NIMBL® The National Institute for Innovation in Manufacturing Biopharmaceuticals

Annual Report

2023 2024

Advancing Technology Innovation & Strengthening Domestic Manufacturing

This Annual Report reflects NIIMBL's accomplishments from July 1, 2023 to June 30, 2024.

Mission

The NIIMBL mission is to accelerate biopharmaceutical manufacturing innovation, support the development of standards that enable more efficient and rapid manufacturing capabilities, and educate and train a world-leading biopharmaceutical manufacturing workforce, fundamentally advancing U.S. competitiveness and security.

Vision

NIIMBL will lead and transform the development and adoption of next-generation biopharmaceutical manufacturing technologies that contribute to patient well-being. As a public–private partnership, NIIMBL will forge and catalyze advancements that are vital to the acceleration of innovative technologies and a skilled workforce, and these strategic efforts and investments will be undertaken to secure U.S. biopharmaceutical manufacturing leadership.

Table of Contents

A Letter to the Community

Dear Colleagues,

Since NIIMBL launched in 2017, our focus has been clear: advance U.S. biopharmaceutical manufacturing capabilities through collaborative innovation. Our 2023-24 Annual Report highlights the NIIMBL community's work toward that goal. You will find examples of how this public-private partnership is strengthening U.S. global leadership in biopharmaceutical manufacturing, bolstering our national security, and contributing to our economic security.

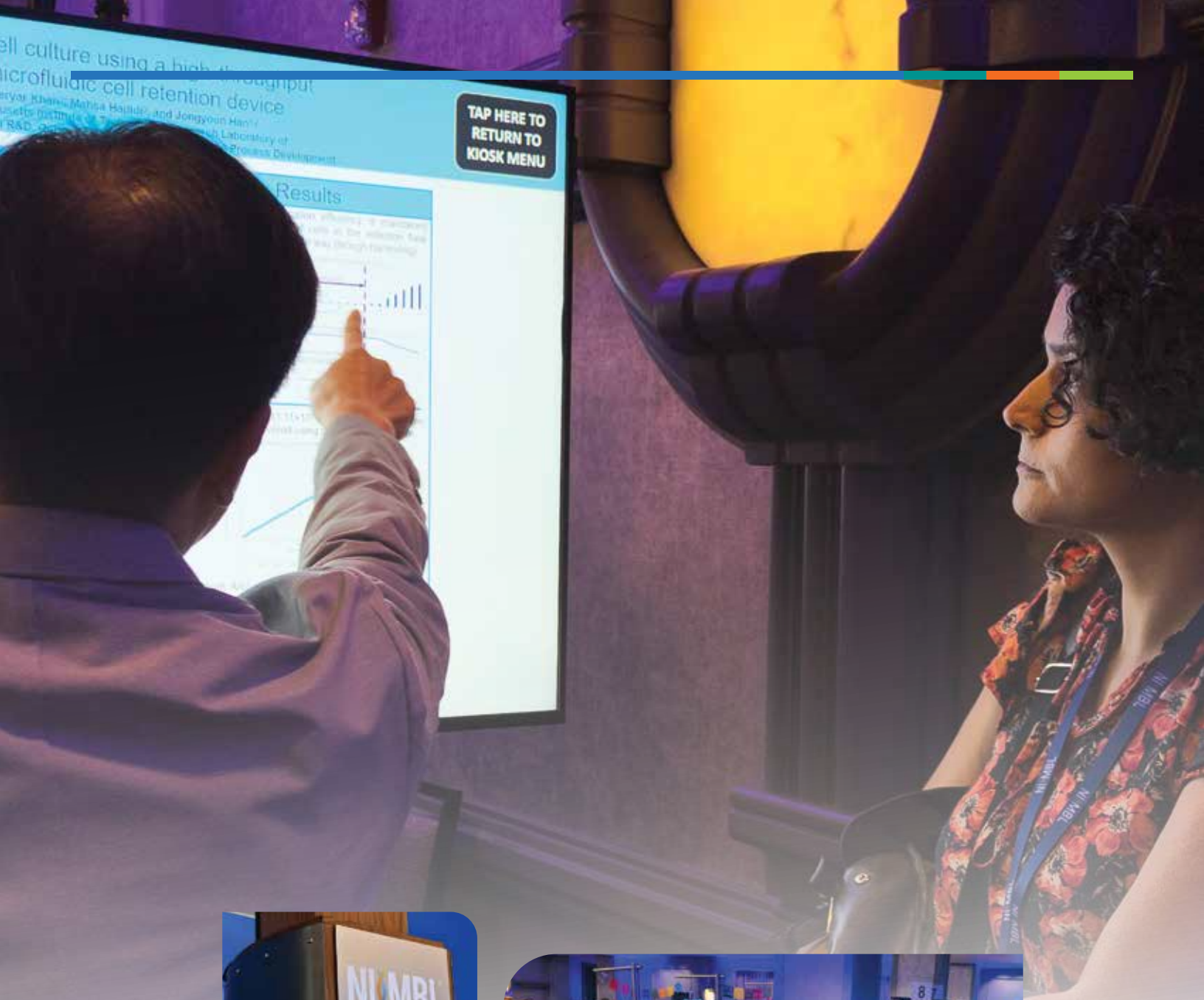
In 2023-24, we authorized 16 new Member-led technology and workforce development projects with an investment of over $11M. Our NIIMBL-led Programs have reached significant milestones over the past year. The Process Intensification Program advanced a testbed facility for continuous manufacturing. The Big Data Program contributed biopharmaceutical industry ontologies as an open-sourced project for continued development by the industry. In October 2023, the Viral Vector Manufacturing and Analytics Program launched to help improve the development and manufacturing of gene therapies.

In addition to technological innovation, our industry members are working to address their talent and workforce needs. In April 2024, we hosted the first-ever U.S. Biopharma Workforce Partnership Conference, designed to cultivate new industry and academic partnerships that will fill talent gaps. Also, in April 2024, our members convened to begin developing an action plan for increasing the flexibility of antibody manufacturing for rapid response, providing a framework for the nation to respond to emerging health needs.

While there are successes to celebrate, we are even more excited about the future. In 2025, we plan to put the finishing touches on a transportable GMP facility for plasmid DNA manufacturing, and we began detailed design of the Securing American Biomanufacturing Research and Education (SABRE) Center. These capabilities will help demonstrate new innovations to the nation and provide a backdrop for workforce training to help the industry meet its needs. Plus, we look forward to the continued maturation of NIIMBL-led Programs and more exciting Member-led Projects.

Through these efforts and others, the U.S. is at the forefront of biopharmaceutical manufacturing innovation and better prepared to respond to future biothreats. We thank our members, partners, and stakeholders for their dedication and commitment to NIIMBL.

Sincerely,
The NIIMBL Team


TAP HERE TO RETURN TO KIOSK MENU
Results


NIIMBL

Accomplishments

Member-led Project Investments

Through our Project Call Program, we fund Member-led Projects that accelerate technology advancement and help industry fill the need for a skilled biopharmaceutical manufacturing workforce.

These collaborative projects bring together innovators from across the biopharmaceutical industrial base to strengthen U.S. biomanufacturing competitiveness, improve national security, and promote economic growth and prosperity. Completed projects have affected real change in areas throughout the biopharmaceutical industrial base, including:

- Reducing costs and measurement duration with real-time monitoring in bioreactors
- Saving millions in facility construction costs for downstream processing
- Delivering software and hardware tools for use by the entire industrial base in R&D labs
- Providing new training and education avenues for workers

2023 – 2024

16 New Projects Funded

$11.4M Total Value

9 New **Technology** Projects

20 Unique Organizations

$8.7M Total Value

7 New **Workforce** Projects

12 Unique Organizations

$2.7M Total Value

Since 2017

156 Publications, Patents, and Intellectual Property

114 **Technology** Projects Since 2017

94 Unique Organizations on **Technology** Projects

46 **Workforce** Projects Since 2017

80 Unique Organizations on **Workforce** Projects

$105.1M Value of all Member-led **Technology** Projects since 2017

$29.5M Value of all Member-led **Workforce** Projects since 2017

Institute Highlights

Workforce Development

Building a national ability to meet the talent needs of the biopharmaceutical industry

The biopharmaceutical industry needs more workers to meet the demands of new treatment modalities and emerging technologies. Our workforce development initiatives bolster the biopharmaceutical talent pipeline, ensuring the U.S. has the most highly skilled and capable workforce globally.

