



The National Institute for Innovation in Manufacturing Biopharmaceuticals

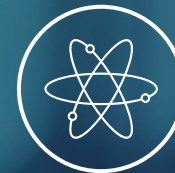
AMERICAN INNOVATION AT WORK

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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.



Manufacturing USA Institutes: public-private partnerships creating a neutral convening space for U.S. industry and academia to collaborate

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)

Funding

\$70,000,000
National Institute of Standards
and Technology
NIST



\$180,000,000
Other Commitments



NIIMBL is funded by a \$70,000,000 cooperative agreement from the National Institute of Standards and Technology and leverages >\$180,000,000 in other 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.



Our local partners



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
- MIIIs
- 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

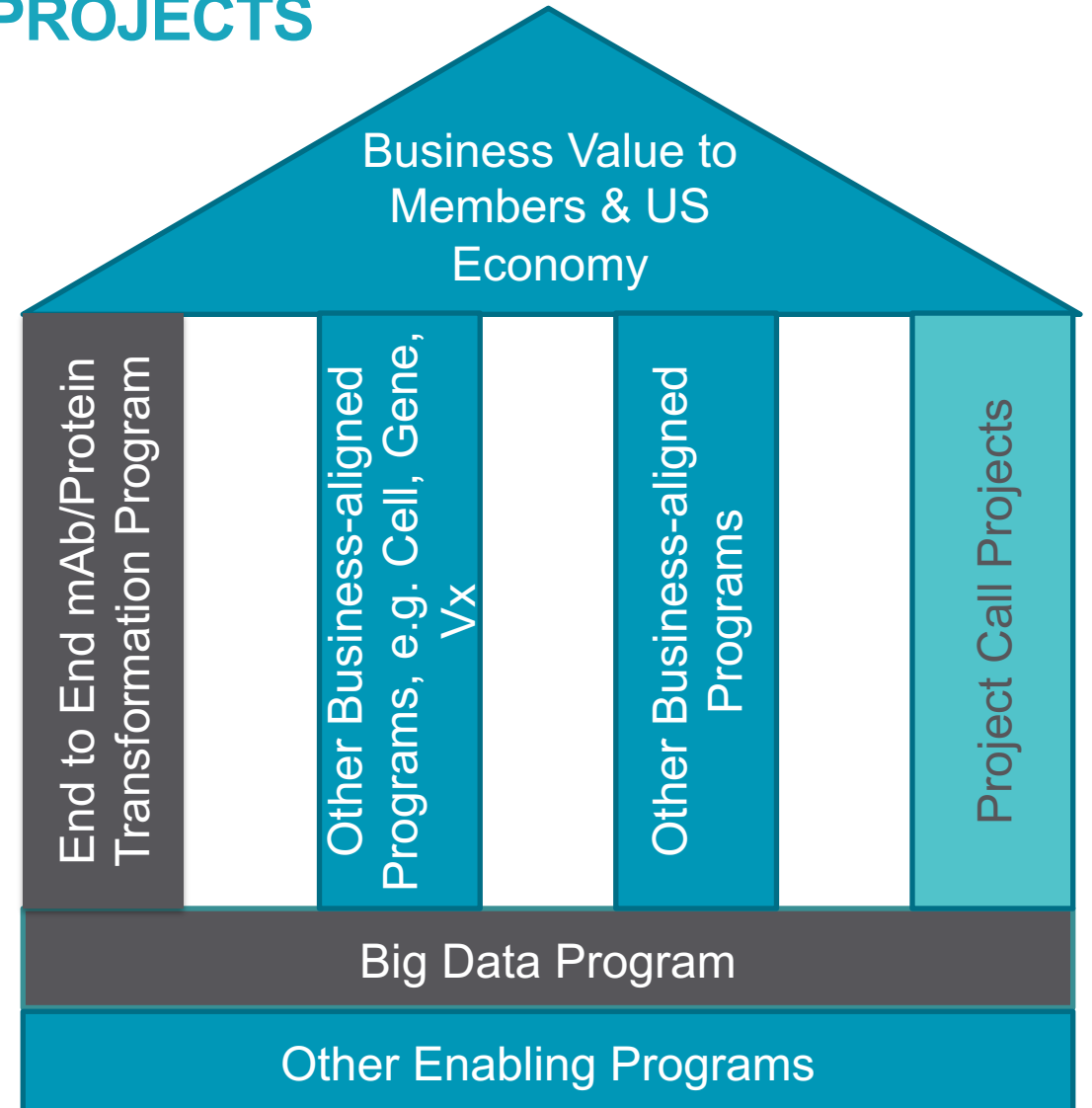
TYPES OF PROJECTS

Project Call

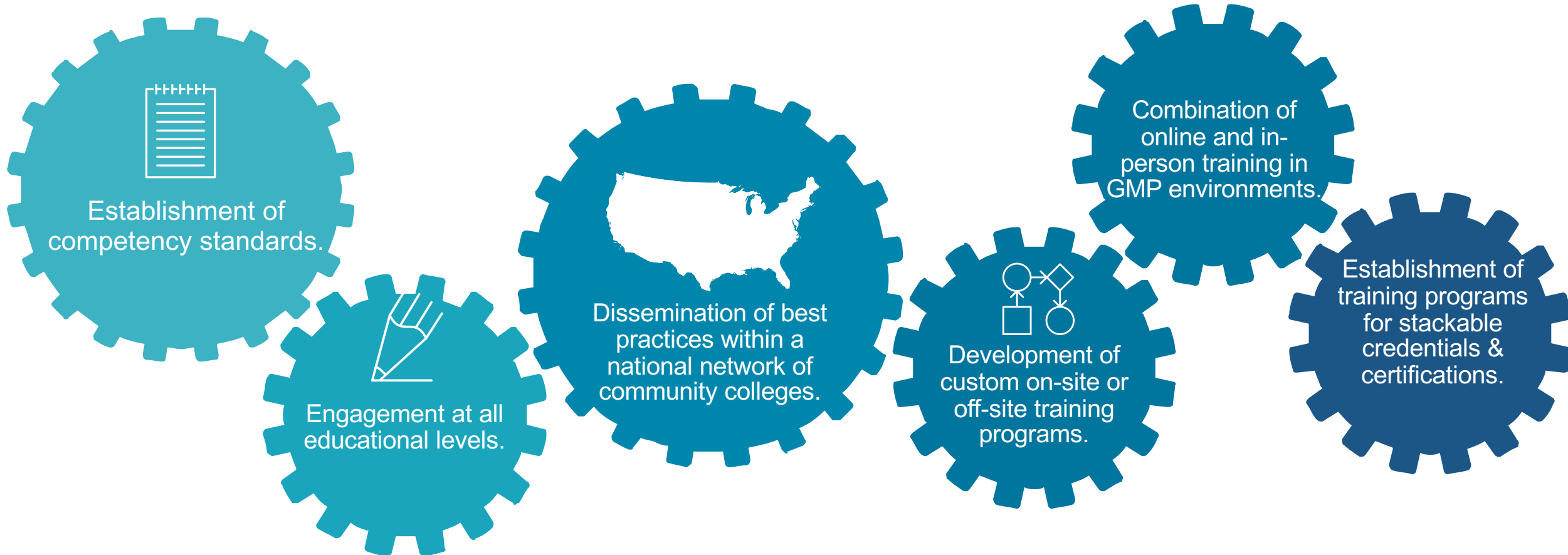
