

Integrated Continuous Biomanufacturing VI

October 20 – 24, 2024
Lansdowne Resort & Conference Center, Leesburg, Virginia

PRELIMINARY PROGRAM
08-08-2024

20 October 2024 SUNDAY

13:00	Conference Check-in
15:00	Opening
15:15	Keynote – ICB life-time award Charles Cooney, MIT
16:00	Regulatory Shark Tank
17:30	Posters Snapshots
18:00	Reception
19:00	Dinner
20:30	Poster Session with dessert

21 October 2024 MONDAY

07:00	Breakfast
08:30	REGULATORY SCIENCE FOR INTEGRATED CONTINUOUS BIOMANUFACTURING Co-chairs: Manuel Osorio, FDA/CBER and Joel Welch, FDA/CDER
08:35	Accelerating industry implementation of continuous manufacturing-The key role of dual supply approach from both batch and continuous processes Takuo Kawase, Chugai Pharmaceutical
09:00	Modeling of virus contamination for integrated continuous bioprocessing to develop rational strategies for un-processed bulk sampling and downstream clearance Takao Ito, Merck Ltd., an affiliate of Merck KGaA, Darmstadt, Germany
09:25	The regulatory journey for implementation of Integrated Continuous Biomanufacturing for a commercial Enzyme Replacement Therapy product Rebecca Berger, Sanofi, United States of America

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09:50	Inert tracers for the distribution of residence time distribution in continuous processes: same properties, but still different Alois Jungbauer, BOKU University, Austria
10:15	Coffee Break
10:45	Tba Riley Myers, FDA
11:10	Regulatory Considerations for Design and Implementation of Continuous Viral Inactivation Reactors Scott Lute, FDA
11:35	KEYNOTE Peter Marks, FDA/CBER
12:20	Lunch
14:00	WORKSHOPS
15:30	ICB CONVERGENCE: CASE STUDIES IN SIMPLIFICATION AND STANDARDIZATION Co-chairs: Elizabeth Goodrich, MilliporeSigma and Joanna Pezzini, PAK BioSolutions
15:35	Novel mAb process development blueprint: Unveiling key process parameters that facilitate intensification through integrated continuous bioprocessing Mark Schofield, Cytiva, United States of America
16:00	Converting a Commercial Fed-Batch Process to Continuous Manufacturing Andrea Squeri, AstraZeneca, United States of America
16:25	Coffee Break
17:00	Co-current Filtrate Flow in Tff Perfusion Processes: Decoupling Transmembrane Pressure from Crossflow to Improve Product Sieving Thomas Villiger, FHNW, Switzerland
17:25	Low Pressure Operations as Worst-Case Situations for Viral Filtration Megan McClure, Just-Evotec, Inc, United States of America
17:50	Delivering a Flexible-Modular Skid for Integrated Continuous Purification Chad Varner, Sanofi, United States of America
18:15	Posters Snapshots
18:45	Dinner
20:30	Poster Session with dessert

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22 October 2024

TUESDAY

07:00	Breakfast
08:30	ADVANCES IN AUTOMATION, PROCESS CONTROL, AND PAT THAT ENABLE EXPANDED ICB DEPLOYMENT Co-chairs: Irina Ramos, AstraZeneca and Leon Pybus, FUJIFILM Diosynth Biotechnologies
08:35	Role of Spectroscopy for Real Time Monitoring and Control of Continuous Bioprocesses Anurag Rathore, Indian Institute of Technology Delhi, India
09:00	Autonomous operation and quality monitoring of a continuous antibody downstream process Madelene Isaksson, Lund University, Sweden
09:25	Advanced Control Strategies for Lab-Scale End-to-End Continuous Biomanufacturing Thomas Kruse, Sartorius, Corporate Research, Germany
09:50	Coffee Break
10:20	Evolving Integrated Continuous Biomanufacturing Control Strategies through Digital twins Tiago Matos, Merck, United States of America
10:45	Demonstration of an integrated and continuous monoclonal antibody purification process with capture via precipitation Matthew Mergy, Rensselaer Polytechnic Institute, United States of America
11:10	KEYNOTE (45 min) Dava Newman, MIT Media Lab, United States of America
12:55	Lunch
13:15	ROUND TABLE: LEVERAGING ICB FOR A SUSTAINABLE FUTURE Co-chairs: Sara Badr, University of Tokyo and Kerry Love, Sunflower Therapeutics
13:20	Environmental impact evaluation of fed-batch vs intensified, continuous mAb manufacturing with a life cycle assessment tool Lisa Connell-Crowley, Just-Evotec Biologics, United States of America
13:40	Innovative Solutions for an Agile and Sustainable Facility: Mechanical Recycling of Post-Use Bioprocessing Plastic Containers—Mechanical Recycling Technical Feasibility' A Sanofi/Sartorius/Veolia collaboration Miriam Monge, Sartorius, France

