NIMBL The National Institute for Innovation in Manufacturing Biopharmaceuticals

ANNUAL REPORT

2017–18

It has been an extraordinary first year for NIIMBL.

Dear Colleagues,

Since our launch in March 2017, the overwhelming enthusiasm of the biopharmaceutical community has helped us throughout NIIMBL's startup phase. We thank the community for their guidance and wisdom in shaping the vision of the Institute.

American innovation in advanced manufacturing is essential to grow our economy and ensure our nation's prosperity. We are thrilled to join our sister Manufacturing USA institutes in the commitment to U.S. global leadership in advanced manufacturing. Our collective work will ensure that innovations and inventions that happen in the U.S. turn into products made here by American workers.

Throughout our first year, we created for our Members a collaborative, precompetitive environment where they can use their expertise to pursue technology advancement and the development of training programs which will advance biopharmaceutical manufacturing in the U.S. By developing these innovative technologies and world-class training efforts domestically, we ensure the U.S. is the leader in the global biopharmaceutical market.

With the strong commitment of our Members, we launched several initiatives to position the Institute for both short and long term success. These efforts include establishing our operational and governance structure, announcing two project calls, initiating technology roadmapping, and onboarding 81 members to NIIMBL's diverse membership base.

We also look forward to an exciting future that includes launching an initial slate of projects in early 2018, announcing more projects calls, completing the roadmaps in three product categories, growing our membership, creating new opportunities to address industry-wide concerns among stakeholders, and, our move in 2020 into a new headquarters facility in Newark, Delaware.

All of these efforts are possible as a result of the dedication, commitment, and hard-work of Members, partners, stakeholders, and our colleagues and sponsors at the U.S. Department of Commerce and at NIST. We look forward to creating a new paradigm for biopharmaceutical manufacturing innovation and training in the United States of America.

Sincerely,

The NIIMBL Team

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.

OUR VISION

Better lives through a healthy society and a strong economy.

Stakeholders gather at the NIIMBL announcement at the University of Delaware in December 2016

Photo courtesy of the University of Delaware/Evan Krape photographer

About NIIMBL

The National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) was established in March 2017 and is one of 14 Manufacturing USA® institutes. Manufacturing USA is a collection of public-private partnerships, each in a unique technology space, dedicated to advancing U.S. global leadership in advanced manufacturing. NIIMBL is funded through a $70 million cooperative agreement with the National Institute of Standards and Technology (NIST) in the U.S. Department of Commerce and leverages an additional $129 million in commitments from industry, academic institutions, non-profit organizations, and the states of Delaware, Maryland, North Carolina, and the Commonwealth of Massachusetts.

NIIMBL is a national network of Members and is administratively headquartered in Newark, DE with staff also located in Raleigh, NC.

CONTENTS

NIIMBL Goals, Plans, and Accomplishments

Improve the Competitiveness of U.S. Biopharmaceutical Manufacturing

Strengthening the Nation Through Biopharmaceutical Innovation

The biopharmaceutical industry develops and manufactures medicines that save, sustain, and improve lives. Biopharmaceutical products include vaccines, monoclonal antibodies, and therapeutic proteins, as well as gene and cell therapies. They are used to treat conditions including cancer, diabetes, and autoimmune disorders.

Biopharmaceutical development and manufacturing is a rapidly growing global industry. In 2022, the global market for vaccines is projected to be $85B and the market for therapeutic proteins and monoclonal antibodies is projected to reach $223B.[1] Cell and gene therapies—revolutionary new treatment options—are expected to become a global market of over $220B by 2030.[2]

The biopharmaceutical industry makes a substantial impact on the health, well-being, and economic prosperity of the nation. The industry develops and manufactures life-changing therapies for patients and contributes significantly to the U.S. economy. Currently, the industry accounts for nearly $800B of total economic activity per year and directly employs more than 850,000 people in high-wage and high-value jobs.[3] Finally, the industry aids in national security by producing products that address public health threats whether natural or man-made.

However, in recent years, the biopharmaceutical manufacturing industry has faced new challenges from a globalized biopharmaceutical industry.

NIIMBL was created, in part, to continue domestic investment and innovation in this crucial industry sector. The establishment of NIIMBL represents a singular opportunity to coordinate national stakeholders and catalyze a multifaceted effort to assure that the U.S. will not only have best-in-the-world biopharmaceutical research and development (R&D), but also retain the value of manufacturing the medicines it discovers, thereby securing the domestic medicine supply, including the ability to respond to national health emergencies and national security challenges.

