



August 2024

Toward National Health Security:

Strengthening U.S. Biomanufacturing Capabilities

WASHINGTON | CORE

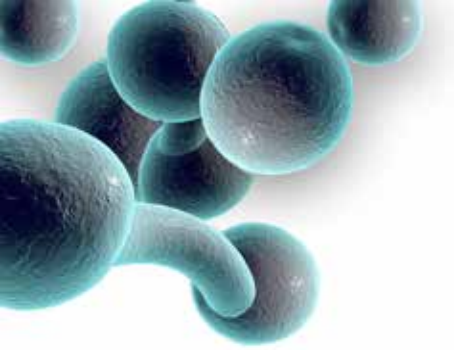


The bioeconomy has emerged as a critical sector with the potential to drive significant advancements in health, environmental sustainability, and economic growth. Traditionally, the United States has led global bioeconomy advancements, but its bio-manufacturing capabilities have struggled to keep pace with developments. The rapid evolution of biotechnology and the increasing complexity of bio-manufacturing processes have underscored the need for robust domestic biomanufacturing capacity.

Domestic biomanufacturing capacity is crucial for the security and reliability of vital biopharmaceutical supply chains, including vaccines, biologics, and therapeutic treatments. The COVID-19 pandemic highlighted vulnerabilities in global supply chains and the necessity for resilient, localized manufacturing capabilities.

In 2022, the U.S. government issued Executive Order (EO) 14081, “Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy,” to advance American competitiveness in this sector. EO 14081 boosts public-private partnerships through the national Manufacturing USA network, managed by the U.S. Department of Commerce’s National Institute of Standards and Technology.

The Manufacturing USA network encourages large-scale collaboration across industry, academia, government, and nonprofits. Within the network, three institutes—BioFabUSA, NIIMBL, and BioMADE—have focused on advancing biomanufacturing and enhancing the U.S. bioindustrial competitive edge.



BioFabUSA's Tissue Foundry



Source: Department of Defense Manufacturing Technology Program¹

BioFabUSA- Strengthening Engineered Cell/Tissue/Organ Production

BioFabUSA, led by New Hampshire-based Advanced Regenerative Manufacturing Institute, focuses on challenges associated with scalable, consistent, and cost-effective manufacturing of engineered cells, tissues, and organs. BioFabUSA seeks to integrate innovative cell and tissue cultures with advances in biofabrication, automation, robotics, and analytical technologies to create disruptive research and development tools and FDA-compliant volume manufacturing processes.

BioFabUSA played a pivotal role during the COVID-19 pandemic, addressing shortages of critical medical supplies. In partnership with DEKA Research and Development and NanoPass Technologies, the institute developed a new drug delivery platform featuring microneedle technology with an easy manufacture and fill reservoir and an administration method that requires no specialized knowledge or training.

In 2023, BioFabUSA launched a Startup Lab to accelerate the commercialization of regenerative medicine therapies using advanced biomanufacturing technologies. The lab hopes to create innovative therapies and future regenerative treatments for conditions such as diabetes, heart failure, incontinence, vision loss, and Parkinson's disease.

In May 2024, BioFabUSA secured a five-year \$50 million funding commitment from the Department of Defense (DoD), with the potential for an additional \$50 million award. This DOD funding extends a 2017 \$80 million award supporting development of biofabrication processes and platforms.

NIIMBL – Scaling Vaccine and Gene Therapy Production Capabilities

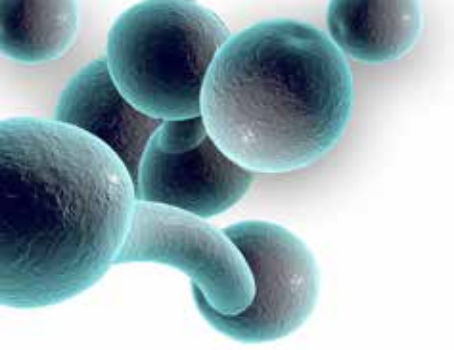
Established in 2017, University of Delaware-based NIIMBL aims to advance biopharmaceutical manufacturing capabilities. NIIMBL has worked to enhance the efficiency and flexibility of manufacturing biologic drugs, including proteins, peptides, RNA, and DNA.

NIIMBL is championing critical biomaterial large scale manufacturing technologies. In 2023, the Bill and Melinda Gates Foundation gave NIIMBL \$1.7 million to fund three new vaccine manufacturing projects involving mRNA and viral vector technologies. NIIMBL is creating different platforms for gene therapies. For example, the Viral Vectors Program focusing on Adeno-Associated Virus (AAV) gene therapy vectors was launched with eyes on gene solutions to treat rare diseases. AAV has gained attention because of its safety, lack of immunogenic viral proteins, and efficient transgene expression in a very broad host range .

This year, a \$10 million investment supported eight new projects led by global pharmaceutical companies such as AstraZeneca, Bristol-Myers Squibb, Genentech, Janssen, Merck, and Pfizer. The projects are aimed at intensified processing for monoclonal antibodies, viral vectors, and cell therapy and measuring critical quality attributes and workforce development initiatives focused on data analytics and strengthening the neurodiverse talent pipeline. Since 2017, NIIMBL has funded 123 technical and workforce development projects with a total investment of around \$111 million.

NIIMBL and the Alliance for Regenerative Medicine's "A-CELL" paper on cell-based therapy manufacturing released in 2022 compiles best practices for chemistry, manufacturing, and controls in cell medicine manufacturing. This paper was translated into Japanese in 2023 allowing further dissemination of best practices.





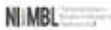
A-Cell: A Case Study-based Approach to Integrating Quality by Design Principles into Cell-based Therapy CMC Programs



A case study-based approach to integrating QbD principles in Cell-based Therapy CMC programs



(日本語)
細胞治療薬のCMCプログラムに QbD 原則を統合するためのケーススタディーに 基づいたアプローチ



Source: Alliance for Regenerative Medicine & iPark Institute Co., Ltd²

NIIMBL's Biopharmaceutical Research Laboratory



Source: Delaware Business Times³

BioFabUSA- Enhancing Bioindustrial Materials Production Capabilities

BioMADE, organized by California-based non-profit Engineering Biology Research Consortium and the University of Minnesota, is dedicated to developing technologies that enhance U.S. bioindustrial competitiveness and expand the biomanufacturing workforce. BioMADE has made advances in building a sustainable domestic bioindustrial manufacturing ecosystem.

After establishing a national network of bioindustrial manufacturing pilot facilities, BioMADE selected Minnesota as the first facility to address the gap in domestic pilot- and intermediate-scale bioindustrial manufacturing infrastructure, receiving a \$100 million from Governor Tim Walz. At the same time, the Congress provided \$300 million to kick-start a national network with BioMADE announcing a list of potential sites in March 2024.

In 2023, BioMADE, supported by Schmidt Futures, funded five new bioreactor innovation projects. These projects focus on scaling up the production of bio-based chemicals, materials, and biomolecules, BioMADE and Schmidt Futures identified bioreactor innovation as a priority area for scaling up production of bio-based chemicals, materials, and biomolecules.

Also last year, BioMADE initiated nine projects to advance domestic bioindustrial manufacturing, focusing on the production of recombinant antimicrobial probiotics and microalgae oils and developing workforce training curricula in bioprocess engineering, bioindustrial automation, and synthetic biology. Finally, BioMADE issued Project Call 4.0 calling for new projects on greener chemistry, low-resource environments, and process intensification, with an emphasis on supporting alternative proteins, cultivated meat, feedstocks, additives, specialty chemicals, and other product categories.

BioMADE's Biomanufacturing Facility



Source: BioMade⁴



