



The National Institute for Innovation in Manufacturing Biopharmaceuticals

AMERICAN INNOVATION AT WORK

Riley Myers, Ph.D.

Director, Technical Operations

WCBP 2026

Institutes Address the “Scale-Up” Gap

Market Failure in Pre-Competitive Applied Manufacturing R&D

Funding/
Investment

High

Government and
Universities

GAP

Private Sector

Low

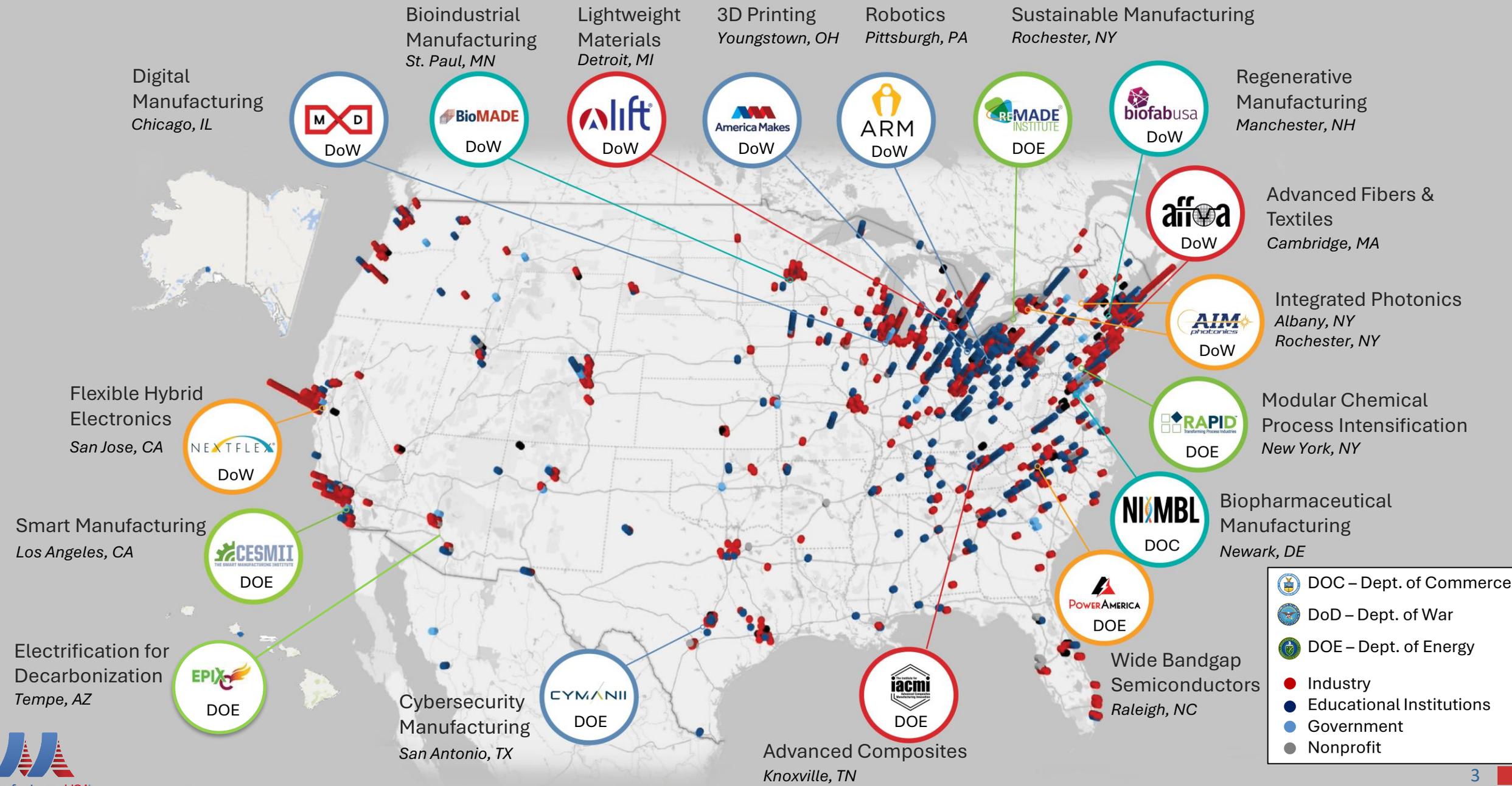
Manufacturing-Innovation Process



Manufacturing Readiness Levels (1-10)

