

One Case for Designation

Consortium Name and Selected Core Technology Area

The Advanced Pharmaceutical Manufacturing (APM) Consortium based in the distressed Richmond Metropolitan Statistical Area (Richmond MSA or Region) requests Designation as a Regional Technology and Innovation Hub (APM Tech Hub). The APM Consortium, formed in 2019 through [Activation Capital \(AC\)](#) as the [Alliance for Building Better Medicine](#) (Alliance) will accelerate the growth, innovation, and sustainability of a U.S.-based APM industry.

Currently, a staggering 73% of Food and Drug Administration (FDA)-registered active pharmaceutical ingredient (API)ⁱ manufacturing facilities are located outside the U.S.ⁱⁱ This flight to overseas manufacturing is decades in the making and caused by cost pressures, environmental regulation and aggressive foreign state investment.ⁱⁱⁱ As a result, the supply of quality medicines is uneven, at risk, and difficult to regulate and monitor.^{iv} Overseas pharmaceutical manufacturing not only poses a national security risk, but also takes essential jobs away from U.S. workers, and contributes to steep prescription costs further exacerbating racial and ethnic health inequalities.^v

For nearly a decade, Alliance members have been working to re-shore safe and affordable medicines and create economic growth in the Richmond MSA. Since 2014, the [Virginia Commonwealth University's Medicines for All Institute](#) (VCU M4All), has led the U.S. in research and development (R&D) to optimize API production to create cleaner, faster, and cheaper APM methods.^{vi} These innovations have not just been “laboratory curiosities,” but have been processes disseminated directly to manufacturers for scale-up and implementation. As a result, academia-industry partnerships have grown, allowing the Region to emerge as a leader in innovative hybrid and continuous flow manufacturing (CFM), an [FDA recognized emerging technology](#). Since 2019 the Region has received more than \$689M in public/private investment to put in place infrastructure and workforce capacities needed to scale-up these R&D efforts. Notably, a subset of Alliance members received a [\\$52.9 million Build Back Better Regional Challenge \(BBBRC\) award](#) in 2022 to complement investments and generate further growth.

While the Alliance has aligned and coordinated APM stakeholders, additional investment in the Region is needed to create a globally competitive APM Tech Hub in the next decade. Tech Hub Designation and investment will accelerate and expand the Alliance’s capacity to deploy and commercialize APIs, catalyze additional job growth and investment (supporting up to [5,500 new biopharma jobs in the next decade](#)), and become a global leader in research and end-to-end manufacturing of medicines. The Alliance is seeking Designation in two key technological focus areas: **1) robotics automation and advanced manufacturing, and 2) biotechnology, medical technology, genomics, and synthetic biology. The selected core technology area is the intersection of biotechnology and advanced manufacturing.**

The APM Tech Hub will be helmed by Alliance member, the [Commonwealth Center for Advanced Manufacturing \(CCAM\)](#) and comprised of 29 Consortium members including: 1) 4 institutions of higher education; 2) 3 state and local governments; 3) 10 industry groups or firms;

4) 4 economic development organizations, and 5) 2 labor organizations or workforce training organizations. All member types are outlined in Letters of Commitment (LOCs). The Regional Innovation Officer (RIO) will be Dr. Joy Polefrone, Executive Director for the Alliance.

Geographic Boundaries and Compliance with EDA Geographic Constraints

Home to over 1.2 million people, the Richmond MSA stretches across Central Virginia from the City of Richmond about 24 miles south to the City of Petersburg.^{vii} The Richmond MSA has 28 [Qualified Opportunity Zones](#) (QOZs) or economically distressed communities across 17 counties and independent cities. The Region is diverse and is 60.2% White, 29.4% Black, 4% Asian, and 6.5% Hispanic or Latino.^{viii} The cities of Richmond and Petersburg, home to the bulk of the core Tech Hub activity, are- and historically have been- distressed, and are majority minority cities. Both are classified as Poverty Persistent County (PPCs) equivalents by EDA.^{ix} Overall, 20% of the Region's population is classified as rural.^x

While the majority of Alliance members are located within the Region, two core partners fueling innovation and workforce development are located outside the Richmond MSA - the [University of Virginia \(UVA\)](#), and the [Commonwealth Alliance for Rural Colleges \(CARC\)](#).