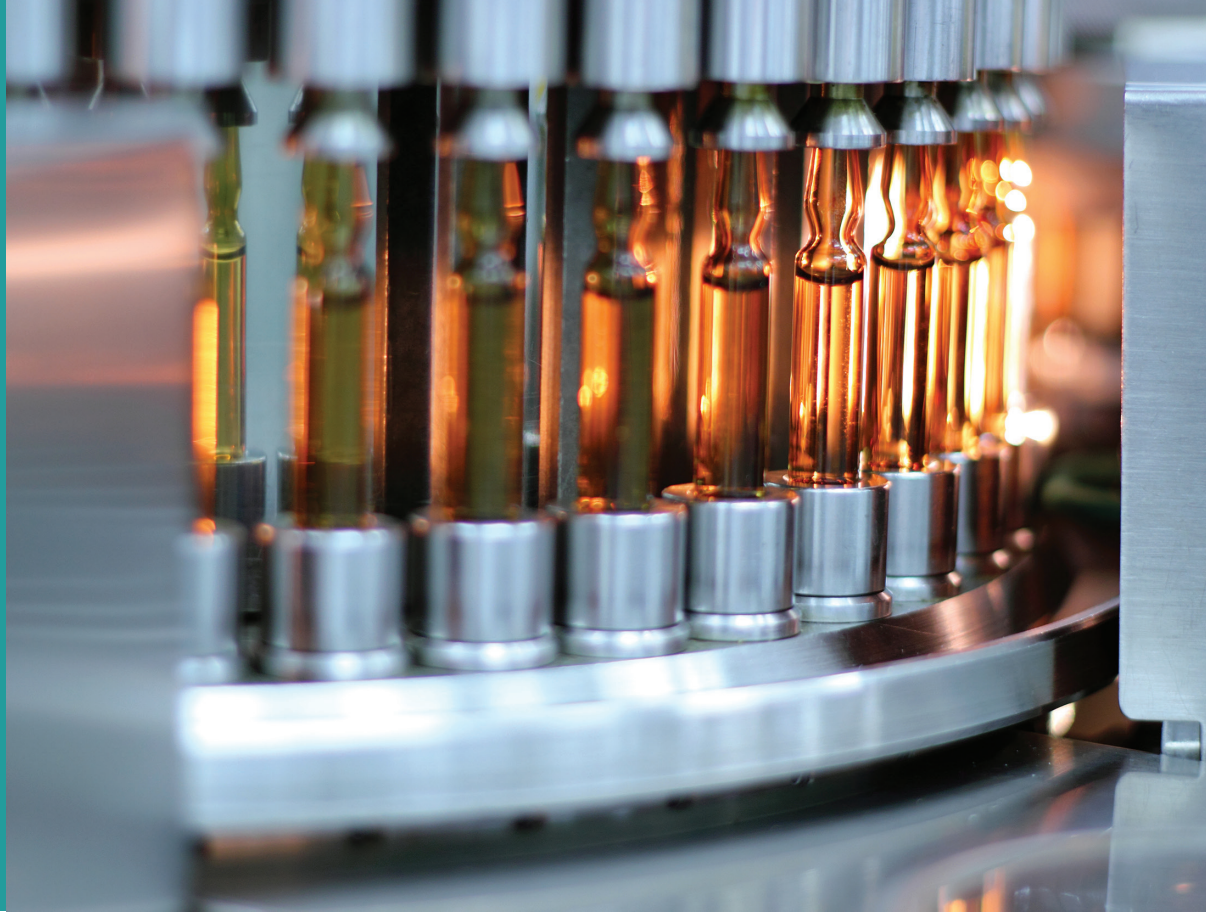
Through this unified commitment to manufacturing technology innovations and workforce development, NIIMBL promises to advance U.S. competitiveness in this globalized field by improving patient access to cutting-edge medical treatments, supporting economic development, and contributing to national security.

[1] Battelle/PhRMA report: *The US Biopharmaceutical Industry: Perspectives on Future Growth and The Factors That Will Drive It (2014).*

[2] Frost & Sullivan. July 28, 2015. *Stem Cell Therapy to Redefine Regenerative Medicine. http://www.prnewswire.com/news-releases/stem-cell-therapy-to-redefine-regenerative-medicine-says-frost--sullivan-300119573.html*

[3] Battelle Technology Partnership Practice report: *The Economic Impact of the US Biopharmaceutical Industry (2013).*

NIIMBL is committed to ensuring that medicines are safe and efficacious.



Meeting the Medical Needs of the Nation

NIIMBL facilitates the development and commercialization of rapid, flexible, and cost-efficient manufacturing technologies to ensure patients have access to the most potent and effective medicines available, and that these therapeutics are safe and available when needed. These activities include large-scale manufacturing of existing products such as therapeutic proteins and monoclonal antibodies targeted to treat Alzheimer's, cancer, and infectious diseases and small-scale manufacturing of precision medicines such as cell and gene therapies used to treat various forms of cancer.

Promoting Economic Development

In 2011, the biopharmaceutical industry supported over 800,000 direct jobs, and approximately 3.4 million total (direct and indirect) jobs[1]. NIIMBL supports job growth by investing in new and innovative training programs for the next generation of biopharmaceutical workers. NIIMBL's workforce development efforts will ensure the U.S. has a supply of highly skilled workers to meet the needs of domestic biopharmaceutical manufacturers, thereby reducing one of the appeals of offshoring.

Improving National Security and the Domestic Supply Chain

NIIMBL is committed to ensuring that medicines are safe and efficacious. To do this, NIIMBL will work to develop and secure the domestic supply chain, including the development of appropriate standards and reference materials to facilitate rapid and more efficient manufacturing. A secure, domestic supply chain coupled with advanced manufacturing processes will protect the U.S. during times of pandemic or emergent crisis by allowing for rapid development of vaccines and other therapies.

NIIMBL is poised to stimulate U.S. leadership in the biopharmaceutical industry and the lives of millions of Americans across the country.

[1] Battelle/PhRMA report: *The US Biopharmaceutical Industry: Perspectives on Future Growth and The Factors That Will Drive It (2014).*

Photo courtesy of BTEC © North Carolina State University

Through the collaboration of Members, NIIMBL facilitates technology advancement.

"NIIMBL has been a valuable platform for my small biotech company to collaborate with large biomanufacturing companies and academic institutions and to demonstrate the power of our novel bioprocessing solutions."

Dhinakar Kompala
Chairman and CEO
Sudhin Biopharma Company

Membership

NIIMBL Members are a diverse set of stakeholders, including large and small companies, prominent research institutions, community colleges, non-profit organizations, and state governments poised to advance the biopharmaceutical industry. Members have the opportunity to collectively revolutionize current biomanufacturing platforms, processes, and educational programs, and share in the benefits of these transformative solutions.

Since we opened membership in mid-April 2017, more than 80 organizations have joined the Institute, with more than 40% of those from industry. The membership base spans the entire biopharmaceutical ecosystem. This membership diversity provides a wealth of expertise and an expansive pool of resources to tackle manufacturing challenges.

We offer a tiered membership structure. Industry tiers are designed to facilitate participation across the entire spectrum from mature, highly-capitalized enterprises to contract manufacturers to Small-to-Medium Enterprises (SMEs). Non-profit tiers aim to include major research intensive universities, community colleges, and other non-profit research organizations focused on economic and workforce development.

