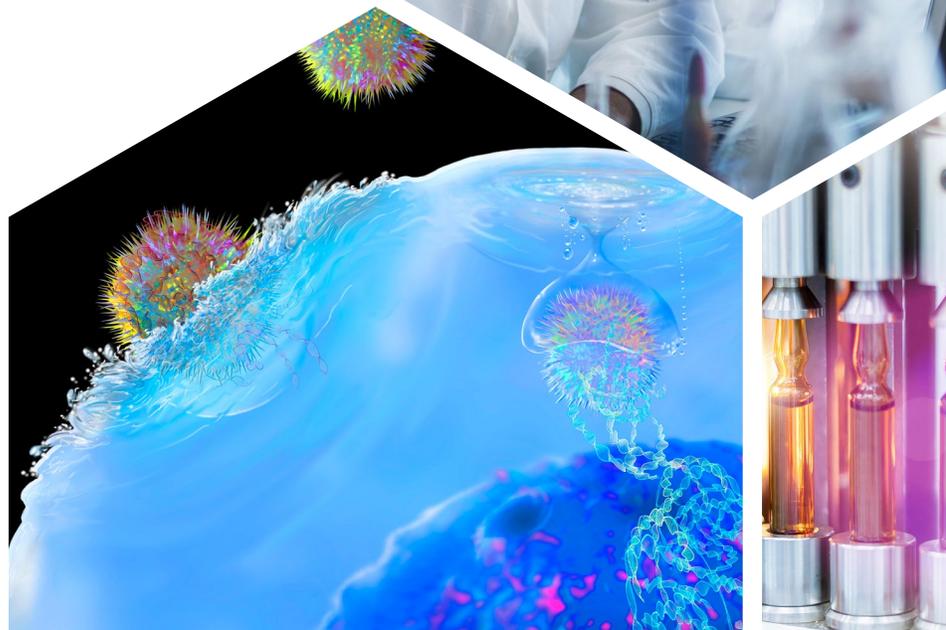
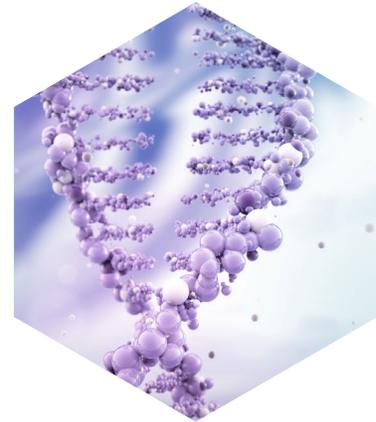


ANNUAL REPORT 2019-20

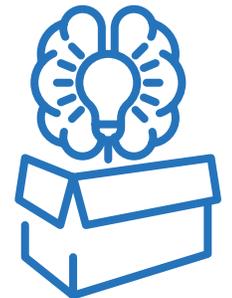


THIS ANNUAL REPORT COVERS NIIMBL ACTIVITIES FROM MARCH 1, 2019 THROUGH FEBRUARY 29, 2020



OUR MISSION

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 in this industry.



OUR 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.





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Dear Colleagues,

We are pleased to share NIIMBL's 2019-2020 Annual Report covering the period from March 2019 through February 2020. It celebrates our collective accomplishments, which reflect the commitment and engagement of diverse individuals and organizations across the biopharmaceutical manufacturing ecosystem.

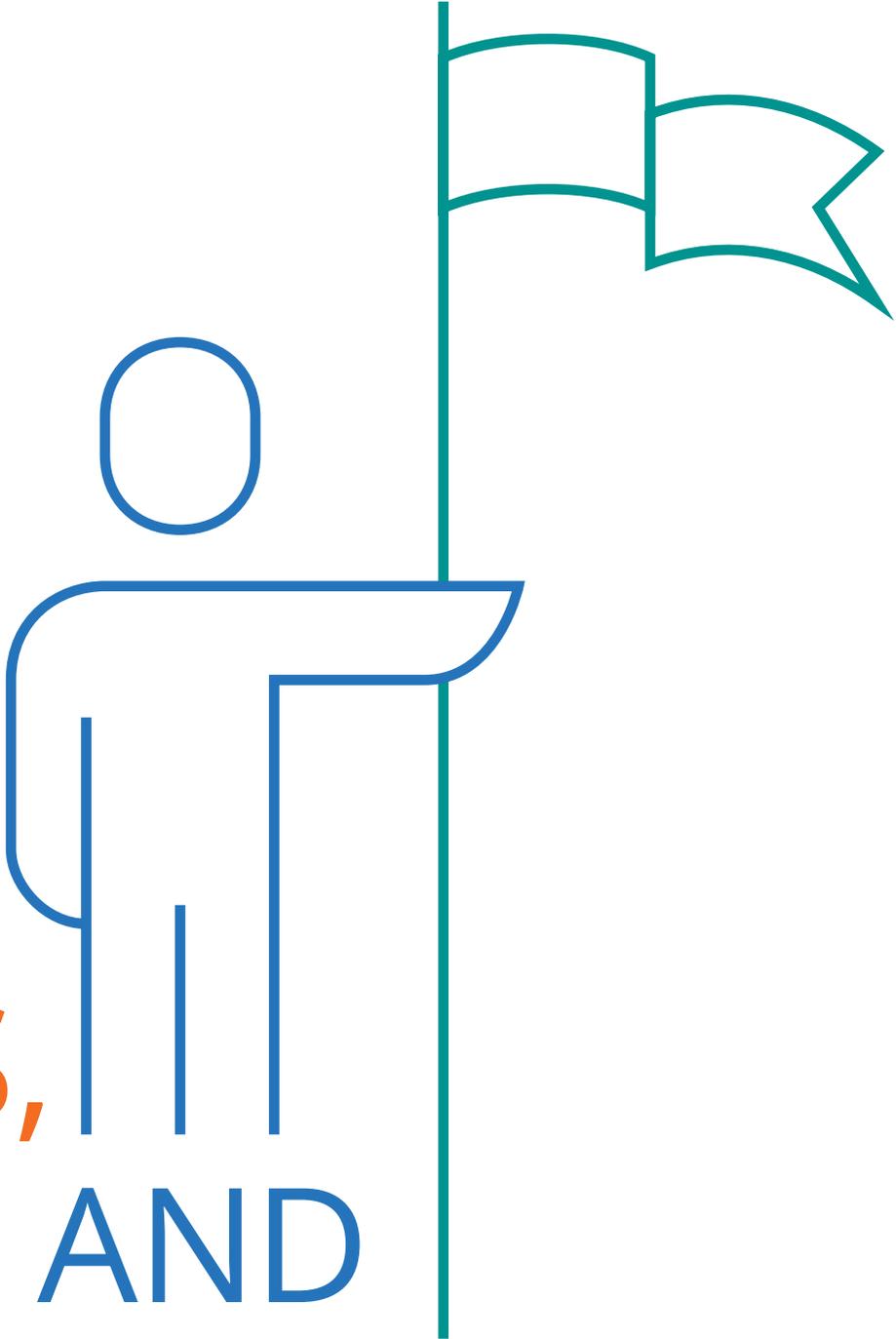
As we share and reflect on NIIMBL's many accomplishments over the last year, the world is experiencing the global crisis brought about by the rise and spread of COVID-19. Our community is responding through an unprecedented effort to accelerate the development and commercialization of medical countermeasures and vaccines, and many of our stakeholders are tirelessly working and collaborating to develop and bring these products to market as fast as possible.