Seven Key Designation Factors

1. Technology-Based Potential of the Region for Global Competitiveness

10-Year Global Competitiveness

The global APM industry's projected compounded annual growth rate (CAGR) through 2028 is 14.3% for APIs and finished dose formulations (FDFs).^{xi} With the Alliance convened, and assets in place, the Region is ripe to clench a significant share of this rapidly growing market. The gross domestic product of the pharmaceutical industry in the Region grew 3.3% per annum from 2010 to 2019 - more than two times the U.S. average growth rate.^{xii}

Existing Assets, Resources, and Capabilities of the Region

The Region is seeded with a growing and diverse array of more than 80 assets, resources and capabilities including 30+ pharmaceutical companies and manufacturers. Key assets, include:

- [Civica](#): A nonprofit drug manufacturer working to prevent drug shortages in the U.S. through conversion of APIs into FDFs, Civica has invested in facilities for [injectable drug manufacturing in Petersburg](#), a [Good Manufacturing Practice](#) testing facility, and a [Scale Up Development Center](#) in partnership with M4All in Chesterfield County.
- [Phlow Corporation \(Phlow\) Facilities](#): Phlow creates APIs and translates them to finished pharmaceuticals. It has multiple advanced manufacturing [facilities](#) under construction in Petersburg and a Richmond-based R&D facility.
- [United States Pharmacopeia \(USP\) Advanced Manufacturing Technologies Lab](#): Develops new methods and standards for APIs made using APM technologies.
- [Ampac Fine Chemicals \(AFC\) Plant](#): AFC is currently expanding its [Petersburg facility](#) which manufactures APIs used for cancer and HIV treatment medications among others.
- [Virginia Bio+Technology Research Park \(Park\)](#): A life science and tech community home to nearly 70 private firms, nonprofits, research institutes, and laboratories in Richmond including AC's [Innovation Center](#), M4All, [Occam](#), Phlow and USP facilities.

A comprehensive list of tightly woven assets and resources can be found [here](#). Please also see Letters of Commitment (LOCs) for further asset information.

Existing Market-Relevant Scientific Capacity

Over the past decade, the Bill and Melinda Gates Foundation has [invested nearly \\$70 million](#) in M4All to maximize the impact of novel development processes for lifesaving medicines. M4All's API optimization practices and scientific capabilities are supplemented by the biotechnology/biomanufacturing and clinical trial capabilities of the University of Virginia [Manning Institute](#), [Virginia State University \(VSU\)](#), and Occam, a VCU spinout that develops artificial intelligence (AI) and machine learning based systems to accelerate manufacturing processes. Combined, these institutions represent \$1 billion plus in sponsored research and give the Region the ability to translate API innovation to manufacturing.

Relevant Ongoing State and Local Development Programs and Federal Investment

Since 2019 Alliance members have received more than \$487 million from federal, state, and local sources. These investments are in alignment with the Region's Comprehensive Economic Development Strategies' which identify three priority sectors for economic development: advanced manufacturing, life sciences, and logistics.^{xiii} Key investments include:

- [\\$2M+ Go Virginia \(GoVA\) Grants](#): In 2019 GoVA provided \$200,000 for a [roadmap](#) to become globally competitive through an APM "Accelerator" – the Alliance. The Alliance received an additional \$1.4M in 2021 to implement this roadmap, and \$450,000 in 2022.
- [\\$354M Health and Human Services \(HHS\) Biomedical Advanced Research and Development Authority \(BARDA\) Phlow Corporation Contract](#): The contract funds APM capability expansion in Petersburg, with potential extension to \$812M over 10 years.
- [\\$52.9M BBBRC](#): In 2022, a Coalition of 14 entities received funding for six APM related projects generating \$145.3M in direct investment and creating/retaining 640 direct jobs.
- [\\$15M in VA appropriations](#): In 2023, AC received \$10M towards the Innovation Center, and \$5M for new method development to onshore key starting material manufacturing.

Core Technology Areas Economic Opportunity

An estimated 1,910 metric tons of APIs are produced annually using APM processes in the U.S. While the Region is not fully built out yet, within the next decade, we will have the capacity to produce 245 metric tons, capturing 12.8% of this rapidly growing market.^{xiv}

Potential to Advance Development, Deployment and Domestic Manufacturing

The potential to advance development and deployment of APM in the Region is significant. This is evident not only from investment by manufacturers, but also from sizable growth across the sector. From 2015 to 2020, the Region experienced 80% higher employment growth in APM relative to national averages and 70% higher employment growth relative to statewide averages. As of 2020, approximately 2,700 APM jobs were in Virginia, 30% of which were in the MSA.^{xv} When compared to peer regions with similar projected investment, the Region's potential job growth could soar from less than 1,000 biopharma jobs to 5,500 in 10 years.^{xvi}

Consortium Sustainability

The Alliance has a strong governing structure ensuring sustainability and growth over the next decade. As part of the GoVA grant which established the Alliance (discussed above),

Committees in Infrastructure, Workforce, Organization/Governance and Business Development were created. Sustainability is evident not only from Alliance formation, but also from the growing market opportunity and investment in the Region. Since October 2022 alone, an additional \$42 million in regional APM investment has been announced.