NIIMBL membership comes with significant benefits including:

- Access to the diverse expertise of fellow NIIMBL Members to foster creative solutions.
- Ability to participate on NIIMBL-funded projects.
- Intellectual Property benefits derived from NIIMBL-funded projects.
- Extensive networking and partnering opportunities.
- Access to member-exclusive workshops and events focused on key topic areas.
- Ability to participate in the governance of the Institute.
- Access to the NIIMBL Community Portal, an online resource to facilitate partnering and collaboration.

Supporting SMEs

NIIMBL places special emphasis on supporting the growth of SMEs, who are often the heart of innovation. More than two dozen of these companies are NIIMBL Members. NIIMBL values SMEs from small companies with innovative therapies to contract manufacturers and suppliers with disruptive technologies.

NIIMBL will help SMEs access sources of intellectual and business capital, technical expertise, training resources, health authorities, and testbeds at NIIMBL sites where they can test development ideas.

To further support SMEs, NIIMBL has the benefit of embedded staff from the Delaware, Massachusetts, and North Carolina Manufacturing Extension Partnership (MEP) programs.

NIIMBL/Manufacturing Extension Partnership (MEP) Collaborative Pilot Project

The Manufacturing Extension Partnership (MEP) Network, funded by NIST, is a valuable resource for SMEs in a variety of industry sectors, including small-to-medium biotechnology companies. As part of our commitment to supporting SMEs, we actively engage with the MEP program. In 2017, the Delaware MEP, located at Delaware Technical and Community College, received an award to launch the NIIMBL/MEP Collaborative Project. As part of this project, NIIMBL now includes embedded staff from the Delaware, Massachusetts, and North Carolina MEP programs.

The goals of the program are to increase SME awareness of NIIMBL, ensure SME engagement in NIIMBL research, enhance SME participation on NIIMBL projects, and foster the transition of NIIMBL innovation to SMEs.

NIIMBL ECOSYSTEM

OUR PARTNERS

as of 2/28/18

Industry Partners

Celgene Corporation
Genentech
Merck & Co.
MilliporeSigma/EMD Serono
A1 Biochem Labs
Accugenomics
Aeneos Biosciences
Aerosol Therapeutics
Akron Biotech
Alcami
Artemis Biosystems
Avitide
BioFactura
Chromatan
Commissioning Agents Inc.
Elektrofi
Fisher-Rosemount Systems
IKA Works
ILC Dover
ImmunoGen
Janis Research Company
LakePharma
Lindy Biosciences
LumaCyte
PBS Biotech
Physical Sciences Inc.
Redbud Labs
Repligen
RoosterBio
Sangamo Therapeutics
SeaTox Research Inc.
SoyMeds
Stratophase
Sudhin Biopharma Co.
Unum Therapeutics
Vericel

Academic Institutions and Non-Profit Organizations

BioBuzz Workforce Foundation, Inc
Brunswick Community College
Bucks County Community College
Cape Fear Community College
Carnegie Mellon University
Clemson University
Delaware BioScience Association
Delaware Technical Community College
East Carolina University
Forsyth Technical Community College
Fraunhofer USA
Georgia Tech Research Corporation
International Academy of Automation Engineering
Johns Hopkins University
Massachusetts Institute of Technology
Montgomery College
National Institute for Pharmaceutical Technology and Education, Inc. (NIPTE)
North Carolina Biosciences Organization
North Carolina Biotechnology Center
North Carolina Central University
North Carolina Community Colleges Systems BioNetwork
North Carolina State University
Pennsylvania State University
Purdue University
Quincy College
Regents of the University of Colorado (Boulder)
Regents of University of Minnesota
Rensselaer Polytechnic Institute
Sloan Kettering Institute for Cancer Research
Southwest Research Institute
Standards Coordinating Body
Texas A&M University System
Tulane University
University of California, Berkeley
University of Delaware
University of Georgia Research Foundation
University of Maryland Baltimore
University of Maryland College Park
University of Massachusetts System
University of North Carolina at Wilmington
University of North Carolina, Chapel Hill
University of Pennsylvania
Worcester Polytechnic Institute

States

State of Delaware
Commonwealth of Massachusetts (Massachusetts Life Sciences Center)
State of Maryland
State of North Carolina

Manufacturing Extension Partnerships (MEP)

Delaware MEP
North Carolina MEP
Massachusetts MEP

Federal

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.

Industry panel at the 2017 NIIMBL National Meeting in Washington D.C.

The NIIMBL community gathers at the National Meeting in Washington D.C.