Beyond these important efforts, there are critical talent development initiatives underway in response to the economic downturn. Moreover, we know individuals from our community are employing their technical expertise in new and creative ways to prevent, prepare for, and respond to pandemic related efforts.

In the face of such challenges, our diversity of perspectives, of expertise, and of experiences strengthens our ability to create and develop innovative solutions to today's problems and to prepare for tomorrow's needs.

Over the past year, we have made significant strides towards realizing this vision, and we look forward to accelerating our progress in the coming year. Thank you for your enthusiasm and engagement. We look forward to having you visit with us in our new facility in the future.

Sincerely,
The NIIMBL team



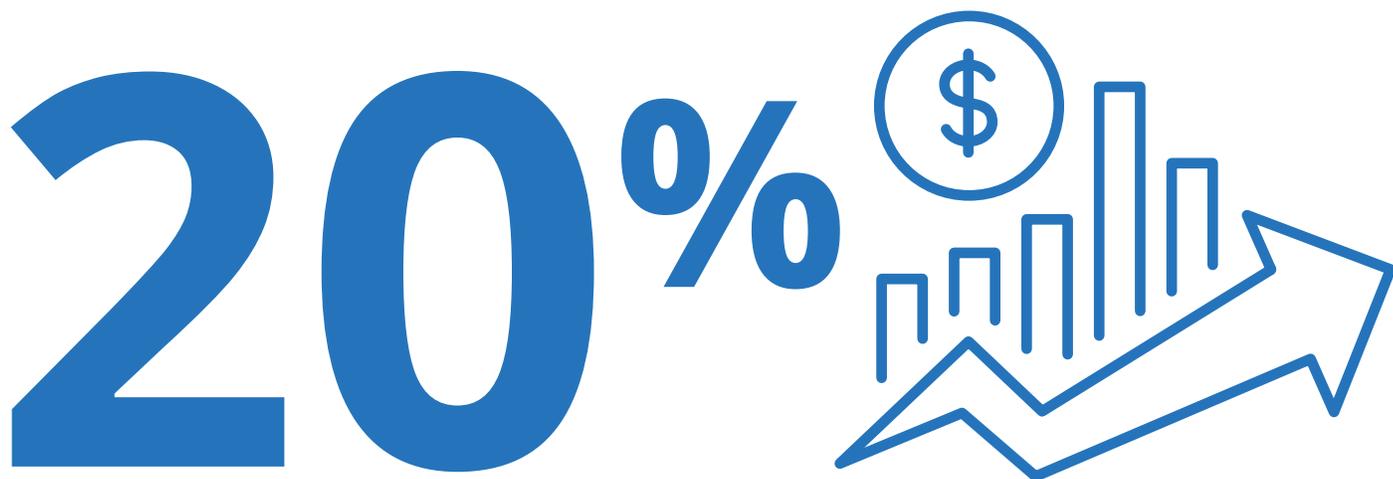
GOALS,
PLANS AND
ACCOMPLISHMENTS

INTRODUCTION

Biopharmaceutical products play a key role in improving the quality of life for people around the world by treating chronic and deadly diseases such as cancer, cardiovascular disease, and autoimmune disorders among others.

Advancing this industry by addressing and possibly solving many of its manufacturing challenges ultimately benefits the world around us.

This is the premise for The National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL).



**INCREASE IN DOLLARS INVESTED IN TECHNOLOGY AND
WORKFORCE PROJECTS SINCE MARCH 1, 2019.**

The biopharmaceutical industry is a significant driver of the U.S. economy, contributing \$1.1T in economic activity and directly or indirectly employing 4M individuals in 2017.*

Founded under the Revitalize American Manufacturing Innovation (RAMI) Act of 2014 and as one of the fourteen Manufacturing USA institutes, NIIMBL supports technology innovation and workforce development in biopharmaceutical manufacturing to strengthen U.S. leadership in this space.

This year marked a time of growth and expansion for NIIMBL. Through our collaborative efforts, we have expanded our portfolio of technology and workforce

projects, launched the Global Health Fund (GHF) to support faster, more cost-effective vaccine manufacturing technologies, and have increased and diversified our membership.

These activities support the objectives we have set as an institute including improving large-scale manufacturing capabilities for existing projects, developing new manufacturing platforms for cell and gene therapies, and funding programs and curricula to train the world's best biopharmaceutical workforce.

