NIIMBL®

The National Institute for Innovation in Manufacturing Biopharmaceuticals

AMERICAN INNOVATION AT WORK

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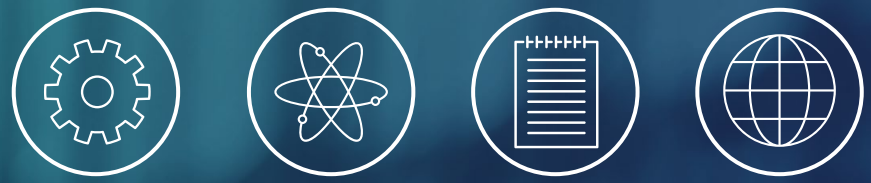
Our Mission

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.



NEEDS

- Global competitiveness
- Reduced offshoring and outsourcing
- Workforce training and education
- Domestic biomanufacturing
- Reduced medical costs
- Precision medicines
- Standardization
- Secure supply of medicines/pandemic readiness

NIIMBL

MEMBERS

- Industry
- Academia
- States
- NIST
- FDA
- MEPs
- MIIs
- NGOs
- NIH
- DOD
- BARDA
- Trade organizations

FOCUS AREAS

Existing products

mAbs, proteins, vaccines

ADCs, bispecifics, virus-like particles

Emerging products
gene and cell therapies

MANUFACTURING PROCESS THEMES

OUTCOMES

- Skilled workforce
- Novel real-time analytical technologies
- Integrated continuous processing
- Automation
- Reference standards and protocols
- Advanced process modeling and control
- Process integration and intensification
- Energy/water savings

IMPACT

NATIONAL

- Growth of globally-competitive domestic industry
- Regional economic development
- Secure, integrated supply chain
- Access to new and improved medicines

INDUSTRY

- Flexible, adaptive manufacturing
- De-risked manufacturing innovation
- Lower costs
- Accelerated development and approval

Funding

National Institute of Standards and Technology

Other Non-Federal Commitments

NIIMBL is funded by cooperative agreements from the National Institute of Standards and Technology and leverages other non-Federal commitments.

NIST is a non-regulatory federal agency within the U.S. Department of Commerce. NIST's mission is to promote U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve our quality of life.

Can collaborative de-risking (& demonstration) of technologies accelerate adoption?

NIIMBL is a public-private partnership dedicated to this.

200+ organizations are Members.

7 Federal agencies are regularly engaged in NIIMBL activities.

TYPES OF PROJECTS

MEMBER-LED Projects (Project Call)

- Ideas initiated by Members
- Collaborative across organizations
- Priorities established by industry
- ~1 year, ~$1 million
- Big companies have unlimited engagement

NIIMBL-LED Programs/Projects

- Strategic collection of projects around a theme
- Longer term *vision* and but projects still ~1 yr
- Aligned to business goals e.g. mAbs, Vx, etc.
- NIIMBL leadership ensures programs work together
- Work done at partners or at NIIMBL
- Significant engagement by industry
- Limited access determined by membership tier

NIIMBL Supports Collaborative Innovation

Received >600 project ideas.

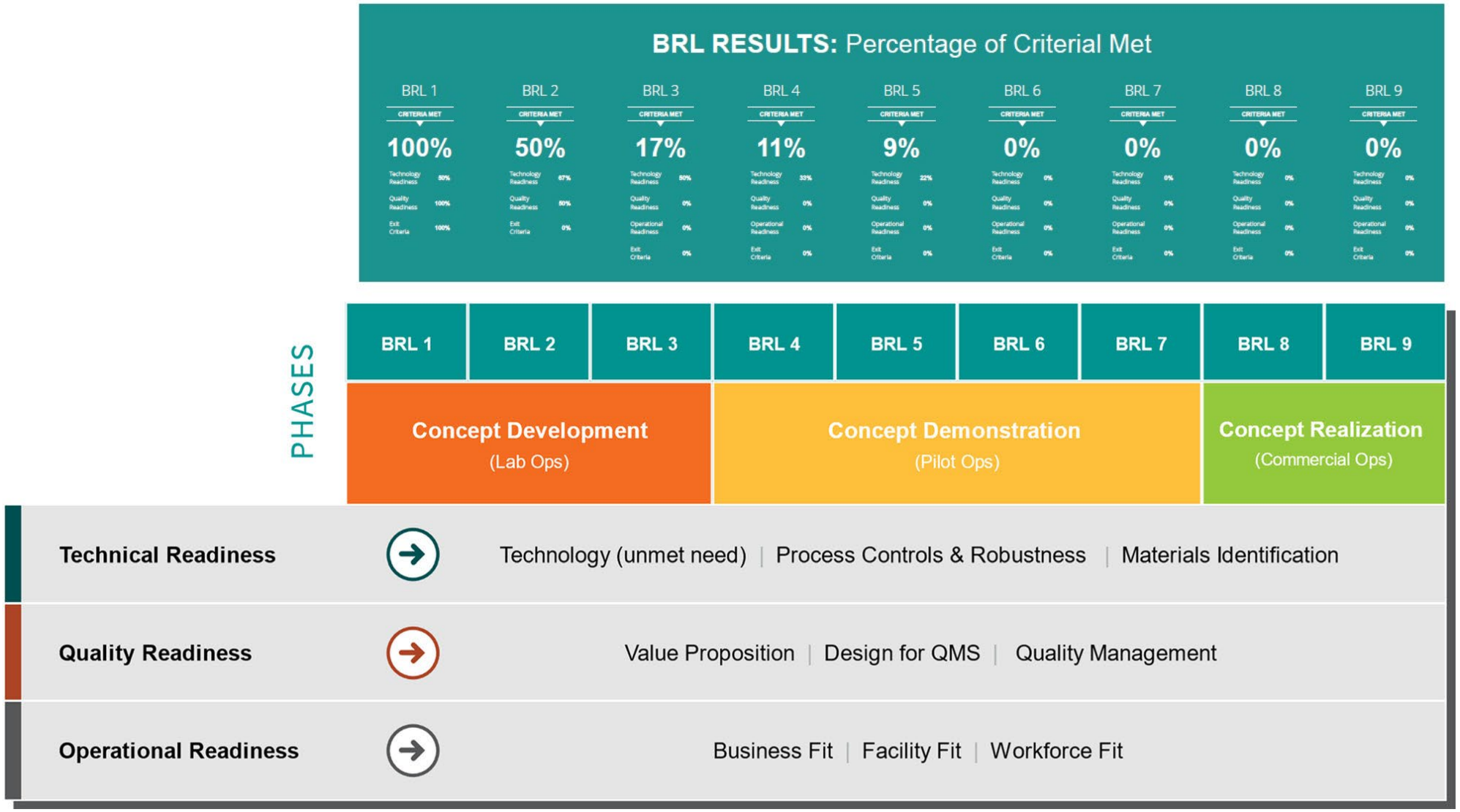
Advanced >150 projects (technology, workforce).