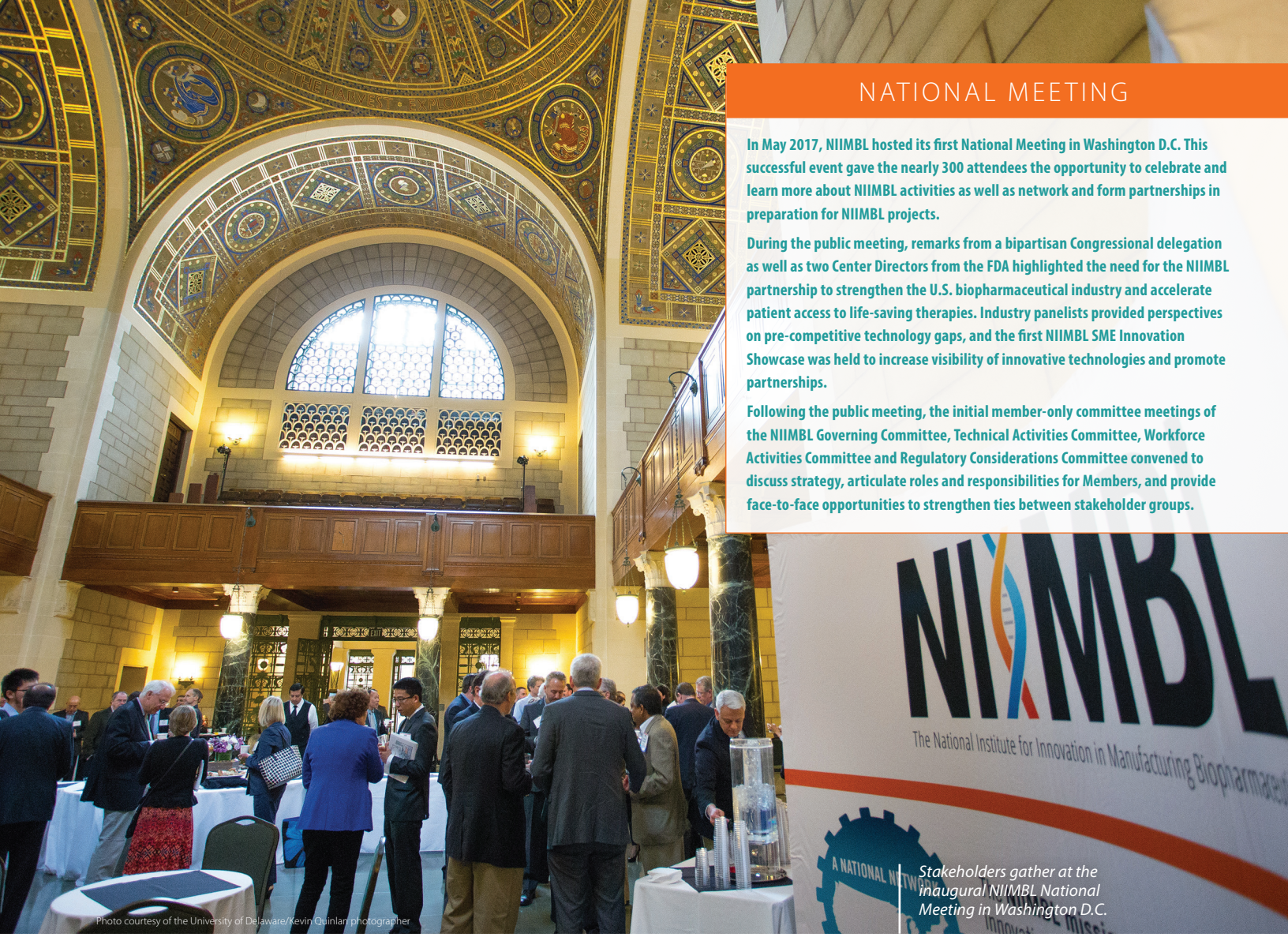
Photos courtesy of the University of Delaware/Kevin Quinlan photographer

NATIONAL MEETING

In May 2017, NIIMBL hosted its first National Meeting in Washington D.C. This successful event gave the nearly 300 attendees the opportunity to celebrate and learn more about NIIMBL activities as well as network and form partnerships in preparation for NIIMBL projects.

During the public meeting, remarks from a bipartisan Congressional delegation as well as two Center Directors from the FDA highlighted the need for the NIIMBL partnership to strengthen the U.S. biopharmaceutical industry and accelerate patient access to life-saving therapies. Industry panelists provided perspectives on pre-competitive technology gaps, and the first NIIMBL SME Innovation Showcase was held to increase visibility of innovative technologies and promote partnerships.

Following the public meeting, the initial member-only committee meetings of the NIIMBL Governing Committee, Technical Activities Committee, Workforce Activities Committee and Regulatory Considerations Committee convened to discuss strategy, articulate roles and responsibilities for Members, and provide face-to-face opportunities to strengthen ties between stakeholder groups.



Stakeholders gather at the inaugural NIIMBL National Meeting in Washington D.C.

Photo courtesy of the University of Delaware/Kevin Quinlan photographer

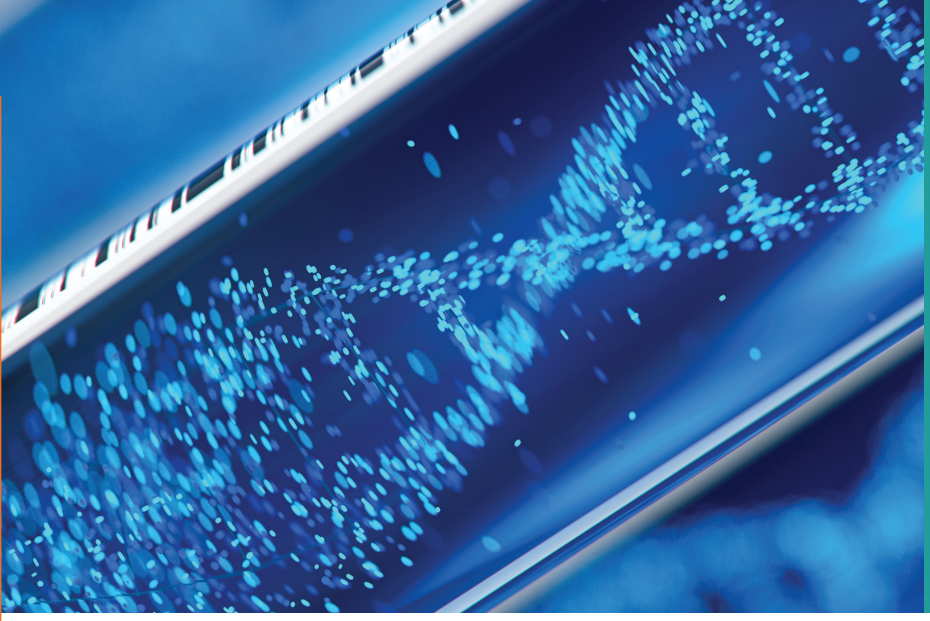
Stimulate Leadership in Advanced Biopharmaceutical Manufacturing Research, Innovation, and Technology

New Opportunities for U.S. Leadership

Over the past 30 years, the biopharmaceutical industry has made a transformative impact on public health, national security, and the U.S. economy; improved patient health by offering new treatment options for numerous conditions; and spurred a prosperous economic sector accounting for nearly $800B[4] in annual economic activity.