*Source: TEConomy Partners, LLC for the Pharmaceutical Research and Manufacturers of America (PhRMA). The Economic Impact of the U.S. Biopharmaceutical Industry: 2017 National and State Estimates, December 2019.

Tech & Workforce Projects

\$9.7M

INVESTMENT IN NEW
PROJECTS FOR 2019-20

14

NEW PROJECTS IN 2019-20



\$53.6M

ALL-TIME INVESTMENT
IN PROJECTS

58

PROJECTS LAUNCHED
SINCE 2017

LEADING BIOMANUFACTURING INNOVATION

We have continued to build our extensive and diverse project portfolio by investing approximately \$6.7M in 8 new technology innovation projects.

- NIIMBL-led initiatives such as the NIIMBL-Biophorum Buffer Stock Blending System and recently launched programs on end-to-end process intensification and big data strengthens our world-leadership of biopharmaceutical manufacturing technology innovation.
- As part of Project Call 3.1 in June 2019, we issued our first call for Global Health Fund projects in partnership with the Bill & Melinda Gates Foundation to support new technologies that will lower costs and increase speed-to-market of vaccines in the U.S. and globally.

Technology Projects

\$6.7M

NEW INVESTMENTS IN
TECHNOLOGY PROJECTS
IN 2019-20

8

NEW TECHNOLOGY
PROJECTS IN 2019-20



\$41.6M

TOTAL INVESTMENT IN
TECHNOLOGY PROJECTS SINCE
NIIMBL'S LAUNCH IN 2017

37

TOTAL TECHNOLOGY
PROJECTS SINCE NIIMBL'S
LAUNCH IN 2017

STRENGTHENING THE BIOPHARMACEUTICAL WORKFORCE

This year, we invested more than \$3M in 6 new workforce development projects including hands-on and blended learning. In addition, digital and e-learning programs were included to provide opportunities for students to build their skills in our current virtual climate.

- Our inaugural week-long NIIMBL eXperience gave five students from underrepresented communities a chance to travel to biopharmaceutical related organizations to gain a first-hand understanding of career possibilities in this industry.
- In February 2020, we launched the NIIMBL job board. As an added benefit to members, the job board provides a way for companies to post open positions within their organizations in an effort to connect with relevant talent faster.

Workforce Projects

\$3M
INVESTMENTS IN NEW
WORKFORCE PROJECTS
IN 2019-20

6

NEW WORKFORCE
PROJECTS IN 2019-20



\$12M
TOTAL INVESTMENT IN
WORKFORCE PROJECTS SINCE
NIIMBL'S LAUNCH IN 2017

21

TOTAL WORKFORCE
PROJECTS SINCE NIIMBL'S
LAUNCH IN 2017

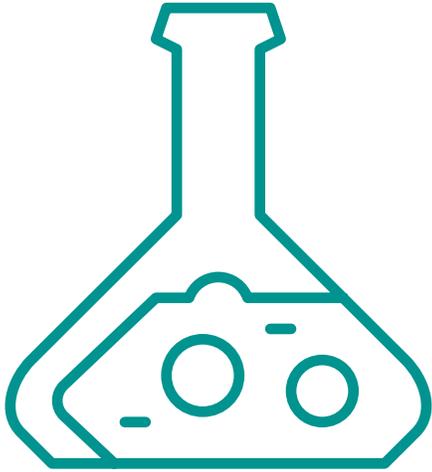
BUILDING A COLLABORATIVE CULTURE

Our membership included 155 organizations, a 37% year-over-year increase, comprising large biopharmaceutical manufacturers and suppliers, universities and community colleges, non-profits, and Small-to-Medium manufacturers (SMMs), who often bring ground-breaking technologies to the table. This year, our membership included 55 of these innovative SMMs.

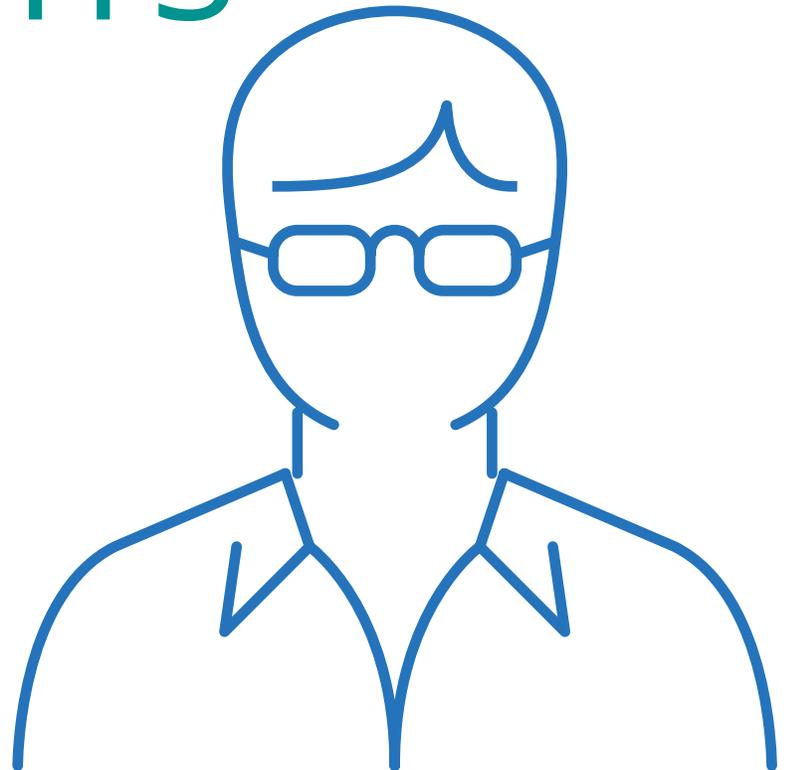
- In July 2019, the University of Delaware, on behalf of NIIMBL, entered into a Collaborative Research and Development Agreement (CRADA) with the FDA to support collaboration on advanced manufacturing technologies for biopharmaceutical products.
- In February 2020, we moved into the new Ammon Pinizzotto Biopharmaceutical Innovation Center at the University of Delaware, a state-of-the-art facility with collaborative lab space for teams to work on next-generation technologies.
- Through our National Meeting in June 2019 and various workshops, we brought together ~1,000 individuals from 302 organizations to collaborate on manufacturing solutions.
- We continued geographic diversity through our outreach efforts in 2019-20 by adding 11 new members from the West Coast.