- Ideas initiated by members
- Normally about 1 yr

NIIMBL-Led

- Coordinated programs of projects
- Longer term *vision* and *program*
 - *Projects* still about 1 yr
- Aligned to goals of specific business, e.g. mAbs, Vx, Cell, Gene Tx
- Underpins and enables several programs and projects
- NIIMBL leadership ensures programs work together



Education and Workforce Training Program



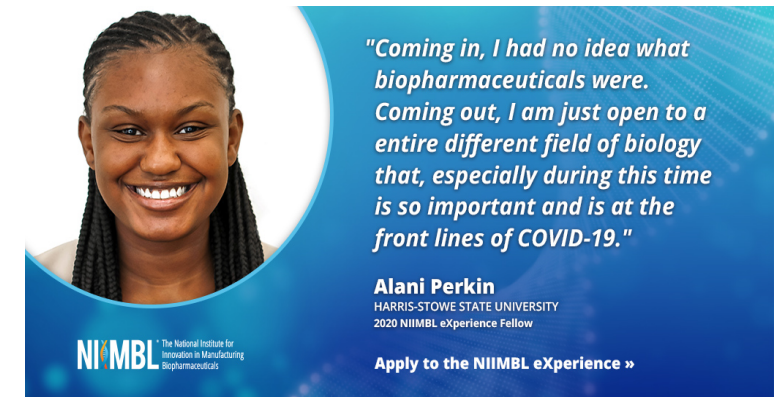
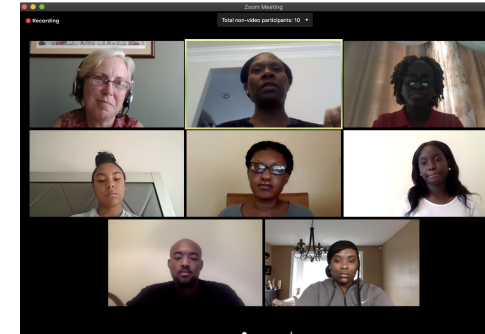
NIIMBL eXperience Program

Students to date 18

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

NIIMBL



- Lincoln University
- Harris-Stowe State University
- Howard University
- University of North Carolina at Chapel Hill
- Morehouse College
- University of Maryland at Baltimore County
- Penn State
- University of Arkansas at Pine Bluff
- Miracosta College
- Delaware Tech CC
- Xavier University of Louisiana
- Alcorn State University
- Florida A& M University
- Univ. of Massachusetts Dartmouth



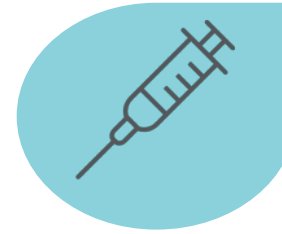
NIIMBL'S GLOBAL HEALTH FUND (GHF)



