AGENDA

USP/BioPhorum Joint Workshop

ADRESSING BARRIERS to ADOPTION

Day One: Wednesday Dec. 7, 2022 *(all times EST)*

8:00 am	**Registration & Coffee -** USP Meeting Center Lobby
8:30 am	**USP Welcome** Fouad Atouf *Vice President, Global Biologics, USP*
8:35 am	**Workshop Overview** John Kokai-Kun *Director, External Scientific Collaboration, Global Biologics, USP*
8:40 am	**Session I – Development and Control Strategies** Session Chair: Mark Schofield, *Senior R&D Manager, Pall Biotech*
8:45 am	Automation and Control of an Integrated Continuous Bioprocess, *Kurt Boenning, Pall Corp.*
9:05 am	Rapid Drug Substance Delivery of a Complex Protein Manufactured with a Perfusion Process, *Nate Ostberg, Sanofi*
9:25 am	Development Roadmap of Continuous Manufacturing Operations at Merck, *Lara Fernandez Cerezo, Merck & Co. -* ***Virtual***
9:45 am	**Session I - Panel Discussion/Q&A**
10:20 am	**Networking Break**
10:40 am	**Session II – Lessons Learned & Case Studies** Chair: Julie Kozaili, *Senior Scientist, Asahi Kasei Bioprocess*
10:45 am	Integrated Continuous Biomanufacturing in GMP Settings: Present State and Future Outlook, *Michael Coolbaugh, Sanofi -* ***Virtual***
11:05 am	MaruXTM: Deployment of a Control Strategy for a 500 L Continuous Biomanufacturing Platform, *Charlie Heise, FUJIFILM Diosynth Biotechnologies*
11:25 am	Semi-continuous Processing of Complex Biologics. A Case for Increased Productivity and Quality for Nanomedicine Production, *Joel Bruegger, Parvus Therapeutics, Inc.*

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11:45 am	**Session II - Panel Discussion/Q&A**
12:20 pm	**Networking Lunch**
1:20 pm	**Session III – Manufacturing Platforms & Strategies** Session Chair: Chris Hwang, *Chief Technology Officer, Transcenta Therapeutics Inc.*
1:25 pm	Evaluation of Fully Automated and Integrated system to Enable Next-Gen Manufacturing for Clinical Trial Material and Commercial Scale, *Irina Ramos, AstraZeneca*
1:45 pm	Development and Industrialization of Highly Intensified Connected/Continuous Biomanufacturing Platform (HiCB) to Address Patient and Business Needs, *Chris Hwang, Transcenta Therapeutics Inc.*
2:05 pm	Advancing Integrated, Continuous Manufacturing in a Flexible cGMP Facility (J.POD®), *Magnus Schroeder, Just-Evotec Biologics*
2:25 pm	Next Generation Bioprocessing (NGB) – Manufacturing and Facility Strategies, *Rob O'Keefe, Eli Lilly and Company*
2:45 pm	**Session III - Panel Discussion/Q&A**
3:20 pm –5:00 pm	**Networking Reception –** USP Lobby/Museum

Day Two: Thursday, Dec. 8, 2022

8:00 am	**Registration & Coffee -** USP Meeting Center Lobby
8:30 am	**Session IV – Regulatory Validation and Considerations** Session Chair: Kristina Pleitt, *Sr Manager, Bioproduction R&D Innovation, Thermo Fisher Scientific*
8:35 am	Designing a Small-Scale Model to Test Continuous In-Line Spiking in Virus Filtration, *Ioana Pintescu, AK Bio*
8:55 am	Opportunities in Continuous Manufacturing and the Emerging Technology Program, *Joel Welch, FDA*
9:15 am	Viral Clearance Strategies for Continuous Manufacturing, *Scott Lute, FDA*
9:35 am	Constant Flow Rate Viral Clearance Study of Planova™ BioEX Virus Removal Filter and Implementation into an End-to-End continuous Process for mAb Purification, *Hironobu Shirataki, Asahi Kasei Medical Co.*
9:55 am	**Session IV Panel Discussion/Q&A**
10:30 am	**Networking Break**

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10:50 am	**Session V – Technologies to Advance Continuous Manufacturing** Session Chair: Rich Chen, *Exec Dir Purification & Viral Safety, Eli Lilly and Company*
10:55 am	Continuous TFF Development: Equipment, Process, and Process Control, *John Moomaw, Eli Lilly and Company*
11:15 am	Towards Automated Pooling Based Upon Real-Time Aggregate Detection During Cation Exchange Bind-and-Elute Chromatography: Phase 1 Proof-of-Concept, *Daniel Some, Wyatt Technology* - ***Virtual***
11:35 am	**Networking Lunch**
12:35 pm	Utilization of Automated Aseptic Sampling for Accelerated Access to Process and Quality Data in Upstream Bioprocessing, *Jens Poschet, MilliporeSigma*
12:55 pm	A Digital Twin of an Integrated and Continuous Biomanufacturing (ICB) Process at Resilience, *Rui Wheaton and Ahsan Munir, National Resilience, Inc.*
1:15 pm	**Session V Panel Discussion/Q&A**
2:00 pm	**Workshop Wrap-up and Next Steps** John Kokai-Kun
2:15 pm	**Workshop Conclusion**