While the industry has achieved a tremendous amount of success, continued innovation is required to ensure and enhance patient access to new medicines. For example, increased demand for existing products such as vaccines, therapeutic proteins, and monoclonal antibodies, requires new paradigms for flexible and adaptive manufacturing. The opportunity to save lives through newly marketed emerging products such as cell and gene therapies will be augmented by innovations that help industrialize the scale-out of the manufacturing of these approaches. The industry also seeks improved analytical methods to streamline process development and manufacturing. Additionally, the industry faces a deficiency in the number of trained workers qualified to manufacture these complex medicines.

[4] PhRMA, *The Economic Impact of the U.S. Biopharmaceutical Industry: 2015 National and State Estimates.*



"Continued innovation is critical for developing new biopharmaceutical therapies to address key medical needs. NIIMBL provides a unique opportunity to accelerate efforts to address manufacturing challenges so that novel approaches and treatments reach and benefit patients in the future."

Dana Andersen
Vice President, Technical Development
Project & Portfolio Management
Genentech

NIIMBL provides a truly unique opportunity for industry, academic researchers, education centers, and federal agencies to collaborate on solutions to these challenges. Never before has the industry seen such a scale of investment and opportunity to address industry-wide, precompetitive challenges. The national strategy associated with Manufacturing USA combined with the broad collection of stakeholders including global manufacturers and suppliers, small innovative businesses, academic institutions, states, and nonprofits, de-risks technology development and encourages the adoption of innovative approaches to biopharmaceutical manufacturing. By coordinating, investing, and expanding on workforce training programs across the country, NIIMBL is positioned to ensure the country's leadership in this industry sector. NIIMBL's activities play a key role supporting national readiness in response to public health threats while supporting economic prosperity and enhancing patient access to medicines.

Stakeholders participate in a NIIMBL roadmapping workshop.

The biopharmaceutical industry has advanced healthcare by developing medicines that treat debilitating conditions such as cancer, autoimmune disorders, and diabetes. Beyond its importance to public health, it also significantly contributes to the U.S. economy and aids in national security.

Health Benefits

- Treats and prevents conditions such as cancer, diabetes, autoimmune disorders, and bacterial and viral infections
- Fewer side effects than traditional chemical-based medicines
- Critical in homeland security through protection from pandemic diseases and treatment of soldiers and first responders

Economic Impact*

- Directly or indirectly supports nearly 4.8 million U.S. jobs
- Direct biopharmaceutical jobs generated $104 billion in total wages
- Average annual salary of workers in direct biopharmaceutical jobs — $129,527
- Nearly $800 billion in annual economic activity

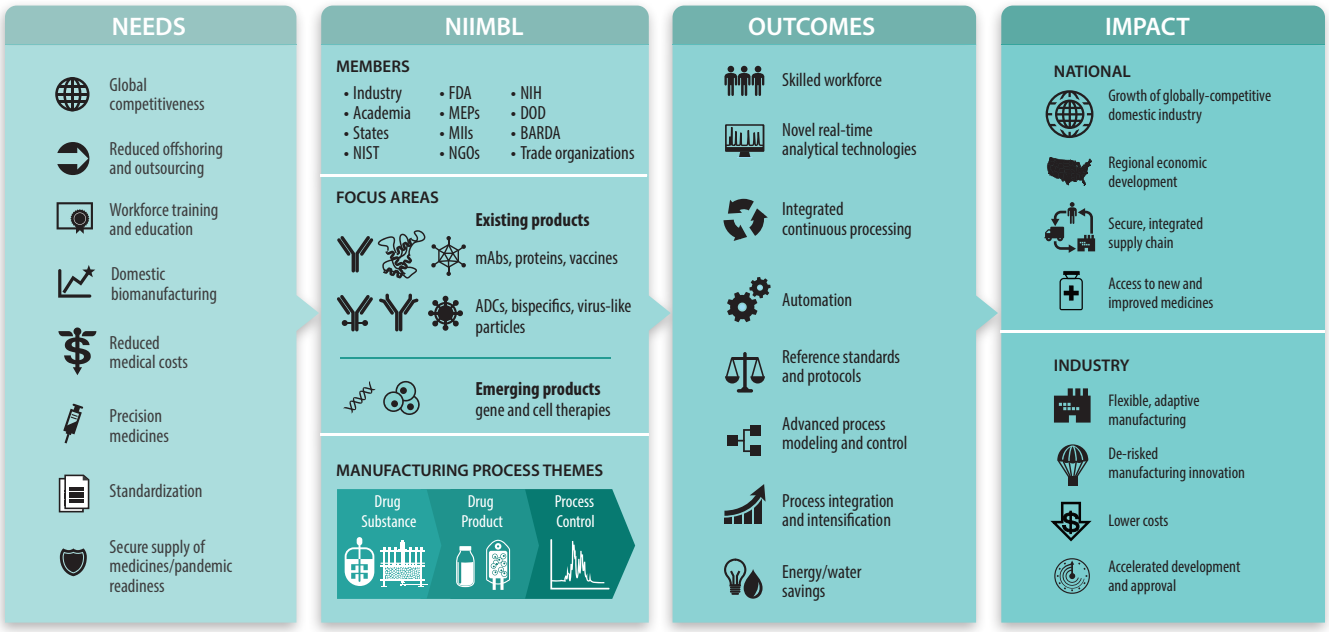
Pathways to Advancement in the U.S.

