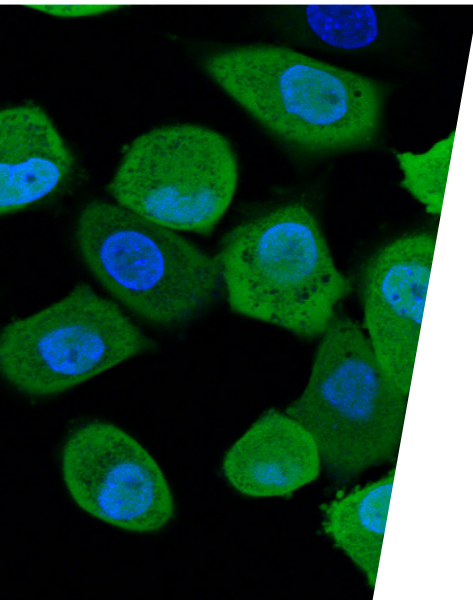


## REVOLUTIONIZING BIOPHARMACEUTICAL MANUFACTURING FOR THE NATION

NIIMBL (National Institute for Innovation in Manufacturing Biopharmaceuticals), a Manufacturing USA® institute, will stimulate leadership in advanced biopharmaceutical manufacturing research, innovation, and technology, support the development of standards, and train a world-leading workforce.

Manufacturing USA, a public-private partnership with 14 manufacturing institutes across the nation, connects companies, academic institutes, non-profits, and local, state, and federal entities to solve industry-relevant advanced manufacturing challenges in new technology areas with the goals of enhancing industrial competitiveness and economic growth and strengthening national security.



### Technology Focus Area

**Biopharmaceutical manufacturing uses the power of biological systems to create medicines that treat many debilitating illnesses such as cancer, diabetes, and autoimmune disorders.** Biopharmaceutical products include vaccines, monoclonal antibodies, and therapeutic proteins, as well as emerging types of products, such as gene and cell therapies. The industry develops and manufactures life-changing therapies for patients and contributes significantly to the US economy. However, developing a new therapy typically requires large investments in time and money, and the highly regulated nature of the manufacturing processes increases the risk for companies to innovate. Through a broad investment ecosystem, NIIMBL facilitates the development and commercialization of rapid, flexible, and cost-efficient manufacturing technologies.

### Approach to Innovation and Collaboration

Through partnerships with industry, federal scientists and regulators, and research institutions, NIIMBL creates the ecosystem needed to tackle the manufacturing challenges associated with biopharmaceutical production while ensuring product quality and consistency. This is done through:



**Technology roadmapping** for emerging products, such as gene therapies, and prioritization of needed innovation for existing products, along with the associated standards, regulatory science, and workforce development needs to successfully deploy innovation



**Balanced portfolio of projects** to move innovative manufacturing technology out of the laboratory into industrial environments with real-world applications



Engaging regulatory scientists through its **Regulatory Considerations Committee** to increase awareness of new manufacturing technologies



Network of **shared facilities** across the nation to enable members, especially small companies, to innovate and test their concepts in industrially relevant settings; facilities will include a state-of-the-art national headquarters at the University of Delaware

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Newark, Delaware  
info@niimbl.org  
niimbl.org

# COLLABORATIVE PROJECT EXAMPLES

“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 Anderson, Vice President, Technical Development Project & Portfolio Management, Genetech

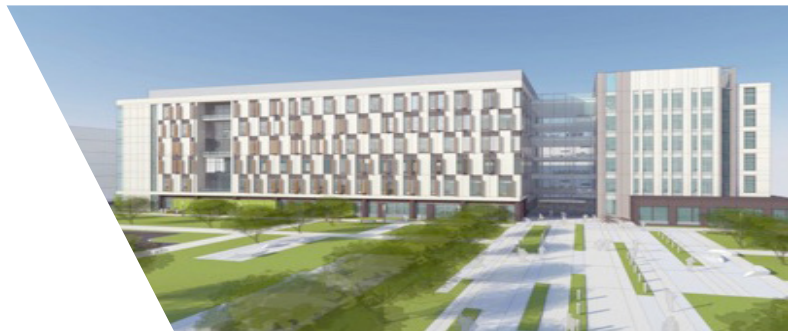


CREDIT: BTEC@North Carolina State University

**NIIMBL** projects address key advancement opportunities for existing and emerging product types. These projects focus on workforce as well as three manufacturing process themes:

1. **DRUG SUBSTANCE:** manufacturing and purification of the active biotherapeutic ingredient;
2. **DRUG PRODUCT:** formulation and packaging of the active ingredient into final dosage form; and
3. **PROCESS CONTROL:** analytics for process and product characterization and regulatory science to assess safety, efficacy, and quality.

**DIGITAL DESIGN** of the NIIMBL Headquarters building to be completed in 2020 (funded by University of Delaware and private philanthropy) which will offer shared laboratories, platform process facilities, a showcase laboratory, and access to a workforce training facility.



Credit: SmithGroupJJR

“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