

# **Integrated Continuous Biomanufacturing IV**

Brewster, Massachusetts, USA  
6-10 October 2019

## **Editors:**

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## **Sunday, October 6, 2019**

14:00 – 16:15	Conference Check-in (Upstairs landing in Mansion Ballroom)
16:15 – 16:30	Welcome
16:30 – 17:15	<b><u>Keynote</u></b> <b>Advanced manufacturing of complex biologics: A CBER perspective N/A</b> Manuel Osorio, FDA/CBER, USA
17:15 – 17:45	Coffee Break
17:45 – 19:15	<b>Workshop 1: Regulatory Gaps in Continuous Processing 1</b> Chairs: Andrew Sinclair, BioPharm Services, United Kingdom Karen Sitney, Boehringer Ingelheim, USA
	<b>Workshop 2: High-throughput Methodologies for ICB N/A</b> Chairs: Marcel Ottens, TU Delft, Netherlands Rohan Patil, Sanofi, USA
19:15 – 19:30	Stretch Break
19:30 – 20:15	Reception (Ocean Terrace, weather permitting)
20:15 – 21:30	Dinner
21:30 – 23:00	Social Hour

### **Room locations and notes**

- General Sessions will be in the Mansion Ballroom.
- Poster Sessions will be in the Carriage House (Addie Nickerson and Roland Nickerson rooms).
- Workshops on Sunday and Wednesday will be in the Carriage House (Addie Nickerson and Samuel Nickerson rooms)
- Meals will be in the Bay Pines Pavilion with the exception of Tuesday lunch (in the poster session room) and the banquet on Wednesday. The banquet will be in the Mansion Ballroom.
- Audio, still photo and video recording by any device (e.g., cameras, cell phones, laptops, PDAs, watches) is strictly prohibited during the technical sessions, unless the author and ECI have granted prior permission.
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## **Monday, October 7, 2019**

07:00 – 08:30 Breakfast

### **Session 1: Case Studies on Integration of Continuous Operations**

*Sponsored by Pfizer*

Chairs: Suzanne Farid, University College London (UCL), United Kingdom  
Joseph Shultz, Novartis, Switzerland

08:30 – 08:55 **Pushing the closed and continuous boundary: End-to-end ICB at the pilot scale 9**  
Kevin Brower, Sanofi, USA

08:55 – 09:20 **Performance evaluation of an automated and continuous antibody purification process in a side-by-side comparability study 10**  
Benjamin Maiser, Bayer AG, Germany

09:20 – 09:45 **Implementing connected processes at-scale - Challenges and opportunities for streamlining operations 11**  
Mark Brower, Merck & Co., Inc., USA

09:45 – 10:10 **Integrated continuous bioprocessing: Costs of goods versus cost of development 12**  
Hanna Mahal, University College London, United Kingdom

10:10 – 10:50 Coffee/Networking Break  
*Sponsored by Sanofi*

10:50 – 11:15 **iSKID: From integrated pilot scale runs to GMP implementation approach 13**  
Raquel Orozco, Boehringer Ingelheim, USA

11:15 – 12:00 **Keynote**  
**Development and future manufacturing of live biologicals N/A**  
John Aunins, Seres Therapeutics, USA

12:00 – 13:30 Lunch

### **Session 2: Beyond CHO and/or Proteins**

*Sponsored by GE Healthcare*

Chairs: Manuel Carrondo, iBET, Portugal  
Scott Estes, Codiak Biosciences, USA

13:30 – 13:55 **The next generation of therapeutics face dramatic challenges – is ICB an answer? 14**  
Joseph Shultz, Novartis, Switzerland

13:55 – 14:20 **Complex new modalities require advanced bio manufacturing platforms: The case of exosome biotherapeutics 15**  
Konstantin Konstantinov, Codiak Biosciences, USA

14:20 – 14:45 **Design of a periodic counter-current chromatography process for efficient oncolytic virus purification 16**  
Ricardo Silva, iBET, Portugal

**Monday, October 7, 2019 (continued)**

- 14:45 – 15:10      **Continuous mode of production for two classes of defective interfering influenza A virus particles as antiviral candidates 17**  
Marc Hein, Max Plank Magdeburg, Germany
- 15:10 – 15:35      **Towards continuous bioprocessing of lentiviral vectors 18**  
Sven Ansorge, NRC, Montreal, Canada
- 15:35 – 16:15      Coffee/Networking Break  
*Sponsored by Sartorius Stedim Biotech GmbH*
- 16:15 – 17:30      **Poster Snapshot Session**
- 17:30 – 19:00      Free time
- 19:00 – 20:30      Dinner
- 20:30 – 22:30      **Poster session # 1**  
*Sponsored by NIIMBL*  
(Authors of odd-numbered posters are asked to stay with their posters)

**Tuesday, October 8, 2019**

07:00 – 08:30 Breakfast

**Session 3: GMP Implementation of ICB Processes**

*Sponsored by Genentech*

Chairs: Nitya Jacob, Amgen, USA

Rohan Patil, Sanofi, USA

08:30 – 08:55 **The new manufacturing paradigm: Challenges and opportunities of integrated continuous bioprocessing 19**  
Matt Shields, Sanofi, USA

08:55 – 09:20 **GMP implementation of connected and continuous process at Amgen 20**  
Art Hewig, Amgen, USA

09:20 – 09:45 **Continuous bioprocessing with Ultra-high productivity to expedite biologics development 21**  
Weichang Zhou, WuXi Biologics, China