The NIIMBL community is sparking conversations on new approaches to address biopharma talent shortages, including skills-first hiring practices and alternate education pathways beyond traditional degree programs. Additionally, our workforce development community collaborates with stakeholders across the biopharmaceutical industrial base to identify skills and training gaps and explore potential solutions and areas of focus.

The NIIMBL eXperience and bioLOGIC programs enhance talent pipelines by helping students discover rewarding and lucrative careers in the biopharma industry. Additionally, we are fostering new opportunities through industry-academic partnerships, highlighted by collaborative events such as the U.S. Biopharma Workforce Partnership Conference.

We have supported the development of new training programs and courses, ensuring workers acquire the critical skills for today's biopharmaceutical manufacturing demands. In 2023, these NIIMBL supported trainings reached more than 3,600 professionals and 3,200 students across the U.S.

Through these initiatives, we are building a national capacity to meet the education and workforce training needs essential for a thriving biopharmaceutical industry.

U.S. Biopharma Workforce Partnership Conference

> **The event is an energizing synergy of different groups that's very rare, very unique."**
>
> **Janae Williams,**
> North Carolina Life Science Organization

Connections and best practice sharing are vital as we work to build a world-leading biopharmaceutical workforce. To facilitate those connections, we hosted the first U.S. Biopharma Workforce Partnership Conference in April 2024. The two-day event convened representatives from over 70 companies, life sciences-focused universities, community colleges, and nonprofits.

The goal of the conference was to stimulate conversations on talent pipeline strategies and foster new academic-industry partnerships. The program featured sessions on skills-first hiring, early career success stories, non-traditional career pathways, the role of intermediaries in connecting talent to careers, and the role of artificial intelligence in hiring processes.

Attendees praised the networking and partnering sessions. Organizations had the chance to provide attendees a quick pitch of their programs, capabilities, and critical talent needs, with reserved time at partnering tables for in-depth discussions. The partnering sessions showed the power of this first-of-its-kind conference by giving representatives who may not normally cross paths a chance to connect and discuss ways to work together and find new talent.

Workforce Development

The NIIMBL eXperience

A staple of our efforts to expand talent pipelines, the NIIMBL eXperience is an exclusive, in-person, all-expenses-paid immersion program designed to introduce first- and second-year college students from a wide range of academic institutions to lucrative career opportunities in the biopharmaceutical industry.

Building off the successful regional model, we expanded the program in 2024 to five locations across the nation through a competitive proposal process. Host locations included:

- Albany College of Pharmacy and Health Sciences (New York)
- North Carolina State University (Biomanufacturing Training and Education Center)
- Santa Clara University (California)
- Thomas Jefferson University (Jefferson Institute for Bioprocessing) (Pennsylvania)
- University of Houston (Texas)

Each location hosted their own unique eXperience week in June 2024, giving students a chance to learn about the different career pathways the industry offers through hands-on activities, facility tours, and interactions with industry professionals.

Across the five locations, 59 college freshmen and sophomores from 38 institutions were selected through an application process to take part in the program. Since 2019, the NIIMBL eXperience has introduced 139 students to the biopharmaceutical manufacturing industry.

NIIMBL bioLOGIC

NIIMBL bioLOGIC is a project-based learning program for high school students that aims to build awareness of the biopharmaceutical manufacturing industry and create student excitement about STEM-based education and career pathways. The program focuses on three key pillars:

- Engagement with advanced technologies
- Familiarization with the principles of entrepreneurship
- Exposure to education and career pathways that lead into the advanced manufacturing sector

In 2023-24, the NIIMBL bioLOGIC program was launched at four schools in North Carolina and Delaware. The North Carolina Biotechnology Center led three successful programs, serving 45 students at three high schools in the Raleigh-Durham, North Carolina area. In Delaware, the program supported 67 students at the Charter School of Wilmington. NIIMBL bioLOGIC served a total of 112 students across the four locations.

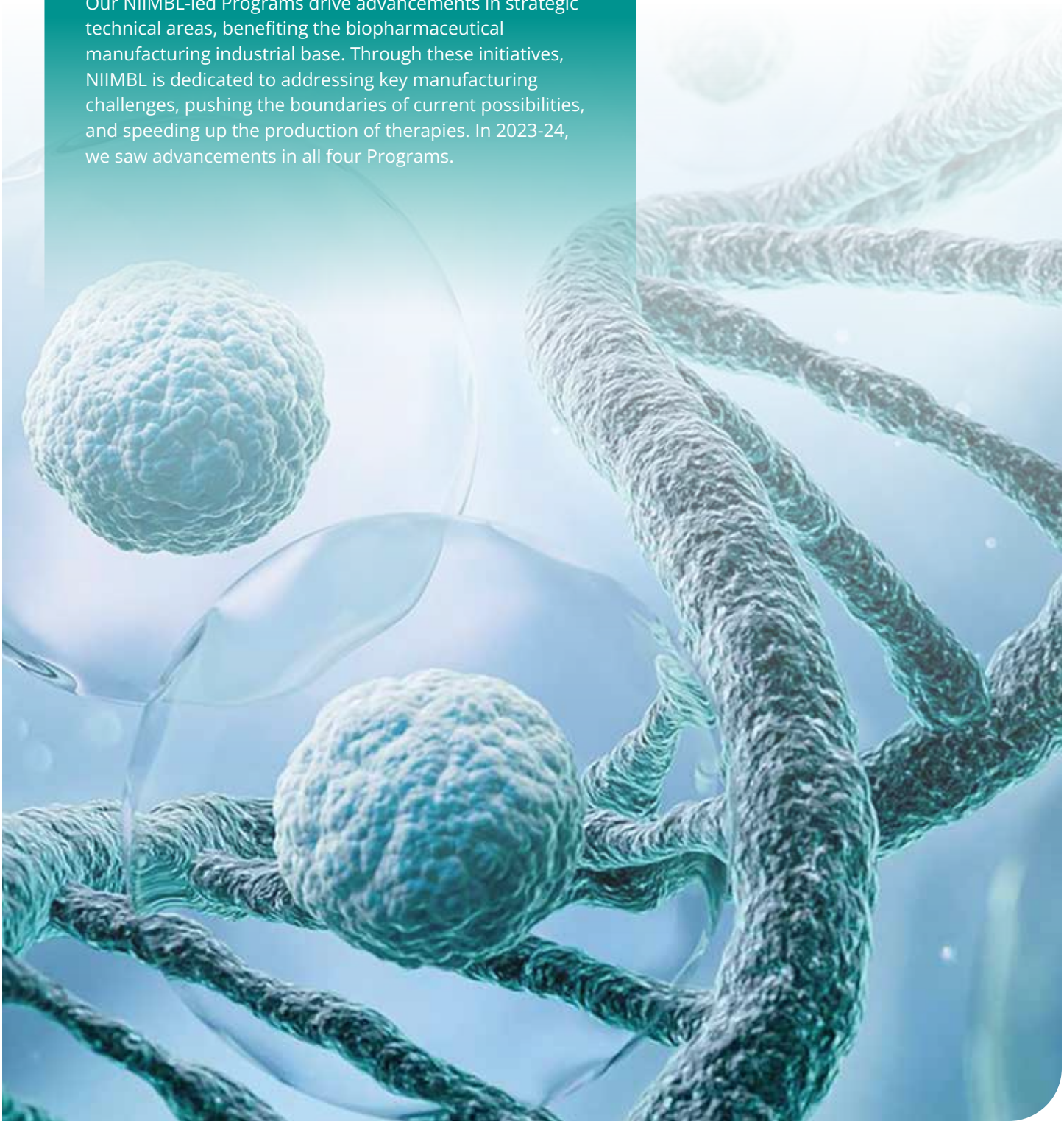
During the program, students researched a health condition, conceptualized a product to address the condition, and developed a plan to bring their product to market, factoring in audience, budget, and marketing strategies. The program gave students a comprehensive understanding of the product development cycle.