Manufacturing USA Institute Network

Slide credit: AMNPO NIST



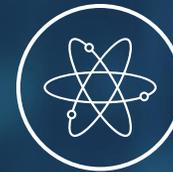
Our Mission

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 in this industry.



Mission Execution

- Bring together industry, academia, nonprofits, and government
- Fund and manage precompetitive projects to de-risk new manufacturing technologies
- Support workforce training and education for current and future biomanufacturing professionals
- Help bridge the gap between early innovation and GMP implementation





*As of July 1, 2025

NIIMBL Supports Collaborative Innovation

Received >600 project ideas

Advanced >150 projects

>\$180 million of non-Federal contributions

Execution of projects (12-18 months each).

Technology & Workforce

Proteins/mAbs, cell and gene therapies, vaccines, etc.

Equipment, assays, digital products/models, etc.



7



TYPES OF PROJECTS

MEMBER-LED Projects (Project Call)

- Ideas initiated by Members
- Collaborative across organizations
- Priorities established by industry
- ~1 year, ~\$1 million

NIIMBL-LED Programs/Projects

- Strategic collection of projects around a theme
- Longer term *vision* but projects still ~1 yr
- Aligned to business goals
- NIIMBL leadership ensures programs work together
- Work done at partners or at NIIMBL
- Significant engagement by industry



NIIMBL-Led Technical Programs

Process Intensification

Invent, design, demonstrate, and support commercialization of integrated biopharmaceutical manufacturing technology to transform drug substance (DS) and drug product (DP) manufacturing capability



Viral Vector Manufacturing & Analytics

Develop and make broadly available a robust, economically viable, shared-access platform for the technical development, manufacturing, and characterization of AAV-based gene therapy vectors



Big Data Analytics

Accelerate the development and adoption of data-driven innovation and standards to increase the speed and resilience of biopharmaceutical manufacturing.



Preventive Medical Countermeasures

Accelerate the implementation of new vaccine manufacturing and analytical technologies across multiple platform processes



NIIMBL-Led Process Intensification Program



Test Bed

Build non-proprietary platform cell line, process and equipment for technology comparison, de-risking and demonstration



Flexibility

Develop vendor agnostic hardware & software standards enabling interchangeable, reconfigurable, portable, adjustable & self qualifying equipment



Sustainability

Develop widely adopted decision tools to make sustainability a key design criterion alongside cost, yield, robustness and quality



Control Strategy

Improve microbial control while eliminating clean rooms through rapid microbial monitoring, closed systems, fit-for-purpose control strategy, and data to validate or challenge assumptions



2nd Generation Factory

Develop conceptual design for green facility that can be built and qualified 6 months after permitting, achieve tech transfer in less than 3 months, and reconfigured to meet changing demands



