Innovative Analytical and Digital Solutions to Advance Biomanufacturing and Product Quality

Draft Agenda (as of 8/05/2021)
All times are in Eastern Daylight Time (EDT)

Day One: Tuesday, August 10, 2021: Analytical Advances

10:00 a.m. – 10:05 a.m. **Welcome and Logistics**
Maura Kibbey, Ph.D., Senior Scientific Fellow, Global Biologics, USP

10:05 a.m. – 10:15 a.m. **USP Welcome and Opening Remarks**
Fouad Atouf, Ph.D., Vice President, Global Biologics, USP

10:15 a.m. – 10:25 a.m. **Introduction and Objectives for today’s Biologics Stakeholder Forum**
Edward Chess, Ph.D., USP Biologics Stakeholder Forum Planning Committee, Chair

10:25 a.m. – 10:45 a.m. **CHO Cell Process Monitoring of Quality Attributes using Raman Spectroscopy at Manufacturing Scale**
Caitlin O'Mahony Hartnett, Ph.D., Scientist, Janssen Sciences Ireland

10:45 a.m. – 11:05 a.m. **In-line Viral Inactivation: Characterization of Key Design and Process Parameters to Ensure Effectiveness**
Michael Phillips, Ph.D., Technical Director, Next Generation Bioprocessing R&D, MilliporeSigma

11:05 a.m. – 11:25 a.m. **Enabling Real-Time Release Testing (RTRT) With Multi-Attribute Methods**
Galahad Deperalta, Ph.D., Senior Scientist and Innovation Group Leader, Analytical Development and Quality Control, Genentech

11:25 a.m. – 11:35 a.m. **Break**

11:35 a.m. – 11:50 p.m. **Q&A with the Speakers and Instructions for Breakouts**

11:50 a.m. – 12:50 p.m. **Moderated Breakout Discussions to Consider the Analytical Issues**

12:50 p.m. – 1:00 p.m. **Emerging Key Themes and Closing Remarks**
Edward Chess, Ph.D., USP Biologics Stakeholder Forum Planning Committee, Chair
Day Two: Thursday, August 12, 2021: Digital Advances

10:00 a.m. – 10:05 a.m.  Welcome and Logistics
Maura Kibbey, Ph.D., Senior Scientific Fellow, Global Biologics, USP

10:05 a.m. – 10:20 a.m.  Summary of Day 1 and Objectives for today’s Biologics Stakeholder Forum
Linda Narhi, Ph.D., USP Biologics Stakeholder Forum Planning Committee, Vice-Chair

10:20 a.m. – 10:40 a.m.  How Can In Silico Models be Accepted in Lieu of Lab Experiments & Manufacturing Runs?
Marcus Fiadeiro, Associate Director, Purification Development, Sanofi
Siddhartha Jain, Ph.D., Director, MSAT Digital, Sanofi

10:40 a.m. – 11:10 a.m.  The Potential of Hybrid Process Modeling and Digital Twins to Master the Goals of Industry 4.0 in Bioprocessing
Michael Sokolov, Ph.D., COO and Co-Founder of DataHow AG

11:10 a.m. – 11:30 a.m.  Advanced Technology for Manufacturing Process Control
Riley Myers, Ph.D., Emerging Technology Team/OPQ and Lead Biologist, Office of Biotechnology Products, CDER, US FDA

11:30 a.m. – 11:40 a.m.  Break

11:40 a.m. – 11:50 p.m.  Q&A with the Speakers and Instructions for Breakouts

11:50 a.m. – 12:50 p.m.  Moderated Breakout Discussions to Consider the Digital Issues

12:50 a.m. – 1:00 p.m.  Next Steps and Closing Remarks
Speaker: Linda Narhi, Ph.D., USP Biologics Stakeholder Forum Planning Committee, Vice-Chair