NIIMBL continues to explore opportunities to scale the program and build more industry awareness amongst high school students.

NIIMBL-led Programs

Harnessing the collective expertise of the community to transform the manufacture of biological medicines

Our NIIMBL-led Programs drive advancements in strategic technical areas, benefiting the biopharmaceutical manufacturing industrial base. Through these initiatives, NIIMBL is dedicated to addressing key manufacturing challenges, pushing the boundaries of current possibilities, and speeding up the production of therapies. In 2023-24, we saw advancements in all four Programs.



Process Intensification Program

NIIMBL's Process Intensification Program is an ambitious 10-year collaborative program designed to invent, design, demonstrate, and support commercialization of biopharmaceutical manufacturing technology to advance U.S. competitiveness. The Program aims to:

- Improve control, robustness, and security of supply
- Reduce capital and operating costs
- Build flexibility to supply diverse and changing product portfolios
- Enable faster development and supply chain velocity with sustainable raw materials components and energy use

The Program is organized into workstreams focused on control strategy, equipment flexibility, next-generation technology, sustainability, and a physical test bed to evaluate and demonstrate technologies. NIIMBL's collaborative process intensification efforts leveraged the contributions of 16 companies, including 105 world-class subject matter experts.

In 2023-24, the Program achieved several key milestones. The team commissioned the test bed facility and equipment to demonstrate fully continuous processing. The flexibility workstream showed the reconfigurability of software used in the biomanufacturing process. The team published six User Requirement Specifications for a variety of systems including a Tangential Flow Filtration System, Single Use Bioreactor Systems for Perfusion Cell Cultures, and a 3 Column Continuous Chromatography System. With an eye toward the industry's future, the Program finalized designs for a next-generation biopharmaceutical manufacturing facility with plans to publish the design in the coming year.

Future activities for the Process Intensification Program include:

- Evaluating new technologies through the test bed
- Publishing next-generation facility designs, a standardized generic process for technology transfer, and business process maps that highlight key opportunities for innovation in digital workflows
- Releasing sustainability models and providing training on their use

Big Data Program

Biopharmaceutical advances across research, technology, and manufacturing create increasingly large and complex data sets and the need for tools and systems that can use this data to optimize productivity, reduce costs, and realize novel therapeutic possibilities. NIIMBL's Big Data Program addresses this need in biopharmaceutical manufacturing through development of data-driven innovations and standards.

In 2023-2024, the Program engaged over a dozen organizations to advance projects in multiple workstreams for data creation, transformation, storage, prediction and control. As a highlight, the Program took a big step to broaden industry adoption of its ontologies through a partnership agreement with the Open Applications Group (OAGi) to transfer its ontologies to the OAGi's Industrial Ontologies Foundry (IOF) open-source platform. This partnership will support the maturation of the Program's biopharmaceutical manufacturing ontology and position it for more widespread applicability and adoption.

Additional accomplishments included advances to the Program's data-driven adaptive control initiative:

- Development of glycosylation assays and analytical platforms for in-line testing (pictured on next page)
- Characterization of the NIIMBL cell-line and media for glycosylation sensitivity
- Development of hybrid glycosylation models for model predictive control
- Completion of the North Carolina State University/ Biomanufacturing Training and Education Center laboratory-scale testbed
- Process Technology Transfer to the testbed for adaptive control demonstrations

As part of the program's Modeling and Simulation initiative, the Big Data program advanced several hybrid models for mammalian cell culture[1,2], depth-filtration harvest, and protein-A chromatography.

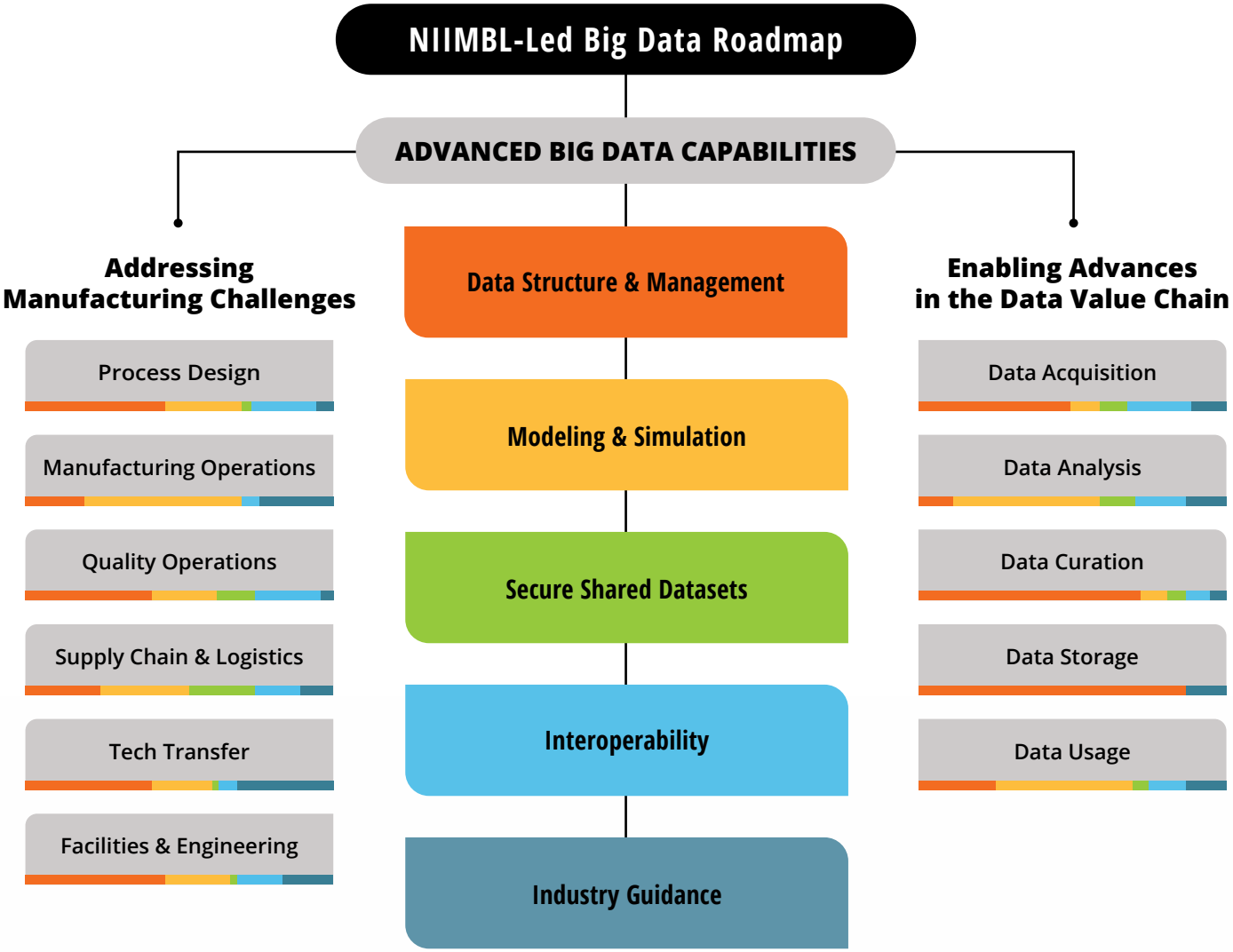
The Program team also analyzed data generated from a two-day roadmapping workshop to identify key capabilities to align future efforts and outcomes with the Program's mission.