Photo courtesy of NIIMBL





MEMBERSHIP HIGHLIGHTS



MEMBERS AND PARTNERS 2019-2020

INDUSTRY

AstraZeneca
Bristol-Myers Squibb
Eli Lilly and Company*
Genentech
GlaxoSmithKline, LLC*
Janssen Research & Development, LLC*
Merck & Co., Inc.
MilliporeSigma/EMD Serono
Pfizer, Inc.
Sartorius Stedim
908 Devices, Inc.
Accugenomics Inc.
Aerosol Therapeutics
Akron Biotechnology, LLC
Alcami Corporation
Applied Biosensors*
Applied Control Engineering, Inc.
Applied Materials, Inc.
Artemis Biosystems Inc.
Asimov*
Automated Control Concepts Inc.*
Automation Anywhere, Inc., Life Science Division*
CellFE, Inc.*
Chromatan Corporation
Commissioning Agents Inc.
CompassRed, Inc.*
Denali Therapeutics
Extrave Bioscience, LLC*
Fisher Rosemount Systems Inc.

ILC Dover LP
ImmunoGen, Inc.
Intabio
Janis Research Company
LEWA-Nikkiso America
LigaTrap Technologies, LLC.
Lindy Biosciences, Inc.
LumaCyte, LLC.
M Davis & Sons Inc.*
MacroGenics, Inc.*
Medinstil*
Metalytics
MOBILion Systems Inc*
MockV Solutions, Inc.*
NewAge Industries, Inc.
Oxford Instruments Magnetic Resonance
Physical Sciences Inc.
PMT*
Potomac Affinity Proteins
ProMechSys-RLP, LLC
Protein Metrics Inc.*
ReForm Biologics LLC
Redbud Labs Inc.
Repligen Corporation
RoosterBio Inc.
Scarab Genomics, LLC / DNASTAR*
Sepax Technologies Inc.*
SP Industries*
Spark Therapeutics, Inc.*
Sudhin Biopharma Co

Sutro Biopharma*
Univercells Technologies, S.A.*
Unum Therapeutics Inc.
Vericel Corporation
Whirlcell LLC

ACADEMIC INSTITUTIONS & NON-PROFITS

Albany College of Pharmacy and Health Sciences
Carnegie Mellon University
Clemson University
Delaware State University
East Carolina University
Florida State University
Georgia Tech Research Corporation
Gustavus Adolphus College
Johns Hopkins University
Massachusetts Institute of Technology
Missouri University of Science and Technology
North Carolina Central University
North Carolina State University
Northeastern University
Regents of University of Minnesota
Regents of the University of Colorado (Boulder)
Santa Clara University*
Texas A&M University System
The Pennsylvania State University
The Research Foundation for the State University of New York, on behalf of State University of New York Polytechnic Institute
Thomas Jefferson University
Tulane University

Membership At-A-Glance



40 NEW MEMBERS
WHO JOINED FROM
MAR 1, 2019 - FEB 29, 2020

37% MEMBERSHIP GROWTH
SINCE MARCH 1, 2019

University of Delaware
 University of Georgia Research Foundation
 University of Maryland Baltimore
 University of Maryland College Park
 University of Maryland, Baltimore County
 University of Massachusetts System
 University of North Carolina at Wilmington
 University of North Carolina, Chapel Hill
 University of Pennsylvania
 University City Science Center*
 University of California, LA*
 University of Maryland, Baltimore County*
 Villanova University
 Virginia Commonwealth University
 Worcester Polytechnic Institute
 Xavier University of Louisiana*
 Alamance Community College
 Brunswick Community College
 Bucks County Community College
 Cape Fear Community College
 Cecil College*
 Center for Entrepreneurial Innovation Maricopa CCCC
 Central Carolina Community College*
 Delaware Technical Community College
 Durham Technical Community College
 Forsyth Technical Community College
 Frederick Community College
 Gaston College*
 Hagerstown Community College
 MiraCosta College*

Montgomery College
 Montgomery County Community College
 North Carolina Community Colleges Systems
 BioNetwork
 Quincy College
 Shoreline Community College
 Skilled KC Technical Institute*
 Solano College
 Vance-Granville Community College
 Wake Technical Community College*
 AABB Center for Cellular Therapies
 AICHe
 Alliance for Regenerative Medicine*
 Bill & Melinda Gates Foundation
 BioBAT, Inc.*
 BioKansas
 Delaware BioScience Association
 Developing Countries Vaccine
 Manufacturers Network*
 Fraunhofer USA
 International Academy of Automation Engineering
 Life Science Washington
 Missouri Biotechnology Association
 National Institute for Pharmaceutical Technology
 and Education, Inc (NIPTE)
 New Jersey Innovation Institute
 North Carolina Biosciences Organization
 North Carolina Biotechnology Center
 PATH Center for Vaccines Innovation & Access*
 Research Corporation Technologies Inc.*
 Sloan Kettering Institute for Cancer Research

Southwest Research Institute
 Standards Coordinating Body
 The American Society of Mechanical Engineers (ASME)
 United States Pharmacopeial Convention*
 Wadsworth Center, New York State Department
 of Health*

MANUFACTURING EXTENSION PARTNERSHIPS

Delaware Manufacturing Extension Partnership
 Massachusetts Manufacturing Extension Partnership
 New Jersey Manufacturing Extension Partnership
 North Carolina Extension Partnership

OTHER PARTNERS

National Institute of Standards and Technology (NIST)
 Food and Drug Administration (FDA)
 National Institutes of Health (NIH)
NIIMBL interacts with several other federal agencies and institutes.