GHF established through **partnership with the Bill & Melinda Gates Foundation (BMGF)**



GHF Request for Proposals focus on lower costs and enhanced access to vaccines

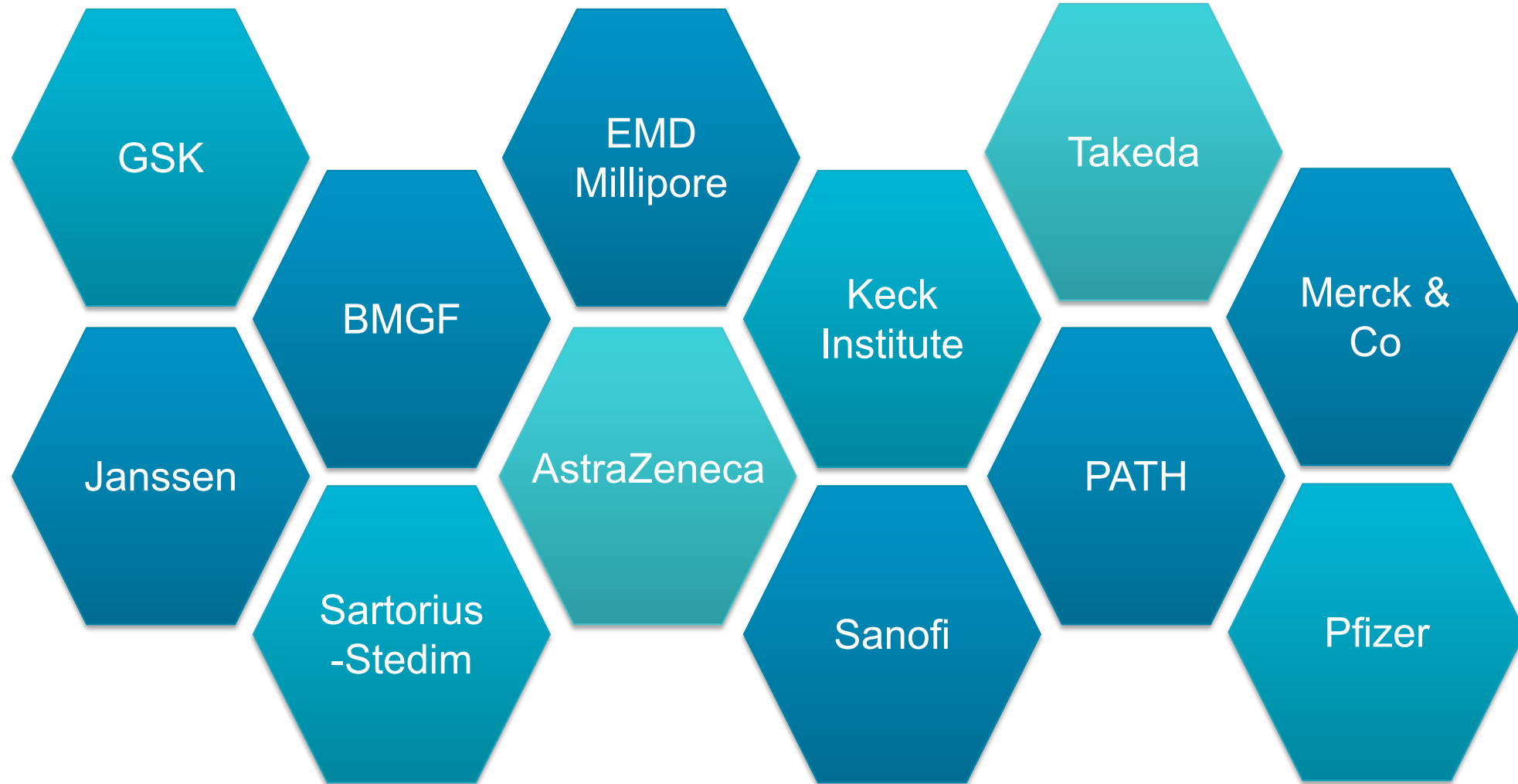


GHF Steering Committee provides strategic guidance. Every major vaccine manufacturer in the USA is a NIIMBL member



The GHF Steering Committee includes participation by GSK, Merck, MilliporeSigma, Pfizer, Sartorius, BMGF, PATH, and NIIMBL

VACCINE WORKING GROUP



\$9 million NIST Award (CARES Act) for NIIMBL Projects



Provide virus proteins to improve blood testing capabilities



Assist CCHS with development & validation of rapid in-house diagnostic testing capabilities



Identify alternative domestic supply chains to reduce foreign dependence for masks



Validate the use of environmental decontamination approaches for clinical spaces



Accelerate development of more flexible manufacturing platforms of biologic therapies and rapid release testing

Images: Adobe Images

NIIMBL

- continues to grow
- has elevated UD's global visibility in this space
- is helping with our nation's response to COVID-19
- has companies, universities, and government agencies asking to partner
- is creating opportunities for new types of education and training programs
- is accelerating patient access to medicines and vaccines