Future activities for the Big Data Program include:

- Publishing the Big Data Roadmap for broad awareness
- Re-envisioning the program structure and implement projects to advance the Roadmap
- Demonstrating the adaptive control tools in the Big Data created NCSU/BTEC testbed

[1]Seber, P. & Braatz, R. D. (2024). Recurrent neural network-based prediction of O-GlcNAcylation sites in mammalian proteins. *Computers & Chemical Engineering*,189. https://doi.org/10.1016/j.compchemeng.2024.108818.

[2]Seber, P. & Braatz, R. D. (2025). Linear and neural network models for predicting N-glycosylation in Chinese Hamster Ovary cells based on B4GALT levels. *Computers & Chemical Engineering*, 194. https://doi.org/10.1016/j.compchemeng.2024.108937.



A graphical overview of the Big Data roadmap currently in development

Viral Vector Manufacturing and Analytics Program

Gene therapies use viral vectors to deliver the genetic material into the patient's cells.

In October 2023, we launched our Viral Vector Manufacturing and Analytics Program focused on improving the manufacturing process and analytical capabilities for adeno-associated virus (AAV) vectors, a prevalent vector platform used in the biopharmaceutical industry. The Program's goal is to develop a robust, cost-effective, shared-access platform for manufacturing and characterizing AAV vectors. This platform will support a gene therapy industry with access to high quality viral vectors without significant cost or speed limitations.

After the Program's launch, Program leadership worked closely with members to form a steering committee as well as identify participants and priority focus areas. The Program established two primary workstreams: Process and Analytics.

In April 2024, we hosted a two-day face-to-face meeting in Baltimore, Maryland, to shape the Program's direction in ways that would increase the value to the rare disease community. The meeting facilitated strategic planning discussions to ensure alignment with the Program's long-term objectives. In addition, the NIIMBL team visited member companies and academic institutions to gain a better understanding of the current AAV vector manufacturing capabilities. As a result, the Program identified subteams with interests and expertise in particular areas.

The Viral Vector Manufacturing and Analytics Program includes contributions from 22 organizations across NIIMBL membership. A phased approach aims to advance the Program's impact on the rare disease community through continuous platform improvement and innovative project development.

Future objectives for the Program include:

- Delivering a publicly shared baseline process and analytics package
- Developing and enhancing the NIIMBL platform for AAV vector production
- Driving future technology innovation

Preventive Medical Countermeasures and Analytical Characterization Program

Approved preventive countermeasures (PCMs) have succeeded in eliminating diseases and currently prevent millions of deaths each year. Yet, manufacturing and supply constraints limit the scale-up needed to provide access and meet increasing demand in the face of recent and future global health scares.

The goal of NIIMBL's Preventive Medical Countermeasures and Analytical Characterization Program is to accelerate the production of safe and efficacious PCMs through new analytical methods—examining critical quality attributes and properties of a PCM to ensure consistent quality, safety, and potency for its intended use—and new manufacturing technologies. The Program seeks to address technology sharing and workforce challenges, ease transfer between manufacturing sites, reduce batch release times, and enable introduction of more productive, robust, and lower-cost manufacturing processes.

Launched in late 2023, the Program took significant steps this year to establish a strong cohort of invested partners from across the industry, creating a framework for the program and collaborating with members and federal partners. The Program held a successful face-to-face kick-off meeting with NIIMBL membership and federal stakeholders in October 2023 and established an industry-led Preventive Medical Countermeasures Manufacturing and Analytical Characterization Steering Committee with monthly meetings that began in December 2023. The Program opened and staffed a Vaccine Analytics Center of Excellence (VACoE) laboratory and focused the Program's first workstream on achieving Program goals and building upon the prior work with support from NIST and the Gates Foundation. This workstream focuses on developing a messenger ribonucleic acid/lipid nanoparticle (mRNA/LNP) "common working material" and better analytical characterization methods, enabling with an eye on future workstreams focused on stabilization methods for mRNA-LNP based products. A recent review publication in *Biotechnology and Bioengineering*, "Vaccine process technology—a decade of progress," led by NIIMBL's executive director, shares the current state of vaccine manufacturing underpinning the motivations and direction of the Program.[1]

Future activities for the Program include:

- Defining goals, objectives, key performance indicators, and other metrics to guide and evaluate Program efforts
- Creating work packages and project plans to achieve initial Program workstream goals
- Exploring additional workstreams and populate with subject matter experts from participating organizations to drive Program progress
- Initiating and executing an initial "quick-start project" for the VACoE to establish impact and visibility for this new program

[1] Buckland, B., Sanyal, G., Ranheim, T., Pollard, D., Searles, J. A., Behrens, S., Pluschkell, S., Josefsberg, J., & Roberts, C. J. (2024). Vaccines process technology—A decade of progress. *Biotechnology and Bioengineering, 2604*. https://doi.org/10.1002/bit.28703

Project Highlights

Project Highlight

Improving Vector Production for Gene Therapy

Multifunctional Microfluidic Chip for Rapid Vector Genome and Empty Capsid Quantification in AAV Vector Production

North Carolina State University
Raleigh, NC

Type
Academic Research Institution

Participating Organizations
Merck & Co., Inc., MilliporeSigma

Industry Need

Adena-associated virus (AAV) vectors are the leading platform for gene delivery in emerging gene therapy treatment of a variety of human diseases. However, these vectors often deliver high rates of empty capsids that bring no therapeutic value as well as the potential for adverse effects.

Solution

Instead of the traditional nucleic acid test for quantification, with its temperature requirement, North Carolina State University and its partners Merck & Co., Inc. and MilliporeSigma designed a CRISPR gene editing system to be a biosensor that can run under mild conditions (e.g. 37 degrees Celsius) and target the AAV genomes to detect the genomic materials. Combining their technology with a spinoff partnership that has developed an immuno sandwich assay to detect the total particles, both readings can be determined on the same chip to deliver the empty to full ratio. With a smartphone-based optical reader device into which the chip slide can be inserted to capture an image on your phone, the team created a prototype of a complete quantification system.