- Improved manufacturing platforms to meet growing demand for existing products
- New manufacturing platforms to commercialize life-saving, emerging products
- Increased supply of highly skilled workers
- Standards and streamlined regulatory approval
- Monitoring and analytical technologies to ensure safety and efficacy while reducing waste
- Lower costs

NIIMBL—Securing U.S. Biopharmaceutical Leadership

- Collaborative approach to develop and de-risk new manufacturing technologies
- State of the art workforce training and education programs
- Standardization of equipment, assays, parts, and methods
- Federal engagement to help streamline regulatory approval
- Support for SMEs with innovative technologies

**Source: PhRMA, The Economic Impact of the U.S. Biopharmaceutical Industry: 2015 National and State Estimates*



Facilitate the Transition of Innovative Technologies into Scalable, Cost-Effective, and High-Performing Manufacturing Capabilities

NIIMBL activities focus on achieving three paramount goals:

- To accelerate the implementation of biopharmaceutical manufacturing innovations
- To create and leverage trusted relationships to deliver meaningful and sustained outcomes
- To lead the community's demonstration of late-stage technologies for speed, quality, and cost

Technology Roadmapping

To fully understand industry's future technology needs, we place a strong emphasis on industry-led roadmaps to guide our efforts. NIIMBL will use recent roadmaps in key technology areas of biomanufacturing, including NIST-funded roadmaps in lyophilization and cell therapies, to help shape our technology agenda. We have also partnered with the BioPhorum Operations Group (BPOG) to leverage the global roadmap for antibodies.

To complement these existing roadmaps, we have also launched our own initiative to develop roadmaps in key areas of biomanufacturing: gene therapy, ADCs/bispecifics, and vaccines. The program began with a Vision Workshop in Baltimore in late November 2017 in which representatives from more than 40 organizations lent their perspectives and created a framework for the NIIMBL roadmap. Amongst the participants were large and small biomanufacturers, suppliers, SMEs, academic institutions, non-profit research organizations as well as federal agencies including NIST, FDA, and NIH. Participants created a high-level overview of the U.S. biopharmaceutical landscape and shared their perspectives on the future market trends and drivers as well as technology, workforce, and regulatory needs. Through a structured process of information capture, mapping, consolidation and voting, the participants identified the three priority topic areas for the NIIMBL roadmap. After the priority topics were established, participants began to form teams and develop a plan for writing the roadmap for each of these topics.

The workshop served as a prime example of the unique value proposition NIIMBL brings to the biopharmaceutical community. Not only did key stakeholders from industry have the chance to discuss future needs and opportunities with each other, but they were also able to network and engage in meaningful conversations with federal agencies. These conversations are the critical first steps to maximize efficiency in implementing new technologies and streamlining regulatory approval. NIIMBL provides a forum for these crucial interactions.

The NIIMBL roadmap process will continue throughout 2018 with roadmaps in the three priority topic areas scheduled for publication in the fourth quarter of 2018. Industry roadmapping will be an ongoing endeavor as NIIMBL will identify and explore additional topics on a regular cycle. The NIIMBL roadmap, along with the input of Tier 1 Industry Members, will guide future project calls.

NIIMBL advances biopharmaceutical manufacturing through technology innovation.

Photo courtesy of the University of Delaware/Evan Krape photographer

"NIIMBL represents a unique opportunity to collaborate on innovative manufacturing technologies that will advance the industry."

Greg Russotti
Vice President, Cell Therapy Process
& Analytical Development
Celgene

Project Calls & Funded Projects

Technology and workforce development projects are the fundamental activity by which NIIMBL achieves its mission. Through bi-annual project calls, Members pool their collective expertise to develop innovative solutions to industry challenges.

Our technology projects focus on three Manufacturing Process Themes:

- **Drug Substance:** Manufacturing and purification of the active biotherapeutic ingredient
- **Drug Product:** Formulation and packaging of the active ingredient into final dosage form
- **Process Control:** Analytics for process and product characterization and regulatory science to assess safety, efficacy, and quality

Project calls rely on the input of our Tier 1 Industry Members who provide direction for the Institute. The input of these large biomanufacturers and suppliers ensures we address the relevant industry needs and demonstrate a strong return on investment for our partners.

In June 2017, we issued a Quick Start Project (QSP) Call. This open-ended call invited Members to submit proposals that addressed any area of biopharmaceutical manufacturing which met the NIIMBL mission, showed a high likelihood of success, and demonstrated significant return on investment for Members. In the fall, we also offered an opportunity for our state partners to leverage their cost share dollars and propose several projects within the scope of the NIIMBL mission.

As a result of the QSP and state-initiated proposals, we elected to fund an initial portfolio of eight projects. These eight projects involve 24 unique Members and represent a combined investment of more than $14 million of NIIMBL funding and member cost-share over an 18-month period. Projects are scheduled to start during NIIMBL's second year.

We followed the QSP and state-initiated calls with Project Call 1.0 in November 2017. Project Call 1.0 featured a more refined set of technical and workforce priority areas developed with input from Tier 1 Industry Members. Proposal teams could request up to $1.5 million in NIIMBL funds with an 18-month project duration and were required to match NIIMBL funds with cost-share dollars.

NIIMBL Quick Start & State-Initiated Projects

Title	Focus Area	Manufacturing Process Theme	Impact
Flow Water Proton NMR as Contact-Free Real-Time In-Line PAT for Continuous Biomanufaturing	Existing Products	Process Control and Analytics	In-line measurement of critical quality attributes thereby enabling real-time process control Reduced time for drug substance release
Scale-up Studies on Single Use Settlers for Clarifying Cell Culture Broth	Existing Products	Drug Substance	Clarification of high cell density cultures Advancement in upstream processing using single-use disposable bioreactors Ease burden on downstream processing for high cell density cultures
Adaptive Process Control and Advanced Sensing for Robust mAb Glycan Quality	Existing Products	Process Control and Analytics	Improved process efficiency and reduced batch-to-batch variability
At-line Detection of Viral and Bacterial Contaminants in Mammalian Cell Culture Using High Affinity Probes and Label-free Single-cell Analysis	Existing Products	Process Control and Analytics	Rapid in-line detection of viral contaminants Allows for process troubleshooting and screening of raw materials, cell banks and bulk harvest materials
SPIDER Network for Automation Training	Existing Products	Workforce Development	Skilled workforce in various components of automation enables process efficiency and product consistency
Preparing for the Future: A Gene Therapy Vector Production Platform	Emerging Products	Drug Substance	Advancement of gene therapy manufacturing through platform process and skills training for adeno-associated virus vectors
Software and Hardware Tools for Pharmaceutical Lyophilization Scale-up	Existing Products	Drug Product	Development of modeling tools and sensors to enable process development and scale-up
Center of Excellence in Host-Cell Protein Analysis	Existing Products	Drug Substance	Standardized mass spectrometry-based methods for HCP detection Support for routine HCP analysis