Process Intensification Program

Test Bed

THE NEED

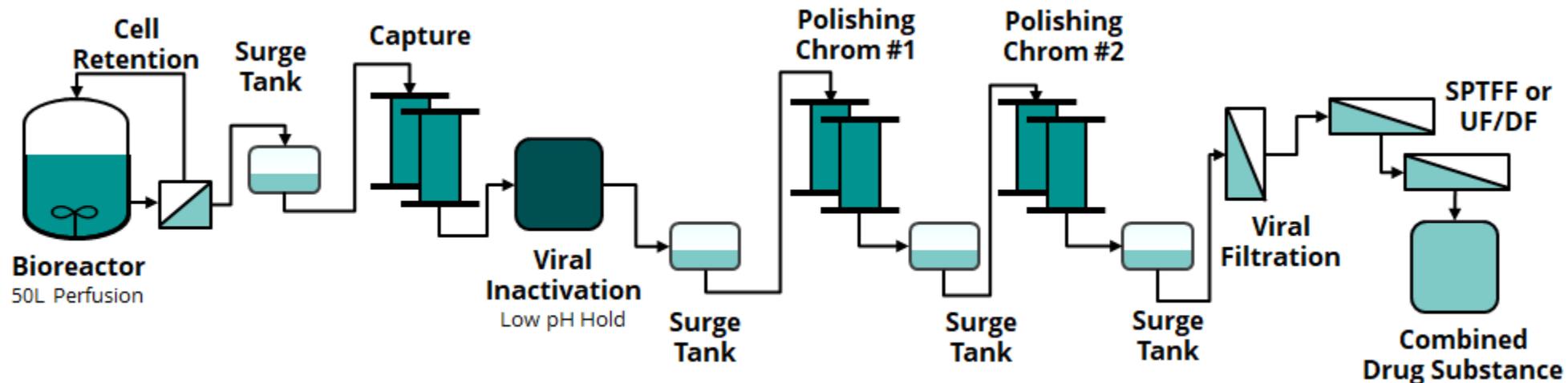
- A non-proprietary, integrated continuous bioprocess platform for technology evaluation, de-risking, and demonstration

THE SOLUTION

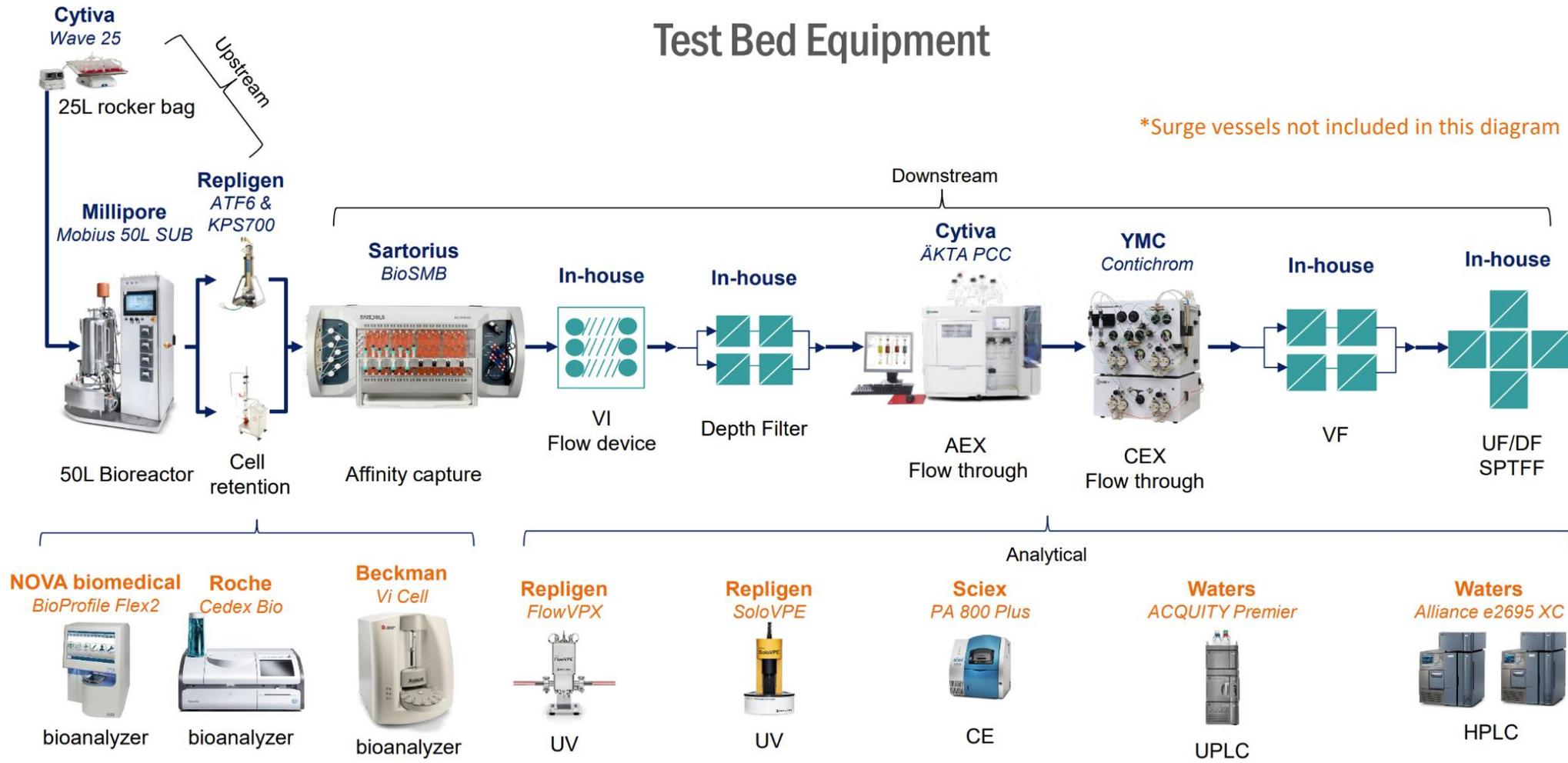
- The team designed, installed, and commissioned a **50L scale end-to-end continuous bioprocess test bed** that produces **cNISTmAb-NIIMBL** using the **NIIMBLCHO1** cell line