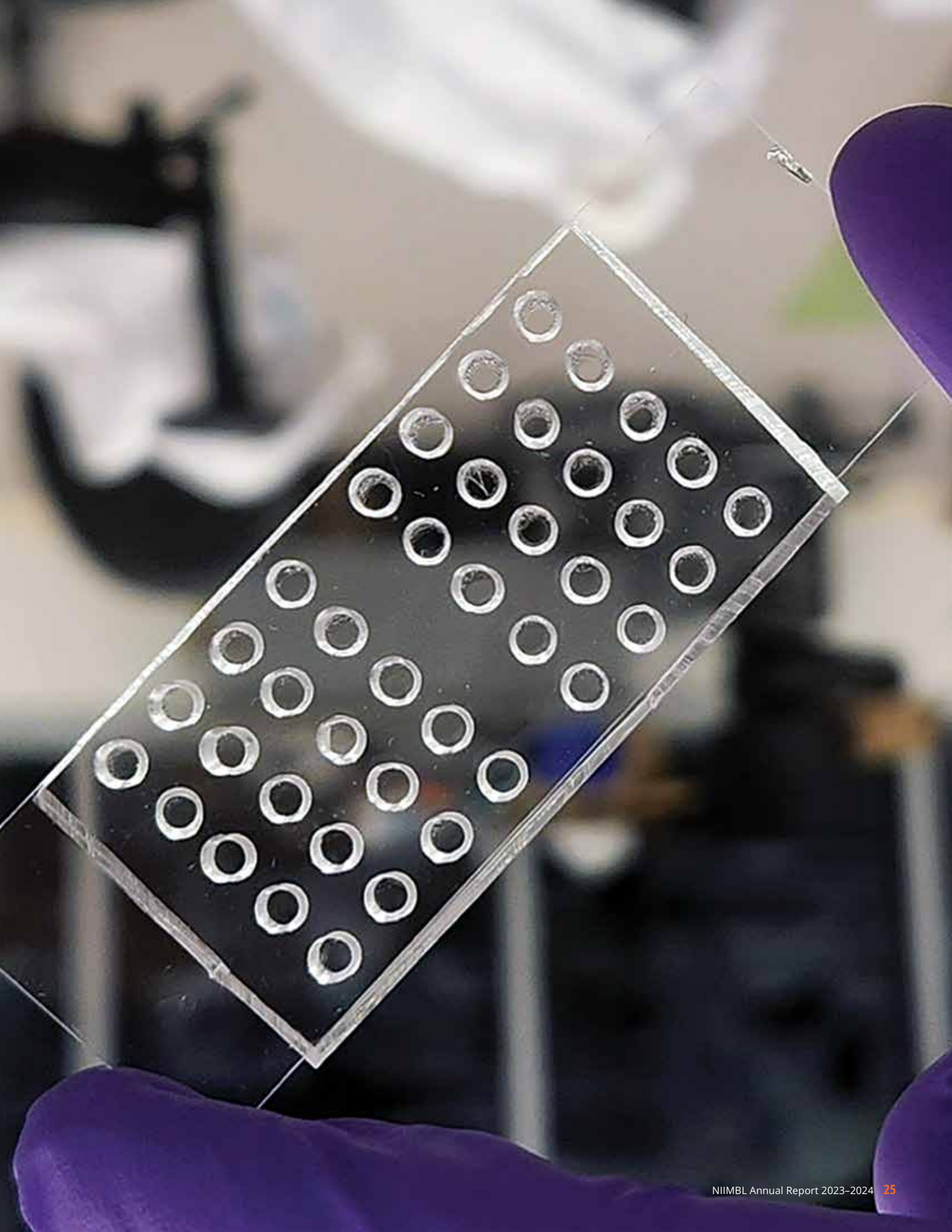
Through NIIMBL, I presented my project and several companies reached out. Without NIIMBL, you can't imagine the amount of work through email and phone calls saying I have this technology you'll be interested in. NIIMBL offers great opportunities for partnerships and collaboration."

Qingshan Wei,
North Carolina State University

Outcome

The team's chip-based rapid test allows for quantification at the bioreactor site, delivering accurate readings of both the copy of the genomes and the copy of the AAV capsids at significantly lower cost and within 30 minutes rather than several days, advancing much closer to the goal of real-time quantification and leading application of CRISPR technology in the new area of biomanufacturing analytics.

This project was developed with an award from the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) and financial assistance from the U.S. Department of Commerce, National Institute of Standards and Technology (70NANB17H002).



Project Highlight

Exploring Efficient Freeze-Drying Solutions for Biopharmaceutical Products

Tunable RF Microwave Drying of Biologics

Purdue University
West Lafayette, IN

Type
Academic Research Institution

Participating Organizations
IMA Life North America, Inc.,
Merck & Co., Inc.

Industry Need

Biopharmaceutical products are often stored in freeze-dried (lyophilized) presentations due to improved stability, shipping, and faster timelines in early clinical development. The current lyophilization technology is capital and energy-intensive, due to the use of indirect, conductive heat exchange. The heat removal and input in freezing, primary drying, and secondary drying are via contact between the product and shelves cooled or heated by a circulating working fluid such as silicone oil. This is slow, inefficient, and leads to non-uniform freezing and drying, especially in large-scale production systems.

Solution

The team developed a tunable RF/Microwave lyophilization technology application for biopharmaceutical manufacturing, integrating microwaves into freeze drying. This method uses solid-state electromagnetic sources with variable frequency for optimizing power absorption by the frozen and liquid phases. It applies statistical electromagnetics theory and electromechanical actuators to provide average power distribution that is uniform to a specified standard deviation within product volume and complex geometries.

Working with NIIMBL was a really, really rare opportunity to work very closely with industry in a very aligned way."

Alina Aleexenko,
Purdue University

Outcome

With the support of NIIMBL's strong project management structure the team of computer scientists, pharmacists, engineers, and manufacturers was able to concentrate its efforts on efficient development of its cage-like prototype into an adaptable, controllable, and commercializable lyophilization technology that has the potential for addressing pharmaceutical needs beyond freeze drying. Operating at a 6x higher frequency than any other microwave-based freezing system, this lyophilization method offers superior uniformity and increases heating efficiency by an order of magnitude. The system cuts drying time in half and creates increased throughput. Because heat can be moved in and out of the product anywhere in the chamber, this technology facilitates drying greater volumes and eases the process for a variety of products such as vials or syringes that now no longer need to be shelved. RF/Microwave lyophilization can be retrofitted to existing equipment, lowering barrier to entry, and is highly compatible with new and emerging technologies. Heating electromagnetically rather than by fluid flow, this system can be autopiloted and improve controllability in lyophilization. As a result of the project, LyoWave, Inc. was formed to commercialize the technology.

This project was developed with an award from the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL).

Project Highlight

Strengthening Biopharma Industry Talent Pipelines

Promoting Careers in Biopharmaceutical Manufacturing Operations to High School Students

North Carolina Biotechnology Center
Durham, NC

Type
Nonprofit Organization

Participating Organizations
Pfizer, Merck & Co., Inc., NC BioNetwork, and Pitt Community College

Industry Need

Raising awareness of the biopharmaceutical industry, on a national and regional level, is critical both for introducing the range of career opportunities available to students in biopharmaceutical manufacturing and for meeting the growing need for a skilled workforce in this industry. Despite proximity to the largest research park in the United States, many North Carolina high school students are unable to name even a handful of the hundreds of biotechnology companies, government agencies, academic institutions, startups and nonprofits in their state.

Solution

North Carolina Biotechnology Center and its partners Pfizer, Merck & Co., Inc., NC BioNetwork, and Pitt Community College created My Future in Biotech, a classroom presentation designed to engage high school students in careers in biopharmaceutical manufacturing. Through a simple 50-minute platform of a video, slides, hands-on demonstrations, next steps, and a leader's manual, the team established an easy-to-implement, fun means to raise awareness and pique student interest in rewarding careers available in their state.

Our goal was to engage and empower high school students to pursue life sciences careers. In addition to meeting the hiring needs of a growing industry, 'My Future in Biotech' aims to connect more North Carolinians with fulfilling and family sustaining careers that make an impact on patients around the world."

Laura Rowley,
North Carolina Biotechnology Center

Outcome

Reaching 371 students in the pilot implementation, a program now exists for teachers to educate students on career pathways in biotech. Pilot participants reported increased understanding of the industry and improved confidence to successfully pursue a biomanufacturing career. 57.6% of student survey respondents reported that the program made them feel like a career in biomanufacturing was something they could do. The program helps to expand biopharmaceutical manufacturing talent pipelines by building industry awareness and interest amongst high school students.

This project was developed with an award from the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) and financial assistance from the U.S. Department of Commerce, National Institute of Standards and Technology (70NANB21H086).

Project Highlight

Improving Decontamination Technologies for Public Spaces

Evaluation of an Automated Vapor-Phase Hydrogen Peroxide Decontamination System for Rapid, Non-Residual Decontamination of Clinical Spaces

SentrySciences, Inc.
Longmont, CO

Type
Small- and Medium-sized Manufacturer

Industry Need

When the COVID-19 pandemic occurred, there was no efficient way to sanitize public spaces. Clinical settings encountered lengthy, labor-intensive decontamination practices, which contributed to hospitals and ambulances being unable to keep up with patient demand. During initial phases of a pandemic, when healthcare resources are strained, having effective methods for rapidly and safely decontaminating exposed facilities in clinics, hospitals, and inpatient transport vehicles is critical for preventing the spread of infection and disease.

