

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

Board on Chemical Sciences and Technology

**VIRTUAL WORKSHOP ON TECHNICAL AND REGULATORY BARRIERS TO INNOVATIONS
IN PHARMACEUTICAL MANUFACTURING**

**HOSTED BY COMMITTEE TO IDENTIFY INNOVATIVE TECHNOLOGIES TO
ADVANCE PHARMACEUTICAL MANUFACTURING**

AGENDA

June 2, 2020

9:00 Welcome and Workshop Introduction

Gintaras Reklaitis
Purdue University

9:05 Perspective from the Office of Pharmaceutical Quality on Barriers to Innovation

Michael Kopcha
Director, Office of Pharmaceutical Quality
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Session 1: Delivering on Manufacturing Innovation: Challenges and Opportunities

Committee Moderator: Matthew DeLisa, Cornell University

Secondary Moderator: Timothy Charlebois, Pfizer

9:25 Regulatory Challenges to Pharmaceutical Innovation

Roger Nosal
Pfizer

**9:50 Innovative Strategies to Control Product Quality Attributes and Reduce Commercialization
Timelines**

Patrick Swann
Amgen

10:15 Break

10:25 The Need for Regulatory Flexibility to Support Flexible Manufacturing

Christine Moore
Merck

**10:50 A Role for Public-Private Partnerships in Advancing Biopharmaceutical Manufacturing
Innovation**

Kelvin Lee
University of Delaware

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11:15 Discussion Panel with Morning Speakers and Audience

Moderator will ask questions submitted by committee or audience members.

12:00 Lunch Break

Session 2: Blurring the Boundaries: Integration, Intensification, and Control

Committee Moderator: Stephen Hadley, Bill and Melinda Gates Foundation

Secondary Moderator: Todd Przybycien, Rensselaer Polytechnic Institute

12:30 Opening the Door to the Future – Why Continuous Manufacturing was the Key

Paul Collins
Lilly

12:55 Considerations for the Design and Construction of Next Generation Biologics Manufacturing Facilities

Jim Thomas
Just – Evotec Biologics

1:20 Janssen’s Journey Towards Improved, More Agile Manufacturing through Deployment of Sensor and Model Based Advanced Process Control: Barriers and Opportunities

Mauricio Futran
Janssen

1:45 “Right-sized” Efficient Multi-Product Manufacturing

Kerry Love
Sunflower Therapeutics

2:10 Break

2:25 The Alchemy of Process Control: Regulatory Flexibility and Supply Robustness

Kim Wolfram
Biogen

2:50 Control Strategy as a Critical Aspect of Manufacturing Innovation: Opportunities and Challenges on the Path to Implementation

Jason Starkey
Pfizer

3:15 Discussion Panel with Afternoon Speakers and Audience

Moderator will ask questions submitted by committee or audience members.

4:00 Adjourn

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June 3, 2020

9:00 Welcome to Day 2

Gintaras Reklaitis
Purdue University

Session 3: Innovative Processing Technologies

Committee Moderator: Kelley Rogers, National Institute of Standards and Technology

Secondary Moderator: Timothy Charlebois, Pfizer

9:05 Addressing Technical and Regulatory Challenges in the Development of Innovative Drug Delivery Technologies to Increase Access in Global Health Settings

Susan Hershenson and Ping Zhao
Bill and Melinda Gates Foundation

9:30 Modern Aseptic Processing – What Are You Validating and Why?

Brent Loeffers
Singota Solutions

9:55 Novel Formulations to Improve Biologics Stability

Patricia Seymour
BDO

10:20 Break

10:30 Innovative Formulations and Delivery Technologies: Practical Aspects from Development to FDA Approvals

Mansoor Khan
Texas A&M

10:55 3D Printing Pharmaceutical Dosage Forms at Commercial Scale: Aprelia's Journey

Jae Yoo
Aprelia

11:20 Innovations in Freeze Drying

Steve Nail
Baxter

11:45 Discussion Panel with Morning Speakers and Audience

Moderator will ask questions submitted by committee or audience members.

12:30 Lunch Break

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Session 4: Disruptive Technologies and Convergent Innovations

Committee Moderator: Todd Przybycien, Rensselaer Polytechnic Institute

Secondary Moderator: Christopher Earnhart, JPEO-CBRND

1:00 Perspectives from an Investor in Start-Up Life Science Industrials that Provide Fundamental Technologies and Services to Biopharma

Gustavo Mahler
Dynamk Capital

1:25 Novel Approaches to Manufacturing to Enable Rapid Response

Amy Jenkins
Defense Advanced Research Projects Agency

1:50 Perspectives from an Institutional Innovation Firm on Pioneering Life Science Platforms and Their Challenges

Noubar Afeyan
Flagship Pioneering

2:15 Discussion Panel with Afternoon Speakers and Audience

Moderator will ask questions submitted by committee or audience members.

3:00 Closing Remarks

Gintaras Reklaitis
Purdue University

3:15 *Adjourn Workshop*