

# **Integrated Continuous Biomanufacturing V**

Sitges, Spain  
9-13 October 2022

ISBN: 978-1-7138-8696-9

**Printed from e-media with permission by:**

Curran Associates, Inc.  
57 Morehouse Lane  
Red Hook, NY 12571



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**Sunday, October 9, 2022**

14:00 – 16:30	Conference Check-in
16:30 – 16:45	Welcome
16:45 – 17:30	<b><u>Keynote 1</u></b> <b>The Role of Digitalization in the Continuous Integrated Manufacturing of Therapeutic Proteins...N/A</b> Massimo Morbidelli, Politecnico di Milano, Italy
17:30 – 18:15	<b>Panel Session on Digitalization</b> Facilitated by Richard Braatz, Massachusetts Institute of Technology, USA  Panelists: Jennifer Pollard, Merck Sharpe & Dohme, USA Massimo Morbidelli, Politecnico di Milano, Italy Cenk Undey, Amgen Inc., USA Kevin Brower, Sanofi, USA Anurag Rathore, Indian Institute of Technology Delhi, India
18:15 – 19:00	Free Time
19:00 – 20:00	Reception (Pool Area)
20:00 – 21:30	Dinner
21:30 – 23:00	Networking

**Monday, October 10, 2022**

07:00 – 08:30 Breakfast

**Session 1: Breakthrough ICB technologies on the horizon**

*(Sponsored by YMC Process Technologies, Inc.)*

Chairs: Astrid Dürauer, BOKU, Austria  
Michael Coolbaugh, Sanofi, USA

08:30 – 08:55 **A truly continuous counter-current downstream...1**  
Jon Coffman, AstraZeneca, USA

08:55 – 09:20 **Democratizing global supply of recombinant proteins...2**  
Kerry Love, Sunflower Therapeutics, USA

09:20 – 09:45 **A fully continuous and modular monoclonal antibody purification process with capture via precipitation...3**  
Todd Przybycien, Rensselaer Polytechnic Institute, USA

09:45 – 10:10 **Exploring different medium exchange regimes in ultra scale-down models...4**  
Marie Dorn, University College London, United Kingdom

10:10 – 10:35 **2-stage continuous growth-decoupled biomolecules production using *Escherichia coli* – Towards microbial small-footprint manufacturing...5**  
Juergen Mairhofer, enGenes Biotech GmbH, Austria

10:35 – 11:15 Coffee / Networking Break *(Sponsored by Sanofi)*

**Poster Snapshot Session**

Chairs: Todd Przybycien, Rensselaer Polytechnic Institute, USA  
Mattia Sponchioni, Politecnico Di Milano, Italy  
Marcella Yu, Sutro Bio, USA

11:15 – 11:21 **Overcoming key challenges during the upstream development of a continous manufacturing process at 500L scale**  
Leon Pybus, FUJIFILM Diosynth Biotechnologies, United Kingdom

11:21 – 11:27 **Understanding factors that cause product retention and fouling of hollow fiber filters in intensified perfusion processes**  
Sri Madabhushi, Merck Sharpe & Dohme, USA

11:27 – 11:33 **Automated control of osmolality in a perfusion bioreactor system via in situ conductivity sensors**  
Amanda Ramsdell, Sanofi, USA

11:33 – 11:39 **Transcriptomics and modelling to understand the benefits of low perfusion rate**  
Meeri Mäkinen, Cell Technology Group, Industrial Biotechnology KTH, Sweden

11:39 – 11:45 **Dynamic process control of continuous twin-column chromatography**  
Giulio Lievore, ChromaCon AG, Switzerland

11:45 – 11:51 **Residence time distribution of continuous protein a chromatography**  
Narges Lali, acib- Austrian Centre of Industrial Biotechnology, Austria

