



Indiana Life Sciences Manufacturing 2024 Summit

Thursday, March 7, 2024

16 Tech Innovation District
Indiana Biosciences Research Institute Conference Room (First Floor)
1210 Waterway Blvd., Indianapolis, Indiana 46202
Co-hosted by Biocrossroads and the Young Institute

- 8:30-9:20 a.m. **Breakfast and Registration**
Indiana Bioscience Research Institute Conference Room (first floor)
- 9:20-9:30 a.m. **Welcome and Introduction**
Elizabeth Topp, Director, William D. and Sherry L. Young Institute for Advanced Manufacturing of Pharmaceuticals, Purdue University
- 9:30-10:10 a.m. **CDER's Perspective and Update on Advanced Manufacturing (Virtual)**
Keynote Speakers: Patrizia Cavazzoni, Director, Center for Drug Evaluation and Research, Food and Drug Administration
Sau (Larry) Lee, Deputy Director of Operations, Office of Pharmaceutical Quality, Center for Drug Evaluation and Research, Food and Drug Administration
- 10:10-10:40 a.m. **A Strategic Triad—Lilly, Government, and Academia—Powering Lilly Manufacturing to Deliver the Next Generation of Quality by Design Facilities**
Edgardo Hernandez, Executive Vice President and President of Manufacturing Operations, Eli Lilly and Company
Johna Norton, Executive Vice President, Global Quality, Eli Lilly and Company
- 10:40-11:00 a.m. **Break**
- 11:00-11:30 a.m. **Flexible Manufacturing: Innovating to Reduce Time to Patients**
Rich Osifchin, Associate Vice President, Pharmaceutical Sciences and Clinical Supply, Merck Research Laboratories
- 11:30-12:00 p.m. **Indiana CDMO Environment, Panel Discussion**
Moderator: **Brad Beach**, Senior Director, Pharma and Biotech Portfolio, Office of Industry Partnerships, Purdue University
Panelists: **Pat Adams**, Plant Manager, Bloomington, Simtra BioPharma Solutions
 Daniel Fricker, Vice President and Site Manager, Evonik Corporation
 David Wilhite, Executive Vice President, Commercial Operations, Genezen

- 12:00-12:30 p.m. **Indiana's EDA Tech Hub**
Andrew Kossack, Executive Vice President, Partnerships and General Counsel, Applied Research Institute
- 12:30-1:30 p.m. **Lunch and FDA Consortium Proposal and Breakout Session**
(led by Liz Topp, Purdue)
- 1:30-1:40 p.m. **16 Tech Innovation District**
Emily Krueger, President and CEO, 16 Tech Community Corporation
- 1:40-2:20 p.m. **A Journey to Implement Continuous Manufacturing for Biologics**
Keynote Speaker: Lucy Chang, Associate Vice President, Global Regulatory Affairs CMC Biologics, Merck & Co., Inc.
- 2:20-3:00 p.m. **AI and Pharmaceutical Manufacturing Innovation, Panel Discussion**
Moderator: **Doug Kiehl**, Senior Director, Eli Lilly and Company
Panelists: **Lucy Chang**, Associate Vice President, Global Regulatory Affairs CMC Biologics, Merck & Co., Inc.
 Gaurav Chopra, Associate Professor of Chemistry and Computer Science; Director, Merck-Purdue Center, Purdue University
 Dan Isaacs, CTO and GM: Digital Twin Consortium; Chief Strategy Officer, Object Management Group
- 3:00-3:15 p.m. **Break**
- 3:15-3:45 p.m. **Transforming Pharmaceutical Manufacturing: The Evolution of Digital Twins and AI's Vital Role**
Dan Isaacs, CTO and GM: Digital Twin Consortium; Chief Strategy Officer, Object Management Group
- 3:45-4:15 p.m. **Indiana's Key Role in Radiopharmaceutical Manufacturing**
Kevin Haehl, Chief Development Officer, Nucleus RadioPharma
- 4:15-4:45 p.m. **The Future of Indiana's Life Science Sector and Closing Remarks**
Ann Lathrop, Chief Strategy Officer, Indiana Economic Development Corporation (IEDC)