategic Focus and Impact of the Projects: Commercialization Pillars

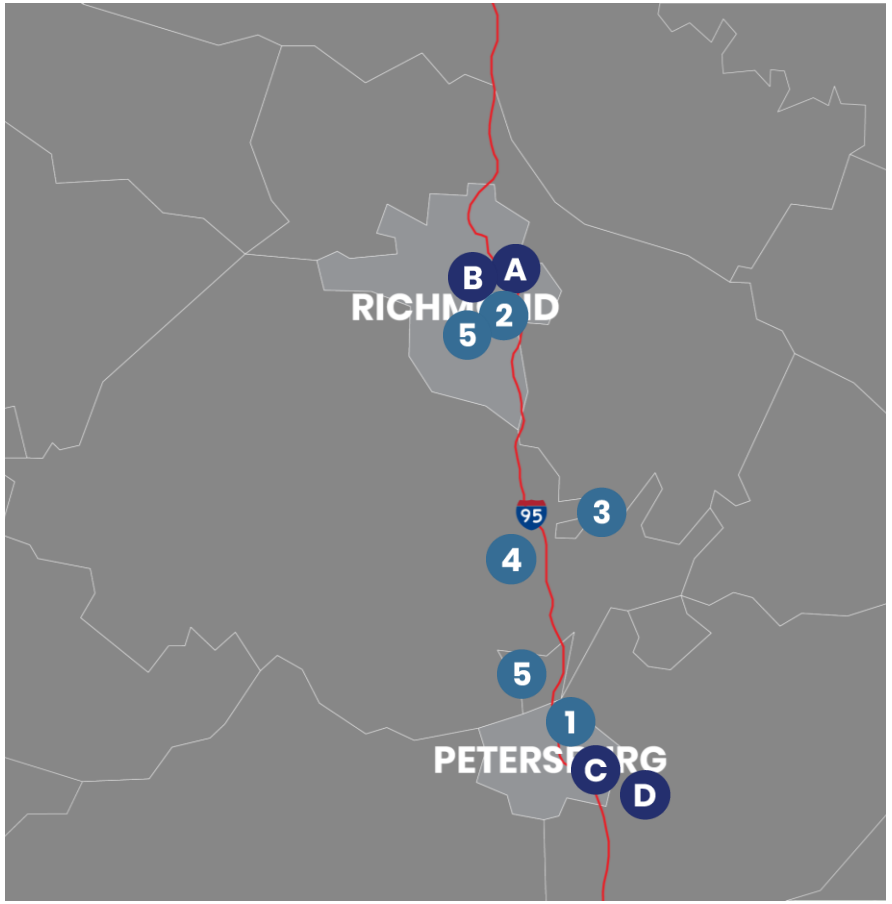


1. Water / Wastewater Infrastructure Petersburg
2. Innovation Center at VA Bio+Tech Park Campus
3. Scale-Up Development Center
4. Talent Pipeline - Adv Pharma Manf Technicians
5. VSU-VCU Education and Research
6. Supply Chain Development

Interrelationship of the Projects

		1	2	3	4	5	6
1	Water and wastewater Infrastructure						X
2	Innovation Center at VA Bio+Tech park			X		X	X
3	Scale-up Development Center		X		X	X	X
4	Talent Pipeline - Adv Pharma Mfg Technicians			X		X	X
5	VSU/VCU Education and Research		X	X	X		X
6	Supply Chain Development	X	X	X	X	X	

Strategic Focus and Impact of the Projects: Geography



Existing

- A Medicines for All Institute
- B VCU College of Engineering
- C Phlow, AMPAC, CivicaRx manufacturing campus
- D Commonwealth Center for Advanced Manufacturing

Component Projects

1. Sewer and Water Infrastructure – Petersburg including manufacturing campus
2. VA Bio+Tech Park Laboratory Complex
3. Scale up Facility and Development Center
4. Workforce Training, Brightpoint Community College
5. VSU-VCU Collaboration
6. Supply Chain Development

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