Three demonstration runs have been completed with targets of:

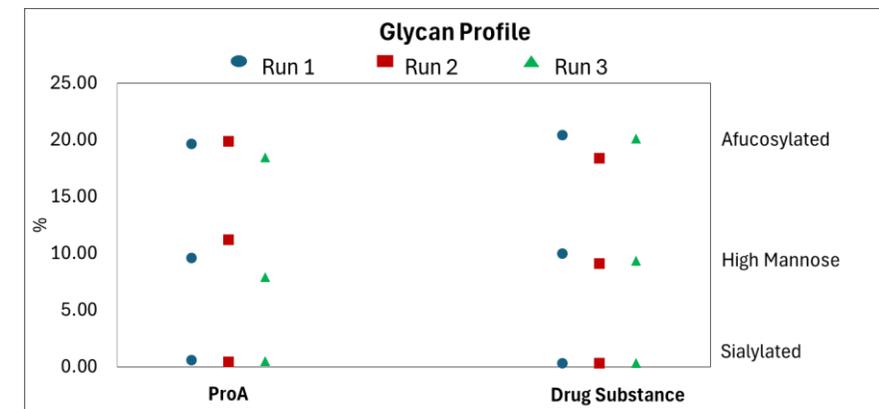
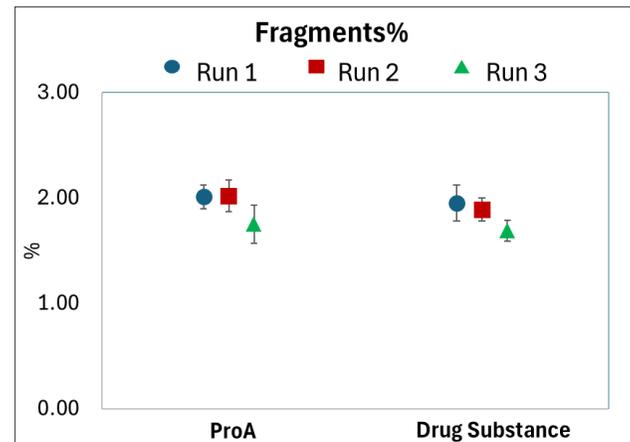
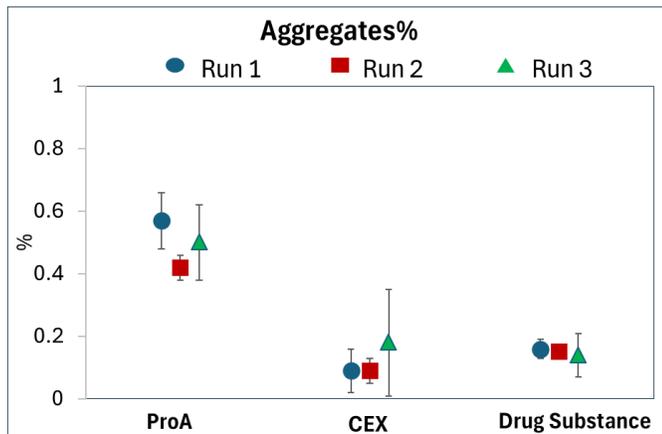
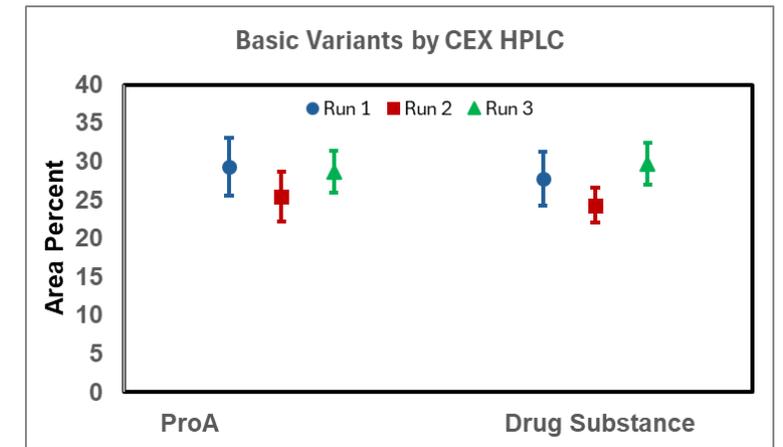
