



Shaping tomorrow's solutions to today's biologics quality challenges

August 10th & 12th, 2021 | 10am – 1pm both days

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

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| 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 |



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Day Two: Thursday, August 12, 2021: Digital Advances

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| 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 |