**Monday, October 10, 2022 (continued)**

- 11:51 – 11:57      **Process and cost modeling approaches for manufacturing operations utilizing multi-column chromatography applications**  
Mattia Sponchioni, Bristol Myers Squibb, USA
- 11:57 – 12:03      **Process Analytical Technology (PAT) for automated, real-time control of continuous manufacturing of mAbs**  
Shantanu Banerjee, Indian Institute of Technology, Delhi, India
- 12:03 – 12:09      **Advanced control strategies for the continuous production of monoclonal antibodies**  
Markus Kampmann, Sartorius, Corporate Research, Germany
- 12:09 – 12:15      **Pilot scale technical establishment and commercial scale business case on integrated continuous biomanufacturing**  
Takuo Kawase, Chugai Pharmaceutical Co., Ltd., Japan
- 12:15 – 12:21      **Successful transition from fed-batch to continuous manufacturing within a mAb process development cycle**  
Karthik P. Jayapal, Merck Sharpe & Dohme, USA
- 12:21 – 12:27      **Establishing a highly automated and digitalized end-to-end bioprocess**  
Martin Purtscher, Baxalta Innovations GmbH, Austria
- 12:27 – 12:33      **Design & construction of a truly continuous and fully automated process skid for the production and purification of a monoclonal antibody**  
Magdalena Pappenreiter, Bilfinger Life Science GmbH, Austria
- 12:33 – 12:39      **Enhanced process control of an integrated and scalable bioprocess for production and isolation of MSC-derived extracellular vesicles for cardiac repair**  
Marta Costa, iBET, Portugal
- 12:39 – 12:45      **Plug-and-play software for mechanistic modelling of end-to-end continuous manufacturing of monoclonal antibodies**  
Moo Sun Hong, Massachusetts Institute of Technology, USA
- 12:45 – 14:00      Lunch
- Session 2: Continuous manufacturing of emerging therapeutic modalities**  
*(Sponsored by Roche)*  
Chairs: Joseph Shultz, Evelo Biosciences, USA  
Cristina Peixoto, iBET, Portugal
- 14:00 – 14:25      **The multidimensional evolution of ICB: New concepts, technology, and therapeutic modalities...N/A**  
Konstantin Konstantinov, Codiak BioSciences, USA
- 14:25 – 14:50      **Mechanistic modeling to predict titers and infected cells in the two-stage continuous production of a viral vaccine...6**  
Krystian Ganko, Massachusetts Institute of Technology, USA
- 14:50 – 15:15      **Towards an integrated continuous manufacturing process of adeno-associated virus (AAVs)...7**  
João Mendes, iBET, Portugal

**Monday, October 10, 2022 (continued)**

- 15:15 – 15:40      **Continuous manufacturing of lentiviral vectors...8**  
Dale Stibbs, University College London, United Kingdom
- 15:40 – 16:05      **Progress towards making a global supply of microbial extracellular vesicles, 100-times cheaper than a typical biologic...9**  
Collin McKenna, Evelo Biosciences, Inc., USA
- 16:05 – 16:30      **Looking beyond the horizon: Exosomes at the vanguard of integrated continuous processing of bionanoparticles...10**  
Aaron Noyes, Codiak BioSciences, USA
- 16:30 – 17:15      Coffee / Networking Break (*Sponsored by Regeneron*)
- 17:15 – 18:00      **Keynote 2**  
**A race to contain a global pandemic: The development of the Pfizer/BioNTech mRNA vaccine...N/A**  
Ranga Godavarti, Pfizer, USA
- 18:00 – 20:00      **Poster Session 1**  
*(Authors of odd-numbered posters are asked to stay with their presentations)*  
Chairs: Todd Przybycien, Rensselaer Polytechnic Institute, USA  
Mattia Sponchioni, Politecnico Di Milano, Italy  
Marcella Yu, Sutro Bio, USA
- 20:00 – 21:30      Dinner
- 21:30 – 23:00      Social Hour