2. Role of the Private Sector

The Alliance has six private members including AFC, Phlow, Civica, Occam, [BrightSpec](#), and USP. Together, they represent a \$202 million+ investment in the Region. These companies have plans for future regional investment and job growth which will help fuel a global Tech Hub by 2033 (See Section 1).

In addition to investment, these companies help drive the commercialization of new technologies and fuel development of a secure supply chain. As part of the Tech Hub, they will continue their work with the [Virginia Economic Development Partnership \(VEDP\)](#), the [Virginia Gateway Region \(VGR\)](#), [Greater Richmond Partnership \(GRP\)](#), and [GENEDGE](#) on a comprehensive Supply Chain Development Initiative aimed at attracting aligned companies to the Region. This work includes outreach and engagement with diverse companies, innovators, entrepreneurs, and investors with specific knowledge of APM supply chain and technology gaps. To date, the Initiative has identified 4,000+ prospective companies and continues its effort to target and recruit private entities. All private sector participation is detailed in LOCs.

3. Regional Coordination and Partnerships

The Alliance has an established and growing ecosystem of partners. The Alliance Leadership Board includes 15 vested members – three of which have joined in the past year. For the purpose of Tech Hubs, committed partnerships have grown to 30 strengthening expertise in R&D, scale-up, workforce, and infrastructure. The Alliance continues to recruit for: 1) manufacturers, 2) supply chain partners, 3) education allies, 4) community partners, and 5) national/international partners to ensure work scales to support a world-class, sustainable APM Tech Hub.

4. Equity and Diversity

The Alliance is committed to diversity, equity, inclusion, and access (DEIA) across the industry and will build on existing opportunities for underserved individuals, particularly for those located in distressed parts of the Region including Richmond, Petersburg, and unincorporated rural areas. As part of BBBRC, the Alliance is implementing an [Equity Action Plan](#) spearheaded by a Diversity Coordinator to drive the creation of long-term DEIA policies and programs. The Plan includes Alliance engagement of eight community/equity driven organizations (six of which are Alliance members) to ensure underserved groups provide feedback on community needs. The Alliance is committed to sustaining and expanding this effort through the creation of talent pipelines, good paying jobs, and a diverse supplier sector. Key DEIA initiatives include:

- [Community College Workforce Alliance \(CCWA\) Talent Pipeline Project](#): Creates APM credited and non-credited certificate programs at [Brightpoint Community College \(BCC\)](#) and [Reynolds Community College \(RCC\)](#), targeting veterans, underserved students, unemployed/underemployed individuals, and those without college degrees. CCWA also runs the [FastForward](#) tuition reduction and will stand up a Bridge Program in 2024.

- CCAM Workforce and STEM Programs: CCAM houses the Regions [Virginia Federation for Advanced Manufacturing Education](#) apprenticeship program, K-12 STEM program and [Great Opportunities in Technology and Engineering Careers](#) program.
- CARC-VCU Program: Opens VCU College of Engineering courses to students attending rural community colleges and develops pathways into the Region’s APM industry.
- VCU-VSU Joint Project: Provides a pipeline for 200 underserved VSU students to obtain education, research experience, and industry training for APM degrees.
- Supply Chain Development Initiative: Targets recruitment of diverse suppliers including at least 10% that are minority led businesses (see Section 2 for more).

Up to 9,732 indirect jobs for underserved individuals are projected as a result of recent APM investment.^{xvii} Tech Hubs funding could nearly double this figure within 10-years. The Alliance will expand opportunities for underserved individuals through added educational and training pathways, entrepreneurial support, and recruitment of DEIA partners.

5. Composition and Capacity of the Regional Workforce

The Region has in place a diverse and qualified workforce that can scale to support further APM investment. While the Region itself has a high unemployment rate^{xviii}, employment within the Alliance’s key technology area has grown rapidly over the past decade. From 2015-2020, the Region experienced 80% higher employment growth in pharmaceutical manufacturing relative to national averages and 70% higher employment growth relative to statewide averages.^{xix} To continue this growth, the Alliance is working to create good paying jobs in urban and rural geographies at all levels, including those that do not require college degrees. The Alliance will build on existing pathways to support end-to-end manufacturing including UVA’s [Bridge to Bio Training Program](#) and [Link Lab](#), as well as the programs mentioned above, CCWA and CARC.