>$180 million of non-Federal contributions.

More than 150 projects have launched (12-18 months each).

Technology & Workforce
Proteins/mAbs, cell and gene therapies, vaccines, etc.
Equipment, assays, digital products/models, etc.

Self-Assessment Tool for Biomanufacturing Readiness Level



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When it comes to biopharmaceutical manufacturing innovations, this industry wants to be a fast second.

The Agency asked NIIMBL for help to understand.

Active listening workshop to understand adoption challenges
- Industry interviews
- Industry-only workshop
- Industry-FDA workshop
- Report out

A big hurdle is business risk associated with speed to market
- What questions may be asked?
- What data is expected?

RESEARCH

NIIMBL-Facilitated Active Listening Meeting between Industry and FDA Identifies Common Challenges for Adoption of New Biopharmaceutical Manufacturing Technologies

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ABSTRACT: The National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) piloted a forum to encourage an exchange of information between the biopharmaceutical industry and the U.S. Food and Drug Administration (FDA). To facilitate this exchange, NIIMBL conducted a survey of industry representatives around the perceived challenges associated with the adoption of new innovative technologies for biopharmaceutical manufacturing or for continuous improvement and then held an Active Listening session with industry and FDA stakeholders to share common themes. The scope was limited to biotechnology products regulated by the Center for Drug Evaluation and Research (CDER). This manner of exchange has not been tested before and led to meaningful dialog between industry and the Agency and valuable takeaways by all involved. One of the general findings and key points of discussion was around the perceived lack of a business case for adoption of new technology in the manufacture of monoclonal antibodies and therapeutic proteins. Tight timelines were the primary constraints for hesitation around pre-approval implementation and the challenges associated with a global regulatory environment were the primary constraint around post-approval adoption of new technology. Mechanisms that would allow industry and regulatory scientists to develop a shared understanding of new technologies, outside of formal applications, could de-risk adoption of new technologies by the industry. The favorable response to this NIIMBL-facilitated exchange suggests that this format could be useful in establishing a more informal dialog between the FDA and industry on industry-wide challenges.

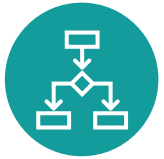
KEYWORDS: Innovation, Manufacturing technology, Monoclonal antibodies, Regulatory landscape.

PDA JPST 74(5):497-508 (2019).

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

Workforce Strategy Overview

Build national capacity to meet the talent, training, and workforce development needs of the biopharmaceutical manufacturing ecosystem. *We believe that ensuring the US has a strong workforce to meet the needs of the industry will help to secure US biopharmaceutical manufacturing leadership.*

- Increase Interest In Biopharma Manufacturing Careers
- Hire From A Range of Talent Pipelines
- Advance Non-Traditional Pathways
- Develop Online and In-Person Trainings
- Catalyze Cross-Regional Collaboration

Awareness & Pipeline Development

Education & Training

How we work?

Community Engagement / Workshops / Working Groups

Project Calls / Project Portfolio

NIIMBL-Led Programs & Initiatives

External Partnerships

Building Industry-Academic Relationships

Thought Leadership / Publications

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