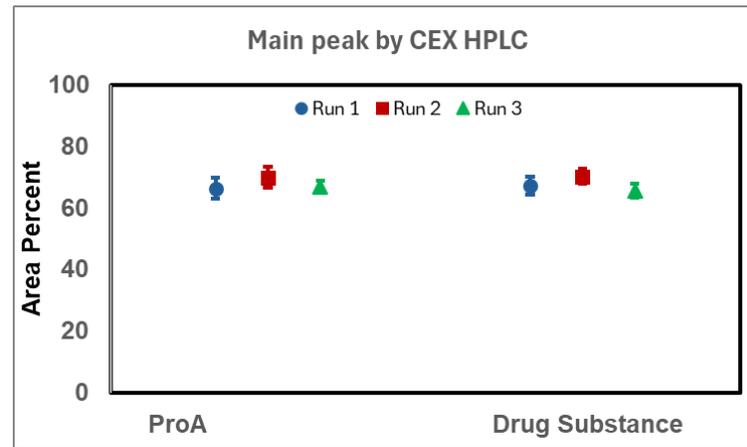
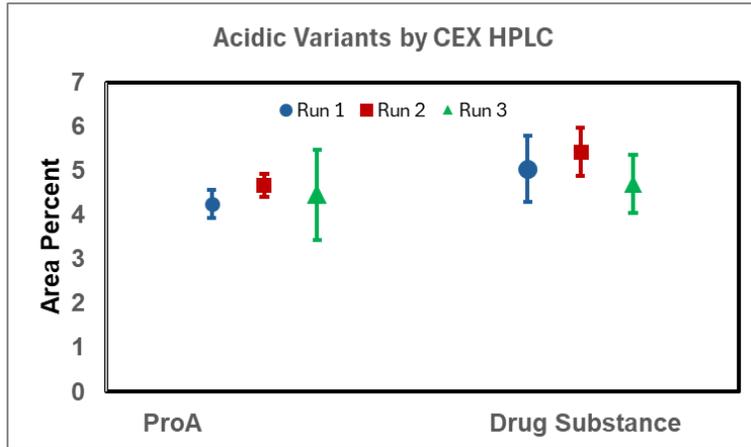
- > 50g/day product throughput
- VCD of 50×10^6 cells/mL
- Productivity > 1 g/L/day
- Viability > 90%
- 30 days of continuous use