*New Members

NIIMBL WOULD LIKE TO THANK THESE STATES FOR THEIR SUPPORT:
 Delaware, North Carolina, and the Commonwealth of Massachusetts

Membership At-A-Glance

139

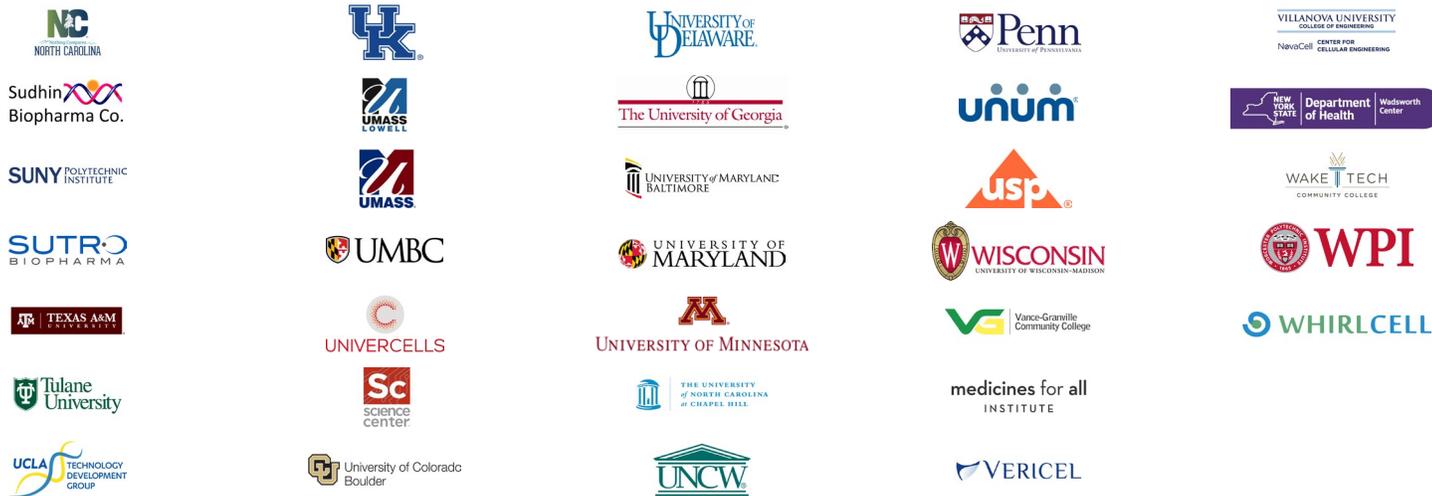
OF MEMBERS ENGAGED IN NIIMBL ACTIVITIES



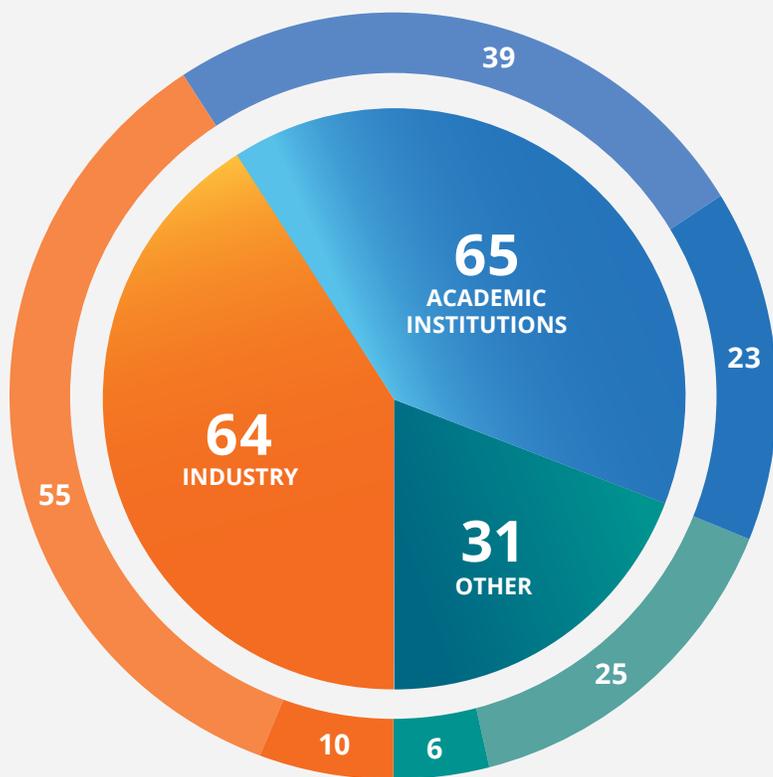
89%

MEMBERS ENGAGED IN NIIMBL ACTIVITIES





NIIMBL Membership and Partners by Institution Type

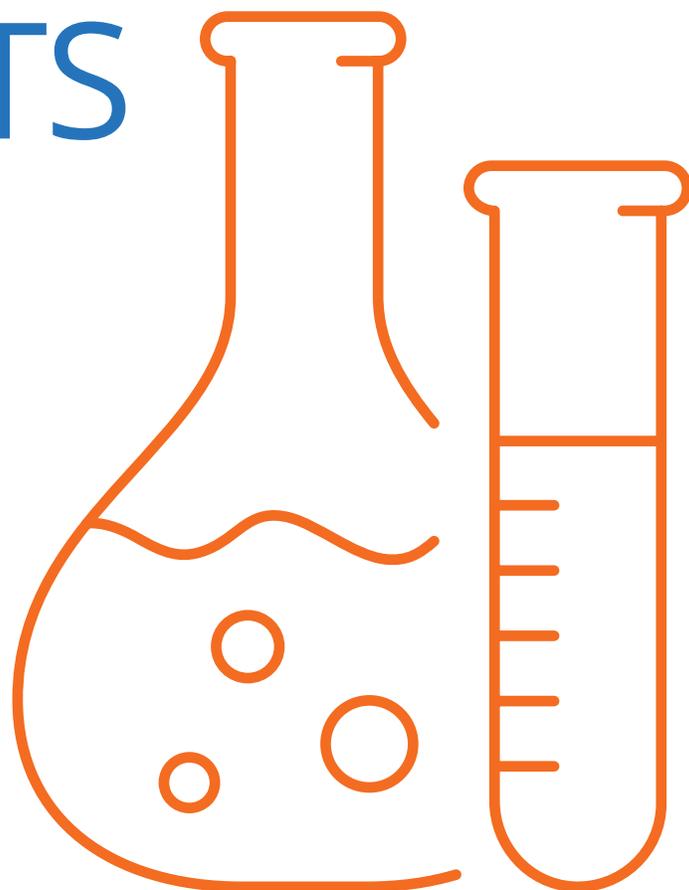


# OF MEMBERS	TYPE OF MEMBERS	% OF MEMBERS
62	ACADEMIC INSTITUTIONS	40%
39	UNIVERSITIES	25%
23	COMMUNITY COLLEGES	15%
65	INDUSTRY	41%
55	SMALL-TO-MEDIUM MANUFACTURERS	35%
10	LARGE COMPANIES	6%
31	OTHER ENTITIES	19%
25	NON-PROFITS	15%
6	MEP & OTHER	4%





PROJECT HIGHLIGHTS



BLAZE™ MICROCHIP SYSTEM FOR REAL-TIME CHARACTERIZATION OF INTACT BIOPHARMACEUTICALS



Intabio, Inc., Newark, CA

Type:

Small-Med Size Company

Participating Organizations:

Merck & Co., Inc., Genentech,

Bristol-Myers Squibb and MilliporeSigma

» **Lena Wu**

INDUSTRY NEED

Complexity of biologics create a need for ongoing product quality analysis that adds significant time and cost to drug development, thus taking longer to get products to market. On average development phase can take up to 15-20 years to commercialize.

SOLUTION

Reducing time and cost during testing to assure high quality product outputs are achieved could get drugs to patients faster. This NIIMBL project facilitated testing of Intabio's Blaze™ system with member company cells to validate efficiencies and improve market access.

OUTCOME

The result reflected a reduction in testing time over 30x that of traditional testing increasing testing capacity from 3-5 samples per month to 100 samples overnight at a cost of \$65/sample vs approximately \$23,000/sample. Time and cost savings could result in bringing drugs to market 1-3 years faster. Intabio was able to increase the number of Early Access Program companies from 2-3 prior to NIIMBL to 20 after joining NIIMBL.



Photo courtesy of Intabio



Photo courtesy of Intabio

“ As an SMM, NIIMBL has helped validate the need for our product in the market faster than we could have imagined. The NIIMBL community provided us access to leading Pharma companies and enabled us to accomplish the same validation and feedback that would normally have required a marketing group and months of work. ”

IMPROVING READINESS OF NEW HIRES THROUGH CGMP HANDS-ON BIOPHARMACEUTICAL TRAINING



**Texas A&M University
College Station, TX**

Type:
Educational Institution

Participating Organizations:
Vericel Corporation and
Akron Biotechnology, LLC.

» **Jenny Ligon**

INDUSTRY NEED

