



INNOVATIONS IN PHARMACEUTICAL MANUFACTURING ON THE HORIZON A VIRTUAL DISSEMINATION WORKSHOP

October 28 – October 29, 2021

AGENDA

DAY 1: THURSDAY, OCTOBER 28, 2021

- 9:00 **Welcome and Overview**
Linda Nhon, *Associate Program Officer*, National Academy of Sciences
- 9:10 **Innovations in Pharmaceutical Manufacturing on the Horizon: Findings, Conclusions, and Recommendations**
Gintaras Reklaitis (Study Chair), *Professor*, Purdue University
- 9:35 **Committee Reflection**
- 10:00 **Advanced Manufacturing and The Future of Pharmaceutical Quality**
Michael Kopcha, *Director of the Office of Pharmaceutical Quality*, CDER

SESSION I: ADVANCES IN MANUFACTURING INNOVATION

- 10:15 **Biopharmaceutical Manufacturing Innovations on the Horizon**
Narendra Bam, *Senior Vice President, Biopharmaceutical Product Development and Supply*, GSK
- 10:30 **Manufacturing Innovation**
Jessica Settimi, *Senior Director of Continuous Manufacturing*, Patheon by Thermo Fisher Scientific
- 10:45 **Community Discussion**
Moderated by: Gintaras Reklaitis (Study Chair), *Professor*, Purdue University

11:30 **Break**

SESSION II: EXISTING MECHANISMS TO ENABLE INNOVATION

11:45 **Enabling Innovation and Emerging Technology Program 2.0**

Larry Lee, *Deputy Director of Science, Office of Pharmaceutical Quality*, CDER
Joel Welch, *Associate Director for Science and Biosimilar Strategy*, Office of
Biotechnology Products, Office of Pharmaceutical Quality, CDER

12:00 **Existing Mechanisms to Enable Innovation**

Rohin Mhatre, *Senior Vice President Pharmaceutical Development*, Biogen

12:15 **Existing Mechanisms**

Sarah Arden, *Director of Global Regulatory Affairs*, GSK

12:30 **Community Discussion**

Moderated by: Kelley Rogers, *Technical Program Manager*, NIST

1:15 **Lunch Break**

SESSION III: CHALLENGES AND OPPORTUNITIES

2:15 **Series of Short Talks**

Moderated by: Timothy Charlebois, *Senior Fellow*, NIIMBL

- i. Tom Ransohoff, *Co-Head Biologicals Franchise*, Resilience
- ii. Dolores Hernan, *CMC Regulatory Specialist*, European Medicines Agency
- iii. Malcolm Barratt-Johnson, *Managing Director*, PharmaMedic Consultancy
- iv. Mike Hourigan, *Owner and Managing Director*, Horizon Controls Group
and International Academy of Automation Engineering

3:00 **Community Discussion**

Moderated by: Timothy Charlebois, *Senior Fellow*, NIIMBL

3:45 **Closing Remarks**

Moderated by Gintaras Reklaitis (Study Chair), *Professor*, Purdue University

4:00 **Adjourn Day 1**

DAY 2: FRIDAY, OCTOBER 29, 2021

9:00 **Welcome and Recap of Day 1**

Kelley Rogers, *Technical Program Manager*, NIST

SESSION IV: POSSIBLE SOLUTIONS AND ACTIONS

9:10 **Actions and Opportunities**

Adam Fisher, *Associate Director of Science & Outreach (Acting)*, Office of Pharmaceutical Quality, CDER

Thomas O'Connor, *Division Director*, Office of Testing and Research, Office of Pharmaceutical Quality, CDER

9:25 **Series of Short Talks**

Moderated by: Saly Romero-Torres, *Senior Director of Digital Quality Systems*, Thermo Fisher Scientific

- i. Kelvin Lee, *Institute Director*, NIIMBL
- ii. Fernando Muzzio, *Distinguished Professor*, Rutgers School of Engineering
- iii. Gillian Sanders Schmidler, *Deputy Director of Academics*, Duke-Margolis Center for Health Policy; Stephen Colvill, *Research Associate*, Duke-Margolis Center for Health Policy

10:10 **Community Discussion**

Moderated by: Saly Romero-Torres, *Senior Director of Digital Quality Systems*, Thermo Fisher Scientific

10:55 **Break**

SESSION V: A PATH FORWARD

11:10 **Workshop Synthesis: A Path Forward**

Moderated by Gintaras Reklaitis (Study Chair), *Professor*, Purdue University

11:20 **Community Discussion**

Moderated by Gintaras Reklaitis (Study Chair), *Professor*, Purdue University

11:55 **Sponsor Remarks**

Michael Kopcha, *Director of the Office of Pharmaceutical Quality*, CDER

12:05 **Closing Remarks**

Moderated by Gintaras Reklaitis (Study Chair), *Professor*, Purdue University

12:15 **Adjourn Workshop**