Manufacturing USA®

Pandemic Response and NIIMBL Update

Visiting Committee on Advanced Technology

June 9, 2020

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National Institute of Standards and Technology
U.S. Department of Commerce

The NIIMBL community responded rapidly to a call to action

Friday, April 3, 2020 – 10:30am email with a request for proposals

Friday, April 3, 2020 – 2:00pm webinar on our process

Monday April 6, 2020 – 3:00pm deadline for submissions

Submissions accepted only from NIIMBL Members, but not limited to biopharmaceutical manufacturing technologies.

We received well over 200 submissions in response to our request:

- Small businesses
- Large, global companies
- Universities and Academic Medical Centers
- Federal scientists
- etc

Going through a process now to finalize which projects will launch.

How the NIIMBL Community Can Contribute

- Testing - antibody, PCR, other
- Contact tracing, technologies associated with tracking for people, equipment, etc.
- Decontamination technologies
- PPE (development, manufacturing, etc.)
- Medical countermeasures* - discovery, development, manufacturing
- Supply chain analysis, modeling, including financial impact forecasting
- Medical equipment (development, manufacturing)
- Other

*Medical countermeasures included small molecules, large molecules, cell therapies, vaccines, and plasma therapies

$9 million NIST Award for NIIMBL Projects






Provide virus proteins to improve blood testing capabilities	Assist regional hospital systems with validation of rapid in-house diagnostic testing capabilities	Identify alternative domestic supply chains to reduce foreign dependence for respirators and masks	Validate the use of environmental decontamina-tion approaches for clinical spaces	Develop automated contact tracing technology w/i facilities to limit the spread of coronavirus in essential workers	Accelerate development of more flexible manufacturing platforms of biologic therapies and rapid release testing

Images: Adobe Images

Other Developments from NIIMBL

Membership growth continues

An initiative related to workforce

An initiative related to technology

Other recent news

Updated March 2020

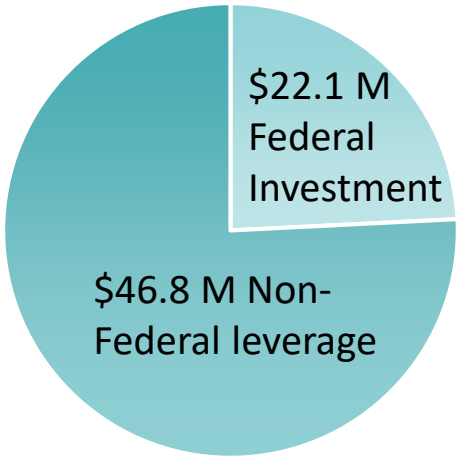
NIIMBL status – 3 years post-launch

Ecosystem -150 + members

- 10 major manufacturers and OEMs
  - > 40% industry
- 24 premier research institutions
- 6 federal agencies
- 4 MEPs

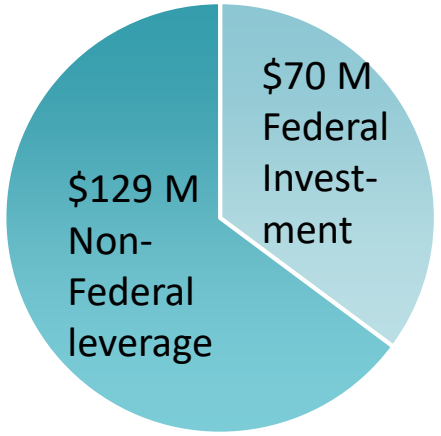
Impacts

- $63 M project portfolio awarded
  - > $9 M workforce development
- 3 Roadmaps published, 2 streams ongoing
- 3 'NIIMBL led' industry-wide programs to launch in 2020



Actual co-investment
(as of Feb 2019)

2.12 to 1 match



Planned over NIST award

1.84 to 1 match

Highlights and Activities | NIIMBL eXperience

Building a highly-skilled and diverse workforce pipeline

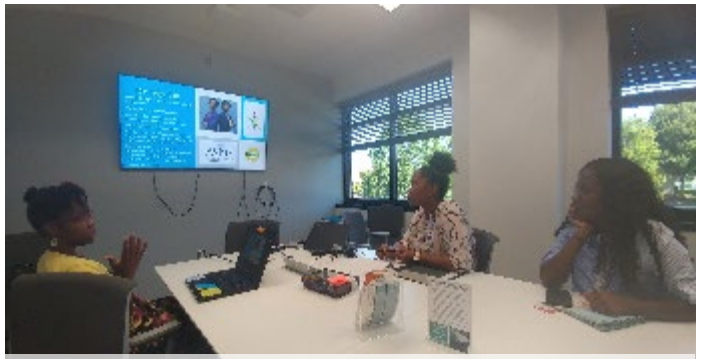
- 5 students participated from Florida A&M University, Howard University, Delaware State University and University of Massachusetts Dartmouth
- Learning goals
  - Explore career paths in biopharmaceutical manufacturing
  - Awareness of internship and training opportunities
  - Networking with career professionals and mentoring
  - Develop a personal brand statement and practice execution


Networking and personal branding from NSBE

Manufacturing tour at Merck

Industry and Federal Agency Participants:

RoosterBio®
AstraZeneca
NIST
MERCK
AMGEN


Hearing “how I did it” from career professional


Hands on at Amgen’s Immersive Research Center

Distinguished R&D and supply chain technical leaders from 14 major manufacturers & suppliers met and agreed:

- Significant opportunity to impactfully transform CMC development & manufacturing through E2E integration and technology advancement.
- Collaboration in consortium will significantly accelerate transformation
- Success enabled by expertise, leadership & capability of committed industry leaders
- We will advocate for our companies to participate
- High level goals/strategy agreed: priorities/details to be refined after participants identified

Organization	Title
Amgen	Scientific Director, Technology & Engineering
AstraZeneca	Head Bioprocess Technology & Engineering
BMS	Head of Biologics MS&T
Eli Lilly	Research Advisor
FDA	Deputy Director, OBP, CDER, FDA
NIST	Technical Program Manager, NIIMBL
GSK	Sr. Director, MS&T
Janssen	Sr. Dir. API Large Molecule Dev & Man. Sci.
Just	Director
Merck & Co	AVP Biologics Process R&D
	Principal Scientist
EMD/Millipore	Director, Next Generation Processing R&D
Novartis	Head, Advanced Process & Technology Biologics
Pfizer	Vice President, Technology & Innovation Strategy
Roche	Head of Biologics for Tomorrow
Sanofi	Senior Scientist
Sartorius	Head of Advanced Materials & Processing

Vision: **By 2029 invent, design, build and commercialize drug substance and product manufacturing capability enabling:**

- **Flexibility** to supply extremely diverse and changing portfolio of products in the face of uncertainty and changing demand
- Improved **Control, Robustness** and **Security of Supply**
- Faster Product Development and Supply Chain **Velocity**
- **Sustainable** plastic and energy use
- **Capital & Operating Cost** dramatically reduced
  - No longer barrier to availability of capacity, innovation or change
- DS & DP expertise and thinking **integrated** vial to vial

The image we used to use…

New NIIMBL HQ Opening Q1 2020
225,000 gsf

Buffer Stock Blending Skid