Solution

Mark Berdovich of SentrySciences, Inc. teamed up with a manufacturer of Vapor-Phase Hydrogen Peroxide (VPHP) generation equipment to adapt VPHP decontamination methods to clinical settings. Used for highly controlled manufacturing environments in which injectable pharmaceuticals are filled and sealed, sterilization in gas form presents a relatively safe method that does no harm to surfaces, building materials, computers, electronics, or plants. Researchers investigated this new technology, employing both mechanical ventilation and a catalyst to break down the hydrogen peroxide vapor into water and oxygen and determine optimum cycle parameters for decontaminating public spaces quickly and safely.

> **The win is that somebody presses a button when they leave at the end of the day and when somebody reopens the door the next morning, they can walk in without a PPE or respirator and be assured that the environment itself has been decontaminated to whatever level they want to achieve."**
>
> **Mark Berdovich,**
> SentrySciences, Inc.

Outcome

The project advanced the qualification of an automated, rapid, and recipe-driven Vapor-Phase Hydrogen Peroxide (V-PHP, VHP) decontamination method for clinical spaces that even an individual with minimal training can deploy. This technology demonstrated a consistent, rapid, 100% kill cycle for up to 1 million spore level in spaces containing only hard, non-porous surfaces, proving reliable and safe for clinical environments. This new decontamination method offers increased efficiency for ensuring public safety, especially during a pandemic, in settings such as hospital isolation rooms, patient transport vehicles, or exam rooms in a doctor's office or local retail pharmacy – spaces that may be nearly-continuously occupied by potentially sick individuals during a pandemic.

This work was performed under a Project Award Agreement from the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) and financial assistance award 70NANB21H085 from the U.S. Department of Commerce, National Institute of Standards and Technology.

Project Highlight

Developing more efficient purification of Virus-like Particles (VLPs) for prophylactic countermeasures

Affinity Precipitation Purification of Virus-Like Particles

University of Delaware
Newark, DE

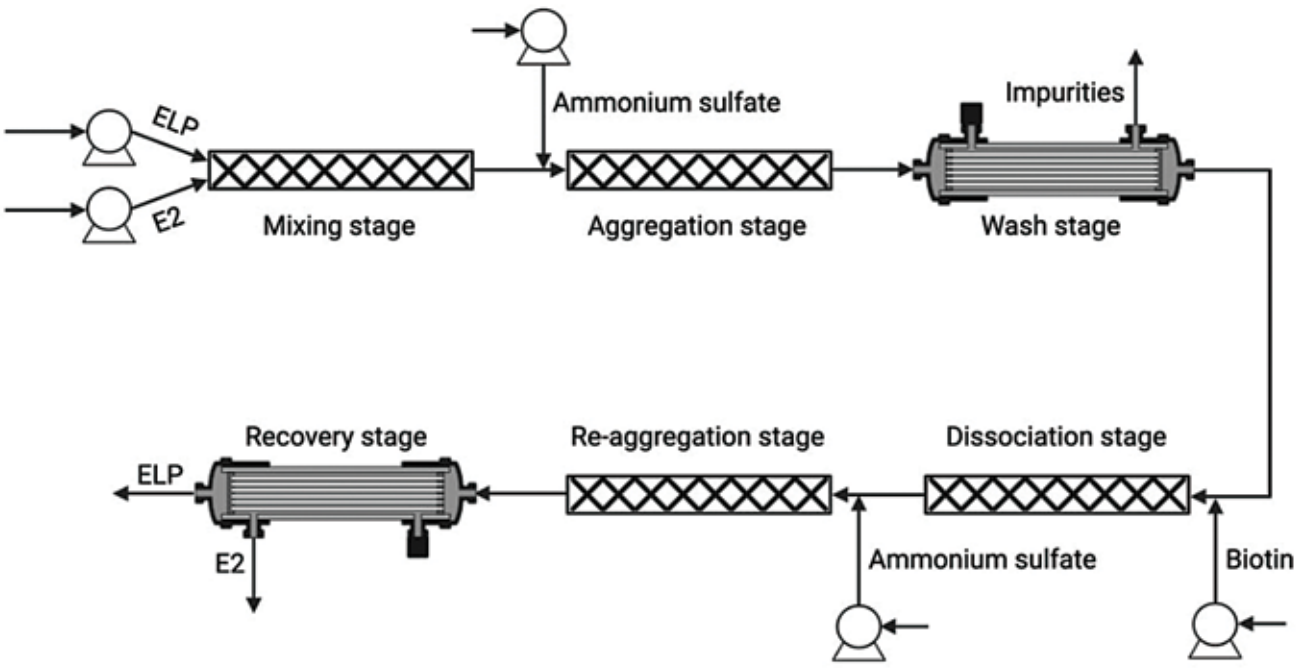
Type
Academic Research Organization

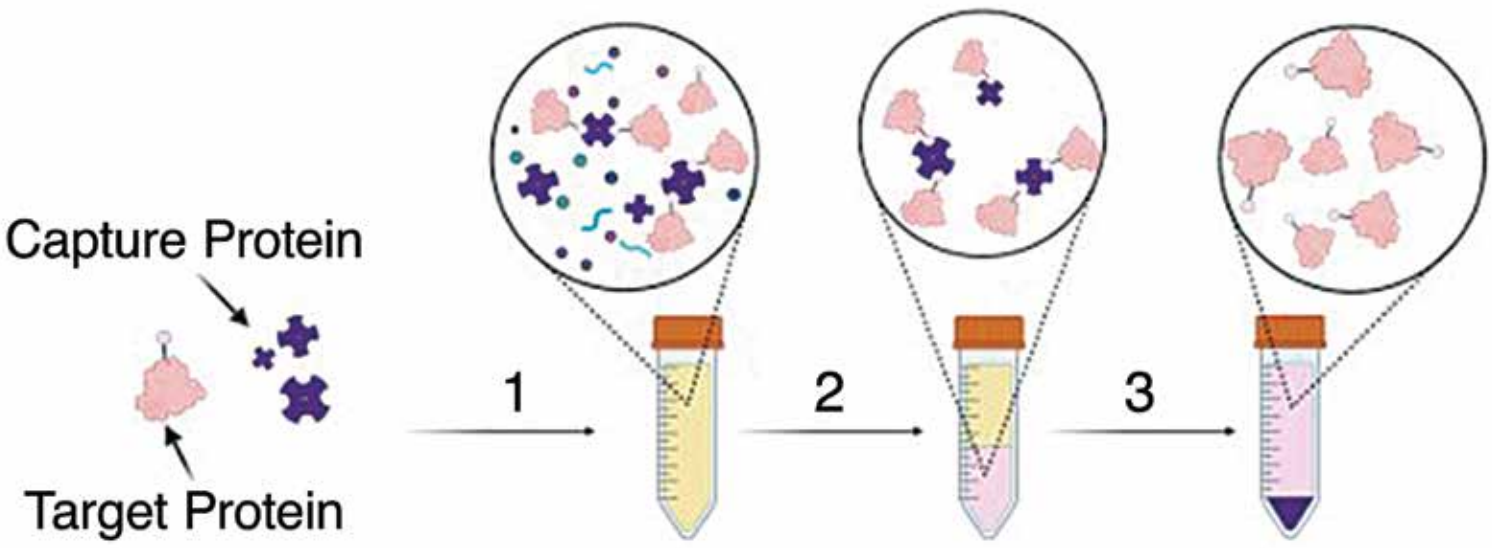
Industry Need

VLPs are widely used in gene therapy as a medical countermeasure and vector to deliver therapeutic genes. VLPs are large and complex moieties that can be expensive and inefficient to manufacture (yields below 50%), requiring significant scale-up to produce enough VLP suitable for patients. Chromotography does not work as well for purification with these viruses or virus-like particles, because their large size prevents them from entering the particle, thus limiting surface area. Alternatives are needed to find cost-effective means for manufacturing VLPs in order to harness their potential for life-advancing therapeutic treatments.

