

Biomanufacturing Excellence Act of 2025

Overview

The Biomanufacturing Excellence Act of 2025 (S.3188 and H.6089) directs the National Institute of Standards and Technology (NIST) to establish a National Biopharmaceutical Manufacturing Center of Excellence (COE). This center would advance biopharmaceutical manufacturing methods to improve reliability and efficiency, engage regulators to ensure alignment with regulatory requirements, and provide workforce training opportunities.

Background

The National Security Commission on Emerging Biotechnology (NSCEB) highlighted in April 2025 that the Chinese company Wuxi AppTec is so entrenched in American biopharmaceutical supply chains that U.S. firms estimate they would need at least eight years to develop alternatives for its services. As precision medicine advances, such dependence will likely grow.

Biopharmaceutical manufacturing requires flexible and affordable infrastructure to ensure that innovative products can rapidly move from the lab to commercial-scale production. Once a manufacturing method has gained regulatory approval, a biopharmaceutical company's incentive to iterate on that method decreases, since a change could require additional regulatory scrutiny. As a result, companies may not pursue manufacturing innovations, even when they are potentially more effective or efficient.

The U.S. government has a role to play in advancing these manufacturing processes to catalyze full-scale production in the United States. Since biopharmaceutical manufacturing deals with complex living systems instead of just chemicals, like traditional small molecule pharmaceuticals, a public-private National Biopharmaceutical Manufacturing Center of Excellence would help ensure that the United States can treat and beat disease while countering China's further domination of the sector.

H.R. 6089

Sponsor:

Rep. Chrissy Houlahan (D-PA)

Original Co-Sponsors:

Rep. Jim Baird (R-IN)
Rep. Deborah Ross (D-NC)
Rep. David Rouzer (R-NC)

S. 3188

Sponsor:

Sen. Chris Coons (D-DE)

Original Co-Sponsor:

Sen. Ted Budd (R-NC)

Congress established the National Security Commission on Emerging Biotechnology (NSCEB) to assess biotechnology's national security impact and recommend strategies to ensure American leadership.

Read the NSCEB's April 2025 Report at <https://www.biotech.senate.gov/final-report>

Legislative Details

Establishment

Directs NIST to establish the COE as a public-private partnership through an open competition.

Cutting-Edge Manufacturing

Allows innovators to test innovative manufacturing methods and engage with regulators to demonstrate the cutting-edge of biopharmaceutical manufacturing, in an environment that supports Current Good Manufacturing Practice (CGMP), Quality by Design (QbD), Chemistry, Manufacturing, and Controls (CMC), and other relevant guidance.

Workforce and Education

Provides hands-on training and educational opportunities to academic and community partners to bolster biopharmaceutical talent.

Activities

- **Creates a center for innovation focused on advancing biopharmaceutical manufacturing;**
 - **Conducts research and development on and houses multi-platform and multi-product manufacturing systems; and**
 - **Prioritizes products and processes that are important to U.S. national security, health security, and economic security.**
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Endorsed by:

- Biotechnology Innovation Organization
- American Alliance for Biomanufacturing
- Delaware BioScience Association
- North Carolina Life Sciences Organization
- North Carolina Biotechnology Center
- Ohio Life Sciences Association
- Life Sciences Pennsylvania
- The Information Technology & Innovation Foundation

For more information or to co-sponsor this bill, please contact: ideas@biotech.senate.gov

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