6. Innovative “Lab to Market” Approaches

APM translation to scale maturity in the Region is evidenced through APM spinouts from VCU and UVA and industry-academia partnerships between Phlow, AFC, USP, OCCAM and Brightspec. These partnerships give the Region the ability to implement APM and overcome commercialization barriers – status quo “batch manufacturing,” which is expensive and slow.^{xx} [VCU TechTransfer and Ventures](#), USP, [Virginia Innovation Partnership Corporation](#), and AC further provide core elements for APM growth which is enhanced through [programming to attract diverse entrepreneurs](#) and a comprehensive [strategic planning effort to grow startups](#).

7. Impact on Economic and National Security for the Entire United States

Designation as an APM Tech Hub will support the national priorities to [Build Resilient Supply Chains and Revitalize American Manufacturing](#) and Advance Biotechnology and Biomanufacturing for a rapidly growing industry segment.^{xxi} Dependency on foreign supply chains creates chronic shortages of medicines required for U.S. healthcare providers to operate.^{xxii} This dependency contributes to the disproportionately high costs of medicines in the U.S.^{xxiii} The Alliance is actively working to re-shore the APM supply chain through the Supply Chain Development Initiative (See Section 1). Tech Hub Designation will expedite this effort and help to minimize supply chain disruptions, mitigate safety concerns, and reduce high costs for consumers while creating job growth and investment in the distressed Richmond MSA.

Appendix

- ⁱ Active Pharmaceutical Ingredient – any substance intended for incorporation into a finished drug product and is intended to furnish pharmacological activity ([FDA CFR Title 21](#))
- ⁱⁱ [Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-Based Growth](#), The White House, P. 213 (June 2021)
- ⁱⁱⁱ 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.
- ^{iv} 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 8, 2019).
- ^v The White House (2022). [FACT SHEET: How the Inflation Reduction Act Helps Black Communities](#). White House Release.
- ^{vi} FDA: [Future of Continuous Manufacturing in Drug Products Containing Nonomaterials](#), Xiaoming Xu. Ph.D (2022)
- ^{vii} American Community Survey (ACS) 2020 5-Year Estimates - DP05
- ^{viii} Ibid
- ^{ix} [FY 2023 Persistent Poverty County List](#)
- ^x U.S. Census Data (2010)
- ^{xi} Frost and Sullivan: [Global Pharmaceutical Continuous Manufacturing Market – Growth Opportunities, Analysis, Forecast, North America, 2023](#) (February 2023)
- ^{xii} U.S. Cluster Mapping Project, regional data set, <https://clustermapping.us>
- ^{xiii} [2019 GVR4's Updated Economic Growth and Diversification Plan \(2022-2024 Update\) / 2021 Crater Planning District Commission \(CPDC\) CEDS](#)
- ^{xiv} [Alliance Market Sizing Data](#)
- ^{xv} U.S. Bureau of Labor statistics, Moody's
- ^{xvi} VEDP: [Job Growth Estimates: Central Virginia Biopharma for Tech Hubs](#) (August 2023)
- ^{xvii} Impact projections derived using data from Economic Modeling Specialists International based on BBBRC investments.
- ^{xviii} EDA StatsAmerica Measuring Distress County Tool (Richmond, VA Metro Area) / U.S. Bureau of Labor Statistics, Local Area Unemployment Statistics Map (Virginia) (May 2023)
- ^{xix} U.S. Bureau of Labor Statistics, [Local Area Unemployment Statistics Map](#) (November 2022)
- ^{xx} FDA: [Modernizing the Way Drugs are Made: A Transition to Continuous Manufacturing](#)
- ^{xxi} [FACT SHEET: The United States Announces New Investments and Resources to Advance President Biden’s National Biotechnology and Biomanufacturing Initiative](#) (September 2022)
- ^{xxii} U.S. Food and Drug Administration. “[Drug Shortages](#).” Inter-Agency Drug Shortages Task Force, FDA (October 2019, Updated February 21,2020). [Report: Drug Shortages: Root Causes and Potential Solutions](#) (p.5)
- ^{xxiii} Mulcahy AW, C., Tebeka, M., Schwam, D., Edenfield, N., & Becerra-Ornelas, A. (2021) [International Prescription Drug Price Comparisons](#). Rand Corporation Research Report, 12-13.