LOOKING AHEAD

The NIIMBL Governing Committee has also elected to fund an additional $18M in projects in response to Project Call 1.0. Projects in this round of funding are scheduled to begin in 2018, pending contract negotiations.

Identification, Characterization and Removal of Host-Cell Proteins (HCP) in Chinese Hamster Ovary (CHO) Monoclonal Antibody Biomanufacturing Processes

Use of Carbon Thin Films to Reduce Leachable Contamination

The Atmospheric Spray Freeze Drying (ASFD) Project

Novel Dehydration Technology to Streamline Drug Substance Processing and Preservation

Rapid Adventitious Agent Testing for Fail-Fast Process Decision-Making

NGS Internal Controls for Adventitious Agent Testing to Ensure Sensitivity for All Targets in Every Sample

At-Bioreactor Trace Metal Quantification And Statistical Process Control In CHO Cell-Culture Production

A Novel Perfusion-Based 3D Bioreactor for Effective Selection, Activation, and Transduction of T-cells for Immunogene Therapy

A Lentiviral Vector Production Platform Process

Label-Free Critical Quality Attributes of CAR-T Cell Products

Quantitative Trilineage Differentiation Assays for cGMP Cell Manufacturing of Human Mesenchymal Stem Cells

Partnership for Workforce Development in the Biopharmaceutical Industry

Reducing Door-to-Floor: Improving Readiness of New Hires through cGMP Hands-on Biopharmaceutical Training

Stackable Credentials to Strengthen the Pipeline to Biopharma

Cell Therapy Manufacturing Courses & Certifications

Facilitate Access by Manufacturing Enterprises to Capital-Intensive Infrastructure

Shared Facilities Network

Access to shared facilities provides an important infrastructure element that is required to support the execution of technical projects and develop curriculum and related workforce activities. NIIMBL has activated a network of shared facilities available to Members for process innovation, technology platform demonstrations, workforce training, and GMP production. These shared facilities will be a resource for Members, particularly small companies, to test and develop their innovative concepts. Among this extensive network of shared facilities are the Biomanufacturing Training and Education Center (BTEC) at North Carolina State University and MassBiologics at the University of Massachusetts Medical School. We highlight these two partners below, but NIIMBL's national network extends well beyond these two distinguished resources.

Biomanufacturing Training and Education Center (North Carolina State University)

The Biomanufacturing Training and Education Center (BTEC) at North Carolina State University offers an extensive array of facilities, equipment, and resources to help NIIMBL Members solve challenges in all phases of the biomanufacturing process, including process development and analytical technology. BTEC's 82,000 square foot facility offers more than $12.5 million in industry-standard equipment and a simulated cGMP (current Good Manufacturing Practice) pilot plant facility. BTEC is also home to one of the premier biomanufacturing workforce training programs in the U.S.

The Biomanufacturing Training and Education Center (BTEC) at North Carolina State University.

MassBiologics at the University of Massachusetts Medical School

MassBiologics at the University of Massachusetts Medical School boasts over 25,000 square feet of cGMP space in its FDA licensed manufacturing facility including areas for fill finish and bulk drug substance production.

New NIIMBL Headquarters

In October 2017, the University of Delaware broke ground on its new Biopharmaceutical Innovation Building, which will include the new NIIMBL headquarters. NIIMBL will occupy 25% of the 200,000 square foot, $156M facility and will be co-located with other biopharmaceutical discovery and process development activities from the campus. This NIIMBL space will include shared laboratories for use by any project team, house NIIMBL platform process facilities, offer a NIIMBL showcase laboratory, and incorporate access to a workforce training facility.

A rendering of the new Biopharmaceutical Innovation Building at the University of Delaware.

NIIMBL provides a network of shared facilities for technology projects and curriculum development.

Photo courtesy of BTEC © North Carolina State University

"NIIMBL's dedication to workforce development, fueled by strong collaborations between academic and industry experts, is a key component to support the expansion and evolution of the biotechnology industry."

Steve Dziennik
Director, Global Technical Operations Biologics
Merck & Co.

Accelerate the Development of an Advanced Manufacturing Workforce

NIIMBL's Workforce Development Program

The biopharmaceutical industry is in the unique position of posting a negative unemployment rate, meaning there are more jobs available than qualified personnel to fill those vacancies. This situation provides a tremendous opportunity for economic growth by creating jobs for those with the skill sets sought by industry.

Through new curriculum development, online and hands-on training opportunities, and the development of certification standards, we are committed to workforce development and training programs aimed to ensure the U.S. maintains a supply of skilled workers for the domestic biopharmaceutical sector.

Our workforce development and education efforts focus on creating a skills standard to influence the future of biomanufacturing careers by:

- Collaborating with diverse industry stakeholders to identify training needs and gaps
- Expanding existing capabilities, facilities, and programs
- Developing online and on-site training opportunities
- Providing relevant skills training to a diverse workforce including those transitioning from other sectors and service members looking to establish a career in the industry

This year, we have undertaken several initiatives to achieve our workforce and education goals:

Needs Assessment

To develop effective training modules, we must first understand what skills and competencies the industry needs for the next generation of biopharmaceutical professionals. NIIMBL has engaged our partners to help us navigate the knowledge gaps in today's workforce and formulate a plan to develop curriculum and training opportunities in those areas.