The biopharma industry is experiencing a major workforce gap from roles in process development to manufacturing. It has become more difficult to find a new entry level candidate, military vets, or career transitioners that can hit the ground running. Qualified individuals are needed to fill this immediate need by the industry to remain and limit or eliminate the initial training costs by a company.

SOLUTION

This project has created a blended program with online and hands-on training that can be completed in 50% less the time it would take a company to on-board a new employee. The program was highly competitive and the NIIMBL award allowed for the curriculum to be developed in accordance with industry standards and offered to participants at an 80% savings from that of other programs.

OUTCOME

More than 70 individuals expressed interest in the course. Cohort was completed by 47 people who now have an Advanced Certificate in Biopharmaceutical Manufacturing. All participants have successfully enhanced their technical skills and are working in the industry with placement at companies such as Merck, Fujifilm, Akron Biotech, BMS, Boehringer Ingelheim, etc.



Photo courtesy of the Texas A&M University



Photo courtesy of Texas A&M University

“ Participants in the Door-to-Floor program have been able to advance their careers with several receiving internships or employment at leading biomanufacturers such as BMS and Merck, as well as innovative start-ups. ”

NIIMBL – BIOPHORUM BUFFER STOCK BLENDING SYSTEM



NIIMBL, Newark, DE

Type:

NIIMBL-led Project

Participating Organizations:

Merck & Co., Inc., MilliporeSigma, Janssen Research & Development, LLC, Sanofi, and GlaxoSmithKline

» *Jeff Johnson*

INDUSTRY NEED

Buffers play a vital role in the stabilization of proteins during downstream processing. However, current buffer preparation methods are wasteful, require significant capital equipment, have a large footprint on the manufacturing floor, and involve significant labor.

SOLUTION

A portable, flexible system will blend highly concentrated single component stock solutions to make buffers, opening up valuable real-estate space and reducing labor.

NIIMBL and industry partners collaborated with BioPhorum Operations Group and its member companies to build an open source buffer stock blending system for which the design and supporting dataset is available to the industry, to improve buffer preparation processes.

OUTCOME

The system has been delivered to the NIIMBL facility in Newark, DE. The community will soon be invited to test the system for implementation in their own facilities. Estimates from the white papers supporting the initial design suggest the system will reduce floor footprint by 61%¹, save \$20M per facility built, and reduce the buffer preparation time by ~30%²

¹ BioPhorum Operations Group. *An Economic Evaluation of Buffer Preparation Philosophies for the Biopharmaceutical Industry*, December 2019.