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14:00	<p>1-SLIDE HIGHLIGHTS (5 min)</p> <ul style="list-style-type: none">• Development of a highly concentrated supplement to decrease volumetric media demand in perfusion Mona Bausch, MilliporeSigma, Germany• Defining an ideal future for reduction, recycling and circularity of single use plastics Lisa Connell-Crowley, Just-Evotec Biologics, United States of America• Toward a truly continuous downstream using affinity nanoparticles and affinity precipitation Jon Coffman, AstraZeneca, United States of America• Leveraging Continuous Unit Operations to Enable a Higher-Yielding Virus-Like-Particle (VLP) Purification Process Adam Kristopeit, Merck & Co., Inc., United States of America
15:00	Excursion followed by dinner on your own

23 October 2024

WEDNESDAY

07:00	Breakfast
08:30	<p>WHAT'S NEW(ER): APPLICATIONS OF ICB FOR EMERGING MODALITIES Co-chairs: Stefano Menegatti, NC State University and Aravindan Ragendran, Pfizer</p>
08:35	<p>Continuous Decapping Using PAT: Stepping Towards Integrated mAb & ADC Process Rebecca Chmielowsk, Merck, United States of America</p>
09:00	<p>Model-based design of continuous reactor configurations for production of mRNA Nathan Stover, MIT, United States of America</p>
09:25	<p>Adeno-associated virus production intensification by continuous bioprocess with repeated transfections in high cell-density perfusion bioreactors Ye Zhang, KTH, Sweden</p>
09:50	<p>ECONTI - Advancing Integrated Continuous Manufacturing with Microbial Cells: An Update Juergen Mairhofer, enGenes Biotech GmbH, Austria</p>
10:15	Coffee Break
10:45	<p>Integrated continuous biomanufacturing of hiPSC-derived cardiomyocytes and extracellular vesicles Margarida Serra, IBET, Portugal</p>

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11:10	Toward a truly continuous downstream using affinity nanoparticles and affinity precipitation Jon Coffman, AstraZeneca, United States of America
11:35	KEYNOTE - Challenges and Opportunities in the Manufacturing of Cellular Protein Yaakov Nahmias, The Hebrew University of Jerusalem
12:25	Lunch
14:00	WORKSHOPS
15:30	ICB GMP IMPLEMENTATION: CELEBRATING ACHIEVEMENTS AND LESSONS LEARNED Co-chairs: Lara Fernandez-Cerezo, Merck & Co. and Jun Tian, WuXi Biologics
15:35	Next Gen Flexible Facility for ICB or Batch, Enabling Technologies and Economics John Erickson, NIIMBL, United States of America
16:00	Implementation of Integrated Continuous Biomanufacturing at Novartis - our journey David Garcia, Novartis Pharma, Switzerland
16:25	Coffee Break
17:00	GMP Implementation of Continuous Manufacturing Edward Wong, Amgen Inc, United States of America
17:25	Successful Implementation of an Integrated Continuous Process in Preparation for Commercial Launch: a Case Study Victor Liu, HJB (Hangzhou) Co., Ltd., China
17:50	Keynote – ICB Award (45 min) Chetan Goudar, Amgen
18:45	GALA DINNER

24 October 2024

THURSDAY

07:00	Breakfast and depart
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