First non-proprietary continuous manufacturing (CM) process



NIIMBL CM process manufactures consistent product



NIIMBL Regulatory Considerations Committee



Pre-Competitive Interaction between Industry and Regulators

- Facilitate alignment with FDA initiatives
- Enable early consideration of regulatory requirements



Address Barriers to Technology Adoption

- Identify and address barriers via case studies & white papers, e.g., N-mAb & Active Listening



Early exposure to New Technology

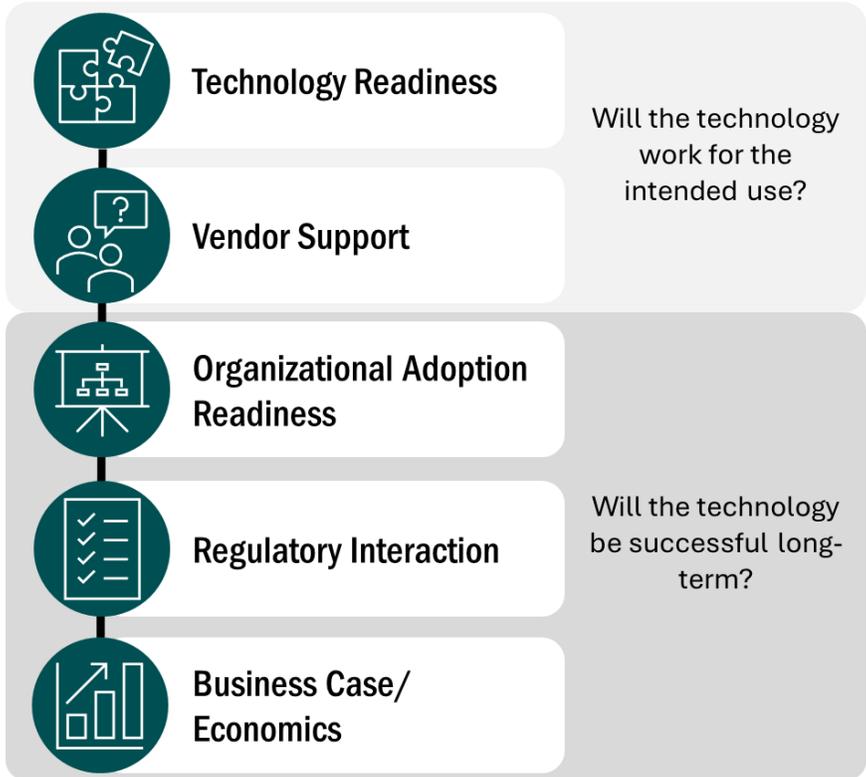
- Reduce regulatory uncertainty for novel manufacturing technologies
- Support risk-based decision making and lifecycle management approaches



Provide a vehicle for collecting and consolidating the Voice of Members for responses to Docket Items, need for updated Standards, etc.

Active Listening Alternative and Rapid Microbiological Methods

Elements of Technology Adoption



Sector	#
Manufacturer	13
Supplier	5
FDA	18
Other Gov't	1



PDA Journal of Pharmaceutical
Science and Technology

NIIMBL-Facilitated Active Listening Meeting between Industry and FDA Identifies Common Challenges for Adoption of Alternative and Rapid Microbiological Methods

Jennifer L. Mantle, Eugene Schaefer and Kelvin H. Lee

PDA Journal of Pharmaceutical Science and Technology November 2025, 79 (6) 707-718; DOI: <https://doi.org/10.5731/pdajpst.2025-000026.1>

- NIIMBL-facilitated an **active listening meeting between industry and FDA representatives** on September 30, 2024, and with EMA/QIG April 8-9, 2025
- Through prework and interviews, **five common elements were identified** as important for technology adoption – often noted as a **key to success** at one organization and a **barrier to adoption** at another
- Questions remain about the **transition from advanced/emerging to standard practice**
- Better communication around current industry status of a technology can help avoid situations where an **organization perceives a technology as new/risky despite its deployment by others**



Pre-competitive Ecosystem Facilitating Technology Adoption

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DOI: 10.1002/bt.27688

ARTICLE



End-to-end collaboration to transform biopharmaceutical development and manufacturing