² BioPhorum Operations Group. *NIIMBL-BioPhorum Buffer Stock Blending System: A More Advanced Concept for Buffer Manufacturing*, December 2019

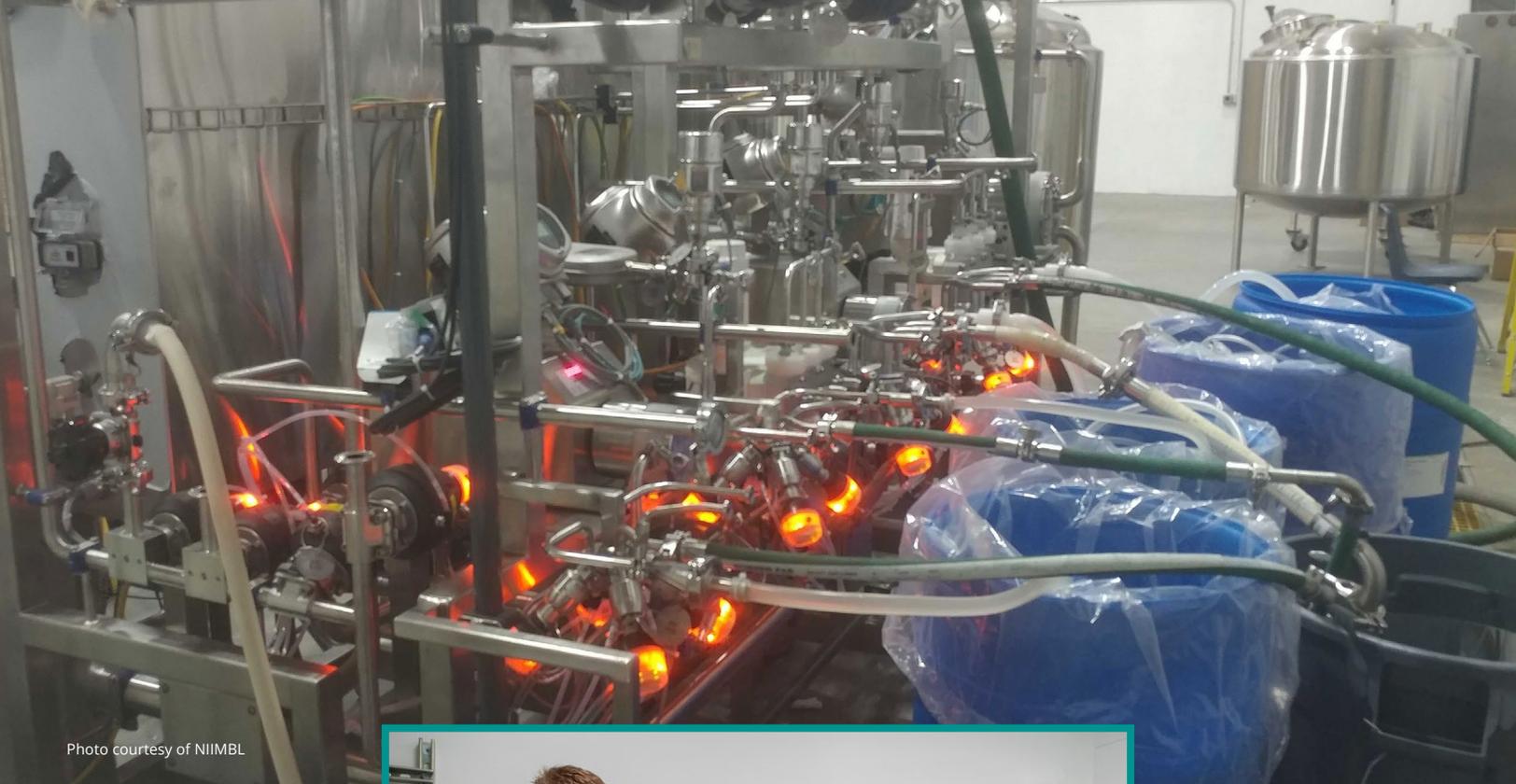


Photo courtesy of NIIMBL



Photo courtesy of the University of Delaware

“ NIIMBL has been very flexible and easy to work with to achieve this NIIMBL-BioPhorum Buffer Stock Blending (BSB) System, rapidly responding to this unique opportunity with both funding and resources to drive the project to realization. ”

DEVELOPMENT OF MICROCHIP CE-HPMS ANALYZER FOR BIOREACTOR MONITORING



908 Devices, Boston, MA

Type:

Small-Med Size Company

Participating Organizations:

University of North Carolina Chapel Hill, 908 Devices, North Carolina State University, Millipore Sigma, and Bristol-Myers Squibb

» **Glenn Harris**

INDUSTRY NEED

Mass spectrometry systems, key for chemical characterization measurements, require a large laboratory footprint. Separations systems are also very large pieces of equipment with complicated functionality requiring a high level of specific training for operation. The combination of equipment size and expertise can strain resources and space in laboratories.

SOLUTION

908 Devices has put together a miniature size mass spectrometry and a miniaturized chemical separation system in one benchtop instrument—The Rebel^{®1}. The compact size is unique and the new system is equipped with sophisticated intelligence allowing a lab technician to operate the system. Benefits of The Rebel[®] include a smaller footprint, reduced capital cost, reduced analysis time and talent efficiency.

OUTCOME

The Rebel[®] allows for samples to be analyzed in-house, almost immediately as they are pulled from the bioreactor. Results for cell analysis are available in 5-10 minutes vs 2-3 weeks, enabling faster decision making to optimize the intended output quicker. Simplified and automated design is easy enough to be used after a short training period with no scientific or technical background compared to the advanced scientific and technical required skills to operate traditional units. This enables PhDs and senior technical staff to focus on high priority tasks vs process development analytics.