Asset Mapping

Several NIIMBL Members offer robust and highly-regarded biopharmaceutical training and education programs to their communities. We have started to collect, analyze, and map these existing programs. This data will be used to assess the strengths of current education offerings and identify gaps for NIIMBL to address.

Roadmapping

Workforce and education is also a central component in our ongoing roadmapping efforts. Experts in workforce and education are actively participating in the development of our vaccine, ADCs/bispecifics, and gene therapy roadmaps. These initiatives will enhance their understanding of the workforce and education needs in those areas.

NIIMBL is revolutionizing biopharmaceutical manufacturing in the U.S. through technology advancement, standards development, and workforce training.

Photo courtesy of the University of Delaware/Evan Krape photographer

EDUCATION AND WORKFORCE TRAINING PROGRAMS

- Establishment of competency standards
- Engagement at all educational levels
- Dissemination of best practices within a national network of community colleges
- Development of custom on-site or off-site training programs
- Combination of online and in-person training in GMP environments
- Establishment of training programs and stackable credentials and certifications


Photo courtesy of the University of Delaware/Evan Krape photographer


Photo courtesy of BTEC. © North Carolina State University


Photo courtesy of BTEC. © North Carolina State University

Facilitate Peer Exchange of and the Documentation of Best Practices in Addressing Advanced Biomanufacturing Challenges

For NIIMBL's collaborative environment to thrive and advance U.S. biomanufacturing, it is essential that mechanisms are put in place to provide for the dissemination and documentation of information and best practices. We are facilitating this communication by creating several avenues for information exchange.

Teaming Events & Technical Workshops

This year, we partnered with several of our Members to host five teaming events and technical workshops throughout the country. Attended by more than 200 participants from 50 different organizations, these events centered on relevant topics in biomanufacturing and offered NIIMBL Members the opportunity to meet in-person to devise innovative solutions to potential challenges and opportunities.

Community Portal

In July 2017, we launched the NIIMBL Community Portal. This online resource facilitates partnerships by allowing Members to search for partners based on research interests, expertise, and facilities. In addition to the extensive member database, Members can also keep up to date with upcoming NIIMBL events, find new members, and view NIIMBL committee information. We continue to invest in this valuable member resource and look forward to the rollout of an expanded portal experience in 2018.

Standards Development

In addition to the peer exchange of best practices achieved through NIIMBL workshops, it is also critical that best practices are disseminated through documented standards that allow in-depth and uniform characterization of products and processes. NIIMBL will complement NIST efforts to engage industry in the development of standards for biomanufacturing. In addition, NIIMBL will develop reference materials, documentation and technical guidelines.

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2017–18
AT A GLANCE

In the past 12 months, NIIMBL set the framework to transform the biopharmaceutical industry. NIIMBL Members helped accomplish many significant milestones this year:

APR

In April, membership officially opened and has steadily grown. To date, NIIMBL is comprised of more than 80 Members from industry, academia, and non-profits, spanning 17 states across the U.S.

MAY

Nearly 300 attendees, representing close to 100 organizations, attended the inaugural National Meeting in May. In addition to remarks from senior officials, the FDA, and industry leaders, the event offered an opportunity for the community to network and collaborate in anticipation of future NIIMBL activities. During the meeting, over 30 small companies and academic institutions promoted their technology, capabilities, and research through the SME Innovation Showcase and poster sessions.

JUN

NIIMBL issued two project calls during its first year – the Quick Start Project (QSP) call and Project Call 1.0.

JUL

In July, NIIMBL launched its Community Portal, an online resource for Members to connect and learn about each other's capabilities, expertise, research interests, and facilities.

Teaming meetings were hosted by Members in San Francisco, CA and Raleigh, NC.

The teaming meetings were attended by more than 200 participants from 50 unique member organizations and provided an opportunity for Members to form partnerships in preparation for NIIMBL project calls.

SEP

NIIMBL announced a partnership with the BioPhorum Operations Group (BPOG) to develop a NIIMBL roadmap in September.

OCT

The University of Delaware broke ground on its new Biopharmaceutical Innovation Building (BPI), scheduled to open in 2020 – the site of NIIMBL's future headquarters.

NOV

The NIIMBL Roadmap program kicked off with a Vision Workshop in Baltimore, MD (November 29 – 30, 2017). More than 70 attendees represented over 40 organizations including biomanufacturers, suppliers, academic institutions, as well as federal participants from NIST, FDA, and NIH. The workshop established gene therapy, antibody drug conjugates/bispecifics, and vaccines as topics for the first edition of the NIIMBL roadmap.

Teaming meetings were hosted by Members in Cambridge, MA and Summit, NJ.

DEC

A teaming meeting was hosted by a Member in College Station, TX.

2018

FEB

NIIMBL convened several reviews for Project Call 1.0. The Governing Committee elected to fund an additional $18 million in projects.

Members Drive Our Success

NIIMBL Members shape the direction of our research and provide expertise in diverse areas of biopharmaceutical manufacturing.

As a NIIMBL member, your organization will have the opportunity to partner with industry, academia, non-profits, as well as state and federal agencies to develop methods, tools, and training programs to drive efficient, effective and safe manufacturing standards and best practices. Your organization will not only have input and involvement on NIIMBL projects, but will also benefit from the shared knowledge of its partners.

Why join NIIMBL?

Projects – Participate in NIIMBL project calls. Your organization will have the opportunity to partner with other NIIMBL members to propose and contribute to Institute-funded projects.

Networking Opportunities – Collaboration with other members will allow you to share resources and ideas.

Shared IP – Depending upon your membership level, your organization will have access to IP developed through this initiative.

Committee Seats – Membership may include seats on the Governing Committee, Technical Activities Committee, Workforce Activities Committee, or Regulatory Considerations Committee. These committees help to shape the direction of the Institute.

Learn more by visiting **www.niimbl.org**.

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