John Erickson¹ | Jeffrey Baker² | Shawn Barrett³ | Ciaran Brady⁴ |
Mark Brower⁵ | Ruben Carbonell⁶ | Tim Charlebois⁷ | Jon Coffman⁸ |
Lisa Connell-Crowley⁹ | Michael Coolbaugh³ | Eric Fallon¹⁰ | Eric Garr⁴ |
Christopher Gillespie⁵ | Roger Hart¹¹ | Allison Haug¹ | Gregg Nyberg⁵ |
Michael Phillips¹² | David Pollard¹³ | Maen Qadan¹⁴ | Irina Ramos⁸ |
Kelley Rogers¹⁵ | Gene Schaefer¹⁶ | Jason Walther³ | Kelvin Lee¹

¹National Institute for Innovation in Manufacturing Biopharmaceuticals, Newark, Delaware, USA

²Office of Biotechnology Products (OBP), Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration, Silver Spring, Maryland, USA

³Global CMC Development, Sanofi, Framingham, Massachusetts, USA

⁴Biologics MS&T, Bristol-Myers Squibb, Devens, Massachusetts, USA

⁵Biologics Process Research and Development, Merck & Co., Inc., Kenilworth, New Jersey, USA

⁶National Institute for Innovation in Manufacturing Biopharmaceuticals, Raleigh, North Carolina, USA

⁷BioTx Pharmaceutical Sciences, Pfizer, Andover, Massachusetts, USA

⁸Biopharmaceutical Development, AstraZeneca, Gaithersburg, Maryland, USA

⁹Process Design, Just-Evotec Biologics, Seattle, Washington, USA

¹⁰Manufacturing Science and Technology, Drug Substance, Genentech, Inc., Oceanside, California, USA

¹¹Process Development, Amgen, Cambridge, Massachusetts, USA

¹²Next Generation Processing R&D, MilliporeSigma, Bedford, Massachusetts, USA

¹³Sartorius Corporate Research, Sartorius, Boston, Massachusetts, USA

¹⁴Biologics Research and Development, Eli Lilly and Company, Indianapolis, Indiana, USA

¹⁵Material Measurement Laboratory and Office of Advanced Manufacturing, National Institute of Standards and Technology, Gaithersburg, Maryland, USA

¹⁶API Large Molecule BioTherapeutics Development, Janssen R&D, Malvern, Pennsylvania, USA

NIIMBL
FDA CDER
Sanofi
Bristol-Myers Squibb
Merck
Pfizer
AstraZeneca
Just-Evotec
Genentech
Amgen
Millipore Sigma
Sartorius
Eli Lilly and Company
NIST
Janssen

NIIMBL PI Test Bed: Addressing Regulatory Science Challenges

- Bring together regulatory (RCC) and process development (PI Program) members to develop industry-wide topics/questions critical for technology adoption
- NIIMBL staff perform fit-for-purpose experiments specifically designed to facilitate interactions between industry and regulators
- Existing pathways (e.g., ETP, CATT, QIG)
- Foster a forum for industry-wide collaboration with regulators and receive written feedback
 - Neutral
 - Transparent
 - Non-proprietary (product agnostic)
- Distribute regulator feedback broadly to NIIMBL members, collaboratively de-risking technology



NIIMBL PI Test Bed: Addressing Regulatory Science Challenges

- Process Analytical Technologies
 - Integration into real time process control
 - RTRT strategy
- Integrated Control Strategy
 - Diversion (and recombining) strategy in accordance with ICH Q13
 - Hybrid models for system predictability
 - Model-based sampling and analysis plan supporting an Incident Command System (ICS)
- Equipment considerations
 - Maintenance approaches given long (30 days) run times
 - Management of “single use” components while maintaining a functionally closed system



NIIMBL Activities help companies go first together



Companies work together to define & shape individual projects & programs



Enable the ecosystem to move at a scale & speed that cannot be achieved otherwise



Structured to obtain deep, direct engagement among industry leaders through a steering committee



Include academic and other partners to advance specific scopes of work