09:45 – 10:10 **Developing a flexible automated continuous downstream processing system for research to clinical supply 22**  
Louise Taylor, CPI, United Kingdom

10:10 – 10:50 Coffee/Networking Break

10:50 – 11:15 **GMP design of a single-use integrated continuous bio manufacturing system 23**  
Robert E. Kottmeier, Pfizer, USA

11:15 – 12:00 **Keynote**  
**Application of continuous processing in cell and gene therapy: Current state and future opportunities 24**  
Susan Abu-Absi, bluebird bio, USA

12:00 – 14:00 **Lunch & Poster Session #2**  
(Authors of even-numbered posters are asked to stay with their posters)

14:00 – 14:15 Stretch Break

14:15 – 19:30 Boat ride to Provincetown and dinner on your own

Buses will depart the hotel at 14:15 for the transfer to Hyannis where we will board the boat. The boat will leave at 15:30 and drop off in Provincetown. There will be time to explore the town and have dinner. After dinner, buses will transfer attendees back to the hotel from MacMillan Pier in Provincetown.

**Wednesday, October 9, 2019**

07:00 – 08:30 Breakfast

**Session 4: Digitalization and PAT for ICB**

*Sponsored by Sanofi*

Chairs: Richard Braatz, Massachusetts Institute of Technology, USA  
Alex Toda, Genentech, USA

08:30 – 08:55 **Leveraging development to advance digital and PAT technologies in manufacturing 25**  
Rick St. John, Genentech, USA

08:55 – 09:20 **Control strategies for integrated continuous bioprocessing 26**  
Christoph Herwig, TU Wien, Austria

09:20 – 09:45 **Digital transformation in bio manufacturing 27**  
Amos E. Lu, Massachusetts Institute of Technology, USA

09:45 – 10:10 **Development of scalable semi-continuous downstream processes 28**  
Xuankuo Xu, Bristol-Myers-Squibb, USA

10:35 – 11:15 Coffee/Networking Break

**Session 5: Validation of ICB Processes**

Chairs: Ana Azevedo, University of Lisbon, Portugal  
Raquel Orozco, Boehringer Ingelheim, USA

11:15 – 11:40 **Process validation approaches to continuous/connected downstream process 29**  
Huanchun Cui, Novartis Pharma AG, Switzerland

11:40 – 12:05 **Continuous virus inactivation using a packed-bed reactor 30**  
Duarte L. Martins, ACIB, Austria

12:05 – 12:30 **Continuous viral inactivation: Understanding fundamental mass transfer enables simplified virus validation 31**  
Matthew Brown, Boehringer Ingelheim, USA

12:30 – 12:55 **Viral clearance validation for a fully continuous manufacturing process for phase 1 studies 32**  
Maarten Pennings, BiosanaPharma, the Netherlands

12:55 – 13:55 Lunch

**Session 6: Methodologies for ICB Process Development**

*Sponsored by Amgen*

Chairs: Lindsay Arnold, MedImmune, USA  
Stefan Hepbildikler, Roche, Germany  
Gerald Striedner, BOKU, Austria

13:55 – 14:20 **Strategy for targeted delivery of key nutrients in high cell density perfusion 33**  
Veronique Chotteau, KTH Royal Institute of Technology, Sweden

**Wednesday, October 9, 2019 (continued)**

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Rui Manuel Freitas Oliveira, New University of Lisbon, Portugal
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David Garcia, Novartis, Switzerland
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Charles Budde, Sanofi, USA
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Christoph Brandenbusch, Technical University Dortmund, Germany
- 16:00 – 16:30      Coffee/ Networking Break
- 16:30 – 18:00      **Workshop 3: Business Cases for Integrated and Continuous Biomanufacturing 38**  
Chairs: Jessica Molek, GSK, USA  
          Daisie Ogawa, Boehringer Ingelheim Pharma, USA
- Workshop 4: Big Data Analytics for Continuous Manufacturing N/A**  
*Sponsored by MilliporeSigma*  
Chairs: Christian Airiau, Sanofi, USA  
          Christopher Herwig, TU WIEN, Austria  
          Joseph Horwitz, Amicus Therapeutics, USA
- 18:00 – 18:15      Stretch Break
- 18:15 – 19:00      **2019 ICB Award Lecture** (Introduction by Konstantin Konstantinov)  
**Automated continuous integrated manufacturing of monoclonal antibodies N/A**  
Massimo Morbidelli, ETH Zurich, Switzerland
- 19:00 – 19:45      Free time
- 19:45 – 20:30      Reception
- 20:30 – 22:30      Conference Banquet and Awards Ceremony
- 22:30 – 23:30      Social Hour

**Thursday, October 10, 2019**

- 07:00 – 09:00      Breakfast & Departure



*Posters*

# Integrated Continuous Biomanufacturing IV

October 6 – 10, 2019

Ocean Edge Resort  
Brewster (Cape Cod), Massachusetts



**Engineering Conferences International**

## Poster Presentations

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Matthias Noebel, University of Queensland, Australia
- 2 **Modeling the residence time distribution of an end to end integrated biomanufacturing process 46**  
Jure Senčar, University of Natural Resources and Life Sciences, Vienna (BOKU), Austria
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Andreas Castan, GE Healthcare, Sweden
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Oleg Shinkazh, Chromatan, USA
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Dharmesh Kanani, Teva Branded Pharmaceutical Products R&D, Inc, USA
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