¹ Rebel[®] is a registered trademark of 908 Devices



Photo courtesy of 908 Devices



Photo courtesy of 908 Devices

“ We had ideas on exploring an additional application in the future; however based on the customer insight we received during our NIIMBL project we were able to validate the application, saving our company almost a year of research. ”

NIIMBL eXPERIENCE: BUILDING THE NEXT-GENERATION OF BIOPHARMA TALENT

In June 2019, five budding scientists discovered first-hand the limitless possibilities of a career in the biopharmaceutical industry through the first ever NIIMBL eXperience.

Designed for underrepresented students at Historically Black Colleges and Universities and NIIMBL member institutions, this one-of-a-kind program fully immerses students in the biopharma world through a week-long tour of companies and federal agencies. Students tour labs and facilities, participate in hands-on activities, and partake in personal development workshops aimed to give them a leg up in their future careers.

Five students were selected to participate after a highly-competitive application process: Laurryn Sells (Howard University),

Ameenah Jackson, Aliyah Ford (Delaware State University), Sadie Doublin (Florida A&M), and Uzochi Uwazuruonye-Anyanwu (University of Massachusetts at Dartmouth).

Students learned about the roles large and small companies play in the biopharma ecosystem during visits with AstraZeneca, Amgen, Merck, and RoosterBio. In addition, they discovered how federal scientists contribute to bringing life-saving treatments to patients during a visit to the National Institute of Standards and Technology.

NIIMBL's next eXperience group is set to begin in summer 2020. The program demonstrates NIIMBL's commitment to cultivating the next generation biopharmaceutical talent.

“

The entire eXperience program was extremely rewarding. When I first submitted my application for the program, I was eager to learn how I could potentially apply my Chemical Engineering studies to an industry that is dedicated to improving lives.

During the eXperience week, I took tours of various company facilities, including RoosterBio and the NIH, sat in on panels, and spoke one-on-one with industry professionals. I even got the chance to speak with the CEO of RoosterBio! Overall, my major takeaway from the eXperience was that everyone's career pathway will not look the same, but that reality is what makes each story incredible.

—Laurryn Sells ”





AMMON PINIZZOTTO BIOPHARMACEUTICAL INNOVATION CENTER

In February 2020, NIIMBL moved into its new headquarters at the Ammon Pinizzotto Biopharmaceutical Innovation Center on the campus of the University of Delaware. NIIMBL occupies two floors of the brand-new, 200,000 square foot building with administrative offices, shared laboratory space, platform process facilities, a showcase laboratory, and workforce training areas. The building is also home to the University of Delaware's biopharmaceutical discovery and development activities.

NIIMBL's new home is positioned to be a hub of innovation. With ample laboratories and state-of-the-art equipment, the space is uniquely designed to foster collaboration and research. It offers the NIIMBL community the opportunity to work together and test drive the latest innovations including new buffer stock blending skid and spray freeze drying equipment.

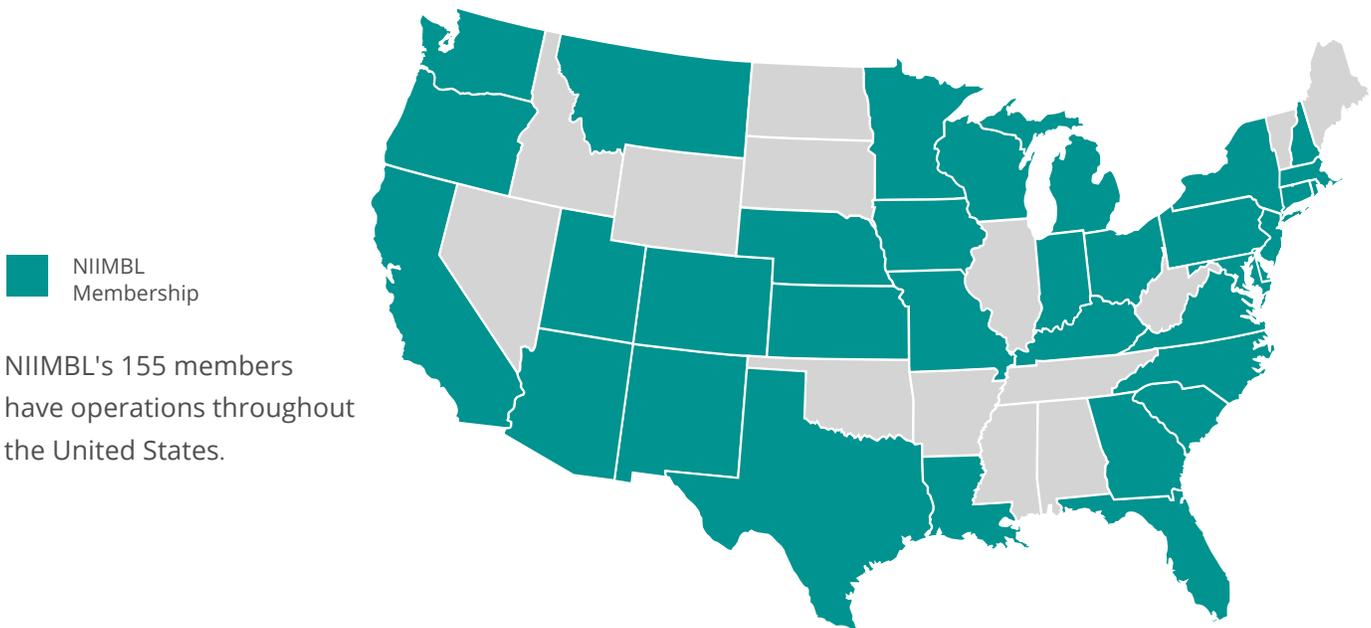
We look forward to welcoming the NIIMBL community to this beautiful new facility in the future.

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 in this industry.

NIIMBL is part of Manufacturing USA®, a diverse 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® The National Institute for Innovation in Manufacturing Biopharmaceuticals

Manufacturing USA

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

www.niimbl.org