

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.



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Please see the What is Biomanufacturing? video hosted at www.niimbl.org





### The NIIMBL Impact



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#### Funding of Standards \$70,000,000 \$180,000,000 National Institute of Other Commitments Standards and Technology ommitme NIST million Technology

# **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.







# Manufacturing USA network





## **Manufacturing USA® Today**



www.ManufacturingUSA.com



Content Credit: Mike Molnar, Director NIST Advanced Manufacturing Office **PROPRIETARY / CONFIDENTIAL** 

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10

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# Who are NIIMBL Stakeholders?



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#### **Education and Workforce Training Program**





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### A "Cure" for Cancer !

The first FDA-approved cell therapy. Aug 30, 2017



#### Notable 'firsts'

Penicillin (first antibiotic) Smallpox vaccine (first vaccine) ✓ NIIMBL-relevant Insulin (first recombinant protein) ✓ NIIMBL-relevant Kymriah<sup>™</sup> (first cell therapy) ✓ NIIMBL-relevant

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## **B-cell acute lymphoblastic lymphoma (ALL)**

Most common type of cancer among children.

Most can be treated with existing approaches.

On relapse (or lack of response), prognosis poor for most: 2-6 weeks.

Kymriah<sup>™</sup>: 89% live >6 months, 79% live >1 year.





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## Kymriah<sup>™</sup> is a "personalized medicine" and unlike any other cancer treatment

Chemotherapy – stop cells from dividing. Many side effects.

Antibodies – target cells cancer cells more specifically.

Cell therapies – harness one's immune system to kill cancer.





"Biopharmaceutical manufacturing provides the critical link between the discovery of a medicine and it's availability to a patient."

> <u>The 22 day Kymriah<sup>™</sup> manufacturing process</u> Go to one of 20 approved hospitals and give blood. Ship it to Morris Plains NJ. NJ facility processes it. Ship it back to hospital to dose the patient.

These medicines are a whole new future: Ava Christiansen





Please see video at: https://www.washingtonpost.com/national/healthscience/tantalizing-counterattack-offers-breakthrough-hope-forchildren-with-leukemia/2016/09/30/cf19b15a-663a-11e6-be4e-





NIIMBL is not inventing these medicines, but is innovating the manufacturing processes, supply chain, and workforce to enable patient access to these medicines.

> Novartis: B-cell acute lymphoblastic leukemia Kite: aggressive non-Hodgkin lymphoma (NHL) Juno: chronic lymphocytic leukemia (CLL) Celgene: relapsed/refractory multiple myeloma many others









## Breaking New Ground on Biopharmaceutical Innovation @STAR: A Nexus where the National Institute for Innovation in Manufacturing of Biopharmaceuticals (NIIMBL) Meets the STAR Campus Vision



### Impact of Biopharmaceutical Innovation Building

- Enhanced academic reputation, rankings and societal impact.
- New graduate programs: Ph.D., M.S. in pharmaceutical sciences; longer-term Pharm.D.
- New undergraduate programs
- Seed new public-private partnerships & accelerate growth of STAR Campus
- Philanthropy: \$50M
- By 2024, generate ~2000 new jobs in Delaware and accelerate growth of STAR Campus (estimated 660,000 to 1.1M new jobs generated nationally due to NIIMBL)

#### STAR Campus F3 Site



ELAWARE.



Groundbreaking: Oct. 2017 Opening: Jan. 2020



ELAWARE.



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ELAWARE.



ELAWARE.