## **Tuesday, October 11, 2022**

- 07:00 – 08:30 Breakfast
- Session 3: The case for ICB industrialization**  
*(Sponsored by Sanofi)*  
Chairs: Jennifer Pollard, Merck Sharpe & Dohme, USA  
Andrea Rayat, University College London, United Kingdom
- 08:30 – 08:55 **GMP implementation of continuous manufacturing: A case study...11**  
Neil Soice, Amgen, Inc., USA
- 08:55 – 09:20 **Business case for continuous mAb production with novel design strategies and enhanced control...12**  
Catarina Neves, University College London, United Kingdom
- 09:20 – 09:45 **Key enablers of continuous manufacturing success through a flexible J.POD® platform...13**  
Eva Gefroh, Just Evotec Biologics, USA
- 09:45 – 10:10 **Demonstration of a commercial scale end-to-end continuous purification process...14**  
Chad Varner, Sanofi, USA
- 10:10 – 10:35 **From lab coats to hard hats: Implementation of GMP continuous manufacturing on the road to commercial readiness...15**  
Mark Brower, Merck Sharpe & Dohme, USA
- 10:35 – 11:15 Coffee / Networking Break *(Biopharm Services Ltd)*
- 11:15 – 12:45 **Workshop 1: Standardization and modularization: A rising tide lifts all ICB processes**  
*(Sponsored by Pfizer)*  
Chairs: Paul Randolph, Janssen, USA  
Michael Phillips, Merck Life Sciences, USA
- Workshop 2: Promoting academic, industrial, government, and non-profit collaborations for next-generation biomanufacturing**  
Chairs: Kerry Love, Sunflower Therapeutics, USA  
John Erickson, NIIMBL, USA  
Veronique Chotteau, KTH, Sweden
- Workshop 3: Continuous biomanufacturing: Opportunities and challenges for a sustainable future**  
Chairs: Sara Badr, The University of Tokyo, Japan  
Priyanka Gupta, Sartorius Stedim, USA
- 12:45 – 14:45 **Poster Session 2 and Lunch**  
*(Authors of even-numbered posters are asked to stay with their presentations)*  
Chairs: Todd Przybycien, Rensselaer Polytechnic Institute, USA  
Mattia Sponchioni, Politecnico Di Milano, Italy  
Marcella Yu, Sutro Bio, USA
- 14:45 – 15:30 **Keynote 3**  
**FDA's progress in advanced manufacturing...N/A**  
Larry Lee, FDA, USA
- 15:30 – Excursion (Winery tour and tasting) followed by dinner on your own in Sitges

## Wednesday, October 12, 2022

- 07:00 – 08:30 Breakfast
- Session 4: ICB strategies to address industry challenges and opportunities**  
*(Sponsored by Cytiva)*  
Chairs: Lisa Connell-Crowley, Just-Evotec Biologics, USA  
Anurag S. Rathore, Indian Institute of Technology Delhi, India
- 08:30 – 08:55 **Process intensification: Modeling the impact of technology and process scenario selection on cost, throughput, facility volume, footprint and sustainability...16**  
Priyanka Gupta, Sartorius Stedim Biotech, USA
- 08:55 – 09:20 **Development of a flexible and modular approach for integrated continuous biomanufacturing...17**  
Michael Coolbaugh, Sanofi, USA
- 09:20 – 09:45 **Highly automated bioburden-free continuous manufacturing biologics GMP operations: How to get there?...18**  
Lara Fernandez Cerezo, Merck Sharpe & Dohme, USA
- 09:45 – 10:10 **Continuous downstream process of monoclonal antibody developed based on the process analysis/understanding and its validation...19**  
Shuichi Yamamoto, Yamaguchi University, Japan
- 10:10 – 10:35 **Intensified bioprocessing: Data, data, everywhere...20**  
Marc Bisschops, Pall Biotech, Netherlands
- 10:35 – 11:15 Coffee / Networking Break
- 11:15 – 12:45 **Workshop 4: GMP implications for fully E2E processes: Are we fulfilling our expectations?**  
Chairs: Mark Brower, Merck Sharpe & Dohme, USA  
Neil Soice, Amgen, Inc., USA
- Workshop 5: Solving the problems of ICB process development to unlock the full potential of continuous manufacturing**  
*(Sponsored by Sartorius)*  
Chairs: Steven Cramer, Rensselaer Polytechnic Institute, USA  
David Garcia, Novartis Pharma, Switzerland
- Workshop 6: Risk assessment for the adoption of ICB: What factors still stand in our way?**  
Chairs: Chris Hwang, Transcenta Therapeutics, USA  
Julie Kozaili, Asahi Kasei Bioprocess, USA
- 12:45 – 14:00 Lunch
- Session 5: Integrated control strategies to advance ICB**  
*(Sponsored by Merck)*  
Chairs: Bernt Nilsson, Lund University, Sweden  
Irina Ramos, AstraZeneca, USA
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Veronique Chotteau, KTH, Sweden



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Inês A. Isidro, iBET, Portugal
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*(Sponsored by Amgen)*  
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Christoph Herwig, TU Wien, Austria
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- 17:35 – 18:00      **Advanced process control strategies for continuous influenza viral particle production...28**  
Pavan Inguva, Massachusetts Institute of Technology, USA
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Veena Warikoo, AstraZeneca, USA
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- 19:30 – 20:30      Reception
- 20:30 – 22:30      Banquet and Awards Ceremony
- 22:30 – 23:30      Social Hour

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