

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

Board on Chemical Sciences and Technology

WORKSHOP ON INNOVATIONS IN PHARMACEUTICAL MANUFACTURING

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

The National Academy of Sciences Building, Room 120
2101 Constitution Ave, NW
Washington, DC 20418

AGENDA

THURSDAY, FEBRUARY 27, 2020

The overall goal of this workshop is to identify and discuss potential innovative technologies that could realistically be implemented in the next 5-10 years.

8:30 Welcome

Gintaras Reklaitis
Purdue University

8:40 Workshop Introduction

Janet Woodcock
Director, Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Session 1: Drug Product

Moderators: Gintaras Reklaitis, Purdue University; Matthew DeLisa, Cornell University

9:00 PCMM and Beyond—Next Gen Innovation for Solid Oral Dosage Forms

Dan Blackwood
Pfizer

9:25 Disruptive Innovation for Next Generation Biomanufacturing

Govind Rao
University of Maryland, Baltimore County

9:50 Enabling Technologies for Manufacturing Thermostable and Cost-Effective Biopharmaceuticals

Akhilesh Bhambhani
Merck

10:15 Challenges for Advanced Drug Delivery

Richard Korsmeyer
Consultant

- 10:40 ***Break/Mingle***
- 10:55 **Innovative Drug Products in the Pipeline**
David Lechuga-Ballesteros
AstraZeneca
- 11:20 Discussion Panel with Morning Speakers and Audience
- 12:20 ***Lunch Break***

Session 2: Control and Analytics

Moderators: Saly Romero-Torres, Biogen; Seongkyu Yoon, University of Massachusetts

- 1:15 **Modeling, Data Analytics, and Machine Learning for Process Development and Verification**
Richard Braatz
Massachusetts Institute of Technology
- 1:40 **Innovative Analytical Technologies and Biopharmaceutical Reference Materials**
John Schiel
National Institute of Standards and Technology
- 2:05 **A Look to the Future: Multi-Attribute Methods and Controls**
Tiffany Thiel
Amgen
- 2:30 **Harnessing the Power of Analytical Sensors in Pharmaceutical Manufacturing: Past, Present, and Future Goals**
Karin Balss
Janssen
- 2:55 ***Break/Mingle***
- 3:15 **Emerging Opportunities and Challenges in Biologics Manufacturing Digital Process Data Analytics**
Jack Prior
Sanofi
- 3:40 **Value-Focused Analytics and Digital Technology Roadmap for Advancing Biomanufacturing**
Jun Huang
Pfizer
- 4:05 Discussion with Afternoon Speakers and Audience
- 5:00 ***Adjourn***

FRIDAY, FEBRUARY 28, 2020

8:30 Welcome to Day 2

Gintaras Reklaitis
Purdue University

Session 3: Drug Substance Production

Moderators: Timothy Charlebois, Pfizer; Todd Przybycien, Rensselaer Polytechnic Institute

8:40 **Compact Factory for Drugs on Demand: Technology, Implementation, and Impact**

Salvatore Mascia
Continuus

9:05 **Innovations in Development of Synthetic Small Molecule Drug Substance**

Jean Tom
Bristol-Myers Squibb

9:30 **The Biopharmaceutical Industry's Emerging Continuous and Integrated Platform for Recombinant Protein**

Jon Coffman
AstraZeneca

9:55 **Hierarchy of High Impact Improvements in Bio Manufacturing**

Günter Jagschies
GE Healthcare (Retired), remote

10:20 Discussion Panel with Morning Speakers and Audience

Additional Panelists: Gregg Nyberg, Merck; Jorg Thommes, Gates; Andy Bommarius, Georgia Tech

11:20 *Break/Mingle*

Session 4: What's Missing?

The goal of this session is to identify innovations that might not have been discussed in earlier sessions. That is, this session provides the opportunity for “free” discussion.

11:45 Discussion Session with Speakers and Audience

12:45 Closing Remarks

Gintaras Reklaitis
Purdue University

1:00 *Adjourn Workshop*