Program

Integrated Continuous Biomanufacturing IV

October 6 – 10, 2019
Ocean Edge Resort
Brewster (Cape Cod), Massachusetts

Conference Chairs
Veena Warikoo
Roche, USA

Alois Jungbauer
BOKU, Austria

Jon Coffman
AstraZeneca, USA

Jason Walther
Sanofi, USA
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Previous conference in this series

Integrated Continuous Biomanufacturing
October 20 - 24, 2013
Castelldefels, Spain

Conference Chairs:
Konstantin Konstantinov, Genzyme-Sanofi, USA
Chetan Goudar, Amgen, USA
Nigel Titchener-Hooker, University College London, UK

Integrated Continuous Biomanufacturing II
November 1 - 5, 2015
Berkeley, California, USA

Conference Chairs:
Chetan Goudar, Amgen, USA
Suzanne Farid, University College London, UK
Christopher Hwang, Genzyme-Sanofi, USA
Karol Lacki, Novo Nordisk, Denmark

Integrated Continuous Biomanufacturing III
September 17-21, 2017
Cascais, Portugal

Conference Chairs:
Suzanne Farid, University College London, UK
Chetan Goudar, Amgen, USA
Paula Alves, IBET, Portugal
Veena Warikoo, Axcella Health, Inc., USA
INTEGRATED CONTINUOUS BIOMANUFACTURING AWARD WINNER

Professor Massimo Morbidelli

Highlights of Contributions to Integrated Continuous Biomanufacturing (ICB)

Massimo Morbidelli has had an outstanding professional and scientific career spanning more that 33 years. His research has addressed key scientific issues in a remarkably broad range of distinct areas including reaction engineering; catalyst design; polymer chemistry and engineering; materials characterization and synthesis; colloids and surface science; modeling of physiochemical interactions in separations; development, modeling and design of separation processes; process control; and, more recently, cell culture and continuous processing for biopharmaceutical manufacturing. With 5 co-authored books, well over 650 publications, and 20 patents, Massimo is a recognized international expert and a thought leader in many areas. He has graduated over 100 PhD students, many of whom have gone on to achieve professional excellence in many areas. Beyond academia, Massimo has been intensely involved in directing and starting up new industrial ventures, including ChromaCon AG, which is focused on continuous chromatography for protein purification, and DataHow AG, which is focused on big data analysis in bioprocessing and other industries.

Massimo has made enormous contributions to Integrated and Continuous Biomanufacturing, which have been instrumental to the scientific and practical progress of this area during the last decade. He is responsible for the invention and development of the Multi Column Solvent Gradient Process (MCSGP) process, which applies the concept of simulated continuous countercurrent operation to purification processes in the bio-pharmaceutical industry. This process has been applied to a growing list of different purifications including capture and purification of monoclonal antibodies from cell culture supernatants, purification of bispecific antibodies and antibody charge isoforms, recovery of pure peptides (Calcitonin) from crude mixtures, the production of omega-3 fatty acid ethyl ester (EPA-EE), the extraction of alpha-1-Antitrypsin from human plasma, and the separation of mono-pegylated from unpegylated and multi-pegylated proteins. Beyond continuous downstream processing, Massimo has also been responsible for the conception and development of innovative processes that couple continuous upstream and downstream steps for truly integrated and continuous bio-manufacturing. While continuous chromatography offers, on its own merits, tremendous advantages in terms of productivity and capacity utilization, even greater advantages are obtained when continuous chromatography is coupled with continuous upstream production. Massimo’s work has made it possible to achieve on a practical scale the end-to-end continuous integrated manufacturing of therapeutic proteins by integrating a perfusion bioreactor with continuous chromatographic capture chromatographic, followed by continuous viral inactivation, and by a MCSGP system for polishing. Such an end-to-end continuous flow integration, without holding tanks and with
controlled operation is indeed the goal of ICB. Massimo’s contributions have been instrumental in making this possible.

Massimo has recently co-authored (with 2 of his former PhD students) the book: D. Pfister, L. Nicoud and M. Morbidelli, *Continuous Biopharmaceutical Processes 2018*, New York, USA: Cambridge University Press. This book brings ICB in sharp focus providing the tools to understand, model, and implement continuous bioprocessing. He keeps contributing to integrated continuous biomanufacturing through his research, industrial activities, and the education of scientists and engineers in this field.

Previous Award Winner: Konstantin Konstantinov, 2017
Welcome from the Chairs

It is our great pleasure to welcome you all to Brewster (Cape Cod), Massachusetts, USA for Integrated Continuous Bioamufacturing IV. This conference is organized under the auspices of the Engineering Conferences International (ECI). ECI is a not-for-profit global engineering conferences program, originally established in 1962, that provides opportunities for the exploration of problems and issues of concern to engineers and scientists from many disciplines. ECI has held more than 2000 conferences covering a multitude of leading edge topics that are uniquely cross-disciplinary and have served the engineering/scientific community for the past 57 years.

ECI's Integrated and Continuous Biomanufacturing Conference (ICB) series is the world's premiere conference in the area of continuous biomanufacturing. In the recent past, impressive technological advances have been made to enable implementation of continuous bioprocessing across the biopharmaceutical industry. Accordingly, the focus of this conference is to build on this momentum and showcase the case studies for implementation for GMP biomanufacturing, automation, digitalization, unit operation integration, process development methodologies, and application for advanced therapy medicinal products (ATMPs). The program was developed to engage thoughtful discussion and will feature oral, poster and workshop sessions, with presenters and session chairs from academia and industry with a wide range of experience and from many countries around the world.

We would like to thank the industrial sponsors for their generous support. We also would like to thank all the board members, session chairs, and dedicated ECI staff for putting together a great program. Finally, we would like to thank all the speakers, poster authors, and attendees for providing the superb scientific content and look forward to the interactions that make this meeting so invaluable and productive. We hope you will enjoy the conference and participate to the fullest extent.

Conference Chairs:

Veena Warikoo, Roche
Alois Jungbauer, BOKU
Jon Coffman, AstraZeneca
Jason Walther, Sanofi
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Teva Pharmaceuticals
Thermo Fisher Scientific
Wuxi Biologics
YMC Process Technologies, Inc.
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 **Keynote**

*Advanced manufacturing of