Solution

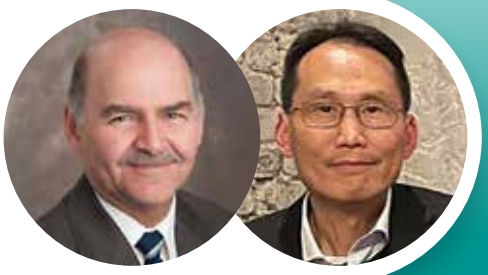
In this project, Dr. Bramie Lenhoff and Dr. Wilfred Chen developed a precipitation process for selective, non-chromatographic separation of viruses and VLPs. Through affinity precipitation, the product is driven to associate with itself in the liquid through a ligand that binds to the target rather than to solid particles, thus forming large clusters that are insoluble and allowing the impurities to be removed with the solvent. The insoluble clusters are then broken up with the addition of a reagent and the target is recovered so the ligand can be reused.





We experienced first-hand the difficulty of making these virus-like particles, but fortunately, by working on this project and with NIST, we were able to demonstrate this new more efficient concept."

Abraham Lenhoff (quoted) and Wilfred Chen,
University of Delaware



Outcome

Through the design and synthesis of the whole molecular machinery for this affinity precipitation on virus like particles, the team has demonstrated the full capture and recovery cycle. This non-chromatographic alternative combines the high selectivity of a chromatography-like affinity system with the operational benefits of working entirely within liquids. Purification is simplified and the capture ligand can be reused for additional VLP purification. Achieving 90% plus recovery of the VLP produced in the original cell culture, this method provides a two fold improvement in yields. The team then developed a proof of principle for using this method as a continuous process for potential use in actual manufacturing and eventual large scale up.

This work was performed under a Project Award Agreement from the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) and financial assistance award 70NANB21H085 from the U.S. Department of Commerce, National Institute of Standards and Technology.

Membership

Members & Partners

July 1, 2023 – June 30, 2024

Industry

4th Phase Technologies, Inc.
908 Devices, Inc.
ABL
Accugenomics Inc
Advanced Materials Technology
Agilent
Aicella, Inc.
Alphinity
Amgen Inc.
Andelyn Biosciences, Inc.
Applied Control Engineering, Inc.
Asahi Kasei Bioprocess America
AstraZeneca
Ballydel Technologies, Inc.
Batavia Biosciences Inc
BioCentriq, Inc.
BioCurie, Inc.
Bio-Rad Laboratories, Inc.
Biostealth Inc.
BioTechnique
Black Mesa
Bristol-Myers Squibb
Boehringer Ingelheim
Calidi Biotherapeutics
CellFE, Inc.
Century Therapeutics
ChromaTan Corporation
Commissioning Agents Inc.
CompassRed, Inc.
Crown Point Technologies, LLC
CSL Behring, LLC
Cytiva
Denali Therapeutics
Dyadic International Inc
Dynamk Capital
Eclipse Bioinnovations, Inc.
Eli Lilly and Company
Emerson Automation Solutions
Endress + Hauser Optical Analysis
Enquyst Technologies Inc
Entanglement Technologies, Inc.
Enzene Biosciences Limited
Extrave Bioscience, LLC
Gate Scientific, Inc.
GeneFab
Genentech
GlaxoSmithKline, LLC
ILC Dover LP
IMA Life North America Inc.
InDevR, Inc.
IPS-Integrated Project Services, LLC
Isolere
Janssen Research & Development, LLC
Just - Evotec Biologics
Landmark Bio
LigaTrap Technologies, LLC.
Lindy Biosciences, Inc.
Lonza Biologics, Inc.
LumaCyte
Lyowave
M Davis & Sons Inc
Mango Inc.
Matterworks, Inc.
Merck Sharp & Dohme LLC
Metalytics
MilliporeSigma/EMD Serono
MTI BioScience, LLC
Nature's Toolbox Inc. (Ntx)
Nirrin Technologies, Inc.
Novilytic LLC
Nuclera
Oklahoma City Innovation District
OUAT!
PAK Biosolutions
Pfizer, Inc.
Phizzle, Inc.
Physical Sciences Inc
Protein Capture Science LLC
Quality Executive Partners, Inc.
Redbud Labs Inc
RedShift BioAnalytics
Refeyn Inc.
Resilience US
Sanofi
Sartorius Stedim
Scientific Bioprocessing
SentrySciences LLC
Sepax Technologies Inc
Sepragen Corporation
SP Industries
Spark Therapeutics, Inc.
Takeda Pharmaceuticals
Univercells Technologies, S.A.
Uvax Bio LLC
VaxForm LLC
Vericel Corporation
Vir Biotechnology, Inc.
Virica Biotech Inc.
Waters Technologies Corporation
WaveGuide Corporation
Xcellerate Biotech Inc.
Yokogawa Corporation Of America

Academic Institutions and Non-profits

AABB Association for the Advancement of Blood & Biotherapies
AIChE
Alamance Community College
Albany College of Pharmacy and Health Sciences
Alliance for Regenerative Medicine
American Type Culture Collection (ATCC)
Austin Community College
Beckman Research Institute of the City of Hope
BioBAT, Inc.
Biocom California
BioNTX
Bioscience Core Skills Institute (BCSI)
BioSTL
Biotility
California Polytechnic State University
Campbell University
Cape Fear Community College
Caring Cross, Inc.
Carnegie Mellon University
CASSS
Cecil College
Cedars-Sinai Biomanufacturing Center
Center for Global Health Innovation
Central Carolina Community College
Clemson University
Delaware BioScience Association
Delaware Prosperity Partnership
Delaware State University
Delaware Technical Community College
Delaware Valley Industrial Resource Center
Developing Countries Vaccine
Durham Technical Community College
Felician University Manufacturers Network
Forsyth Technical Community College
Fraunhofer USA
Frederick Community College
Gaston College
Gates Medical Research Institute
Georgia Tech Research Corporation
Hudson Valley Community College
International Academy of Automation Engineering
Joan & Sanford I. Weill Medical College of Cornell University
Johns Hopkins University
Johnston Community College
Kansas Bioscience Organization
Keck Graduate Institute
Life Sciences Pennsylvania
Life Science Washington
Maryland Tech Council
Massachusetts Bay Community College
Massachusetts Biomedical Initiative

Massachusetts Institute of Technology

Massachusetts Life Sciences Center

MassBio Education Foundation

MiraCosta College

Missouri University of Science and Technology

Montgomery College

Montgomery County Community College

Montgomery County Economic Development Corporation

National Institute for Pharmaceutical Technology and Education, Inc (NIPTE)

New Jersey Manufacturing Extension Partnership

New York Blood Center, Inc.

New York State Department of Health (Wadsworth Center)

North Carolina Biosciences Organization

North Carolina Biotechnology Center

North Carolina Central University

North Carolina Community Colleges Systems BioNetwork

North Carolina State University

Northeastern University

Oklahoma State University - Oklahoma City

Open Applications Group, Inc.

