

Opportunities and Challenges of Expanding US-based Pharmaceutical Manufacturing 2026

Schedule

Thursday, 7 May, 2026

08:45-09:00

CASSS Welcome & Virtual Summit US Manufacturing 2026 Introduction

Presentation type: V - Virtual

09:00-10:20

Session I – Infrastructure and Building

Celeste Frankenfeld, Joe Kutza

Presentation type: V - Virtual

This session will discuss:

Permitting and Construction

Preoperational and Operational Assessments

Workforce Capacity

Session Speakers:

Delivering State-of-the-Art Manufacturing Facilities at an Unprecedented Pace

Victor Cruz, *Eli Lilly and Company*

Vaughn Tunstall, *Genentech, a Member of the Roche Group*

Capability Architecture: Engineering the Future Workforce for Supply Chain Resilience

Christie Weaver, *NC BioNetwork*

Workforce Capacity & Training: Building the Pipeline for the US Biomanufacturing Wave

Jared Auclair, *Northeastern University*

10:20-10:35

Break

Presentation type: V - Virtual

10:35-12:00

Session I Panel Discussion

Celeste Frankenfeld, Joe Kutza

Presentation type: V - Virtual

Additional Panelists:

Lisa Haflett, *Merck & Co., Inc.*

12:00-12:05

Session I Summary and Closing Remarks

Celeste Frankenfeld, Joe Kutza

Presentation type: V - Virtual

12:05-13:05

Lunch Break

Presentation type: V - Virtual

13:05-13:15

Session II Welcome & Introduction

Cecilia Tami, Lisa Wright

Presentation type: V - Virtual

13:15-14:35

Session II – Regulatory Aspects

Cecilia Tami, Lisa Wright

Presentation type: V - Virtual

This session will discuss:

Post Approval Changes

Dossier, Tech Transfer, & Inspections

Session Speakers:

Post-Approval Changes: Navigating Complexity, Delivering Solutions

Nina Cauchon, *Amgen Inc.*

Building It Is the Easy Part. Changing the Playbook Is Harder

Julia Edwards, *Eli Lilly and Company*

Mary Farbman, *Merck & Co., Inc.*

Accelerating Us Manufacturing Onshoring: Eu Landscape Insights and Innovative Approaches

Karim Kacimi, *Novo Nordisk Inc.*

14:35-14:50

Break

Presentation type: V - Virtual

14:50-16:15

Session II Panel Discussion

Cecilia Tami, Lisa Wright

Presentation type: V - Virtual

Additional Panelist:

Cyrus Agarabi, *CDER, FDA*

Paresma Patel, *Gilead Sciences Inc.*

Ben Stevens, *Anylam Pharmaceuticals, Inc.*

Boris Zimmermann, *Genentech, a Member of the Roche Group*

16:15-16:30

Session II Summary & Concluding Remarks

Cecilia Tami, Lisa Wright

Presentation type: V - Virtual