Open Biopharma Research and Training Institute

Oregon Bioscience Association

PATH Center for Vaccines Innovation & Access

Pennsylvania Biotechnology Center - B+labs

Pitt Community College

Project Lead The Way

Puerto Rico Science Technology and Research Trust

Purdue University

Quincy College

Raritan Valley Community College

Regents of the University of Colorado (Boulder)

Rensselaer Polytechnic Institute

Research Corporation Technologies Inc

Rutgers, The State University of New Jersey

Rx Research Services Foundation

San Jacinto College District

Santa Clara University

Shoreline Community College

Solano College

Southwest Research Institute

Standards Coordinating Body

Stevens Institute of Technology

Texas A&M University System

The Ohio State University

The Pennsylvania State University

The Research Foundation for the State University of New York, on behalf of State University of New York Polytechnic Institute

The Wistar Institute

Thomas Jefferson University

United States Pharmacopeial Convention

University City Science Center

University of Albany

University of California, Davis

University of California, Los Angeles

University of Colorado Denver | Anschutz Medical Campus

University of Delaware

University of Florida

University of Georgia Research Foundation

University of Houston

University of Louisiana at Lafayette

University of Maryland

University of Maryland, Baltimore County

University of Massachusetts System

University of North Carolina, Chapel Hill

University of Pennsylvania

University of Virginia

Vance-Granville Community College

Virginia State University

Wake Technical Community College

Washington State University

Waubonsee Community College

Worcester Polytechnic Institute

Xavier University of Louisiana

University City Science Center

Additional Partners

National Institute of Standards and Technology

Food and Drug Administration

National Institutes of Health

NIIMBL interacts with several other federal agencies and institutes.

Members & Partners

July 1, 2023 – June 30, 2024


Janssen
Lilly
Lonza
MERCK
MilliporeSigma
EMD Serono
Pfizer
RESILIENCE
SANOFI
SARTORIUS
Takeda
Waters
ForsythTech Community College
IMA Life North America
Life Science Washington
Massachusetts Institute of Technology
MTI BioScience
NIH
Fraunhofer
Isolere Bio
LigaTrap Technologies
Matterworks
ncbio the north carolina biosciences organization
NIPTE
Frederick Community College
iBio
Lindy Biosciences
MDAVIS
New York Blood Center Enterprises
NIST
Gaston College Opportunities For Life
LumaCyte
Northeastern University
GATE SCIENTIFIC
Johnson & Johnson Innovative Medicine
METALYTICS
nirrin illuminating insights
NOVILYTIC
GENEFAB
Jefferson Philadelphia University + Thomas Jefferson University
LyoWave
MANGO
North Carolina Biotechnology Center
Georgia Tech Research Corporation
JOHNS HOPKINS UNIVERSITY
MBI
MISSOURI S&T
NC BioNetwork
ntx
Hudson Valley Community College
Just EVOTEC BIOLOGICS
MARYLAND TECH COUNCIL
MONTGOMERY COLLEGE
NORTH CAROLINA CENTRAL UNIVERSITY
OAGi Open Applications Group
ILC DOVER
KGI
MASSACHUSETTS LIFE SCIENCES CENTER
Investing in the State of Innovation
NC STATE UNIVERSITY
inDevR
LANDMARK BIO
MASSBAY COMMUNITY COLLEGE
MONTGOMERY COUNTY COMMUNITY COLLEGE
nuclera
OKLAHOMA CITY INNOVATION DISTRICT
IAAE International Academy of Automation Engineering
LSPA Life Sciences Pennsylvania
MassBioEd
MONTGOMERY COUNTY ECONOMIC DEVELOPMENT CORPORATION MARYLAND
NJMEP
open biopharma training

Members & Partners

July 1, 2023 – June 30, 2024

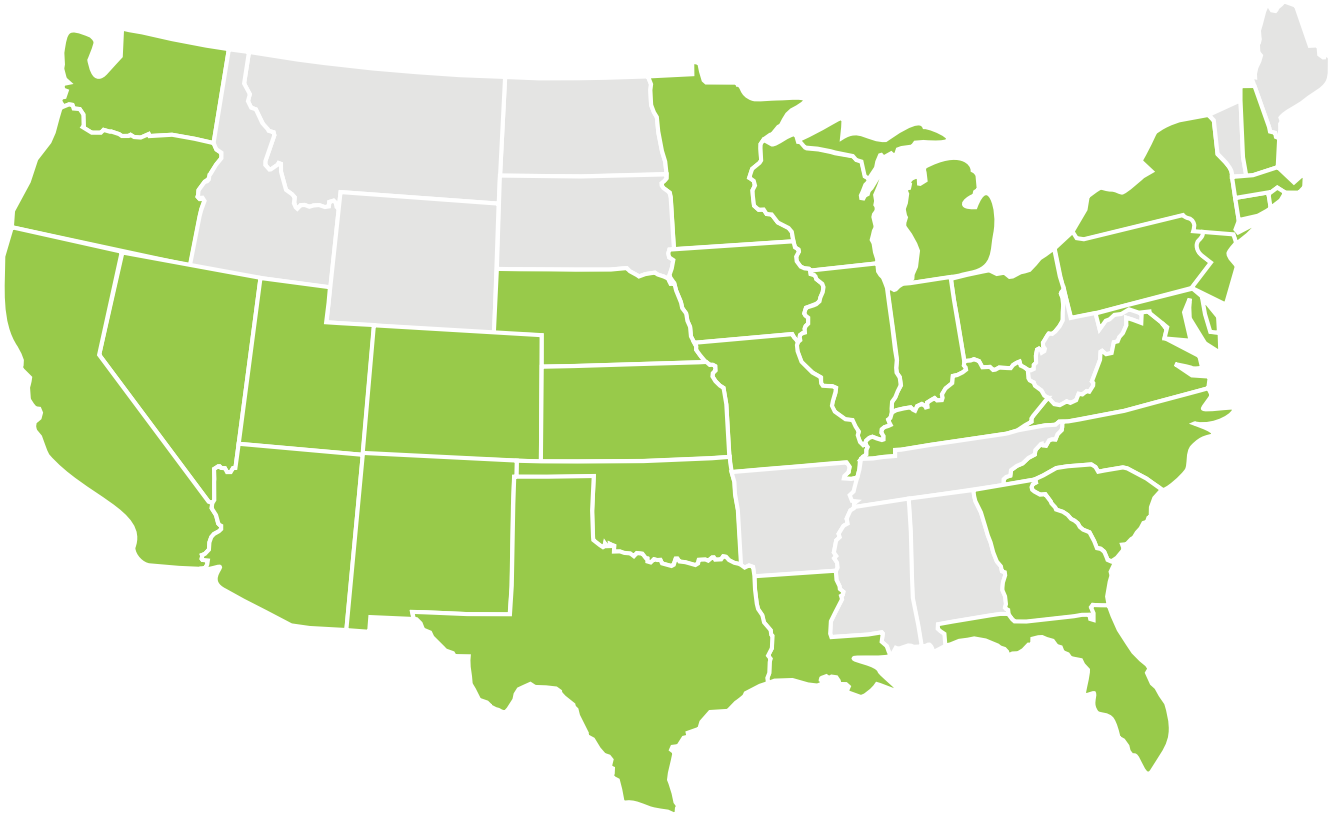
About NIIMBL

The National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) is a public-private partnership whose mission is to accelerate biopharmaceutical innovation, support the development of standards that enable more efficient and rapid manufacturing capabilities, and educate and train a world-leading biopharmaceutical manufacturing workforce, fundamentally advancing U.S. competitiveness and security. NIIMBL is part of Manufacturing USA®, a network of federally sponsored manufacturing innovation institutes, and is funded through a cooperative agreement with the National Institute of Standards and Technology (NIST) in the U.S. Department of Commerce with significant additional support from its members.

A National Network

NIIMBL's 226 members have operations throughout the U.S. and Puerto Rico

NIIMBL Membership



NIIMBL® The National Institute for Innovation in Manufacturing Biopharmaceuticals

Ammon Pinizzotto Biopharmaceutical Innovation Center
590 Avenue 1743, Newark, DE 19713

www.NIIMBL.org | info@niimbl.org | 302-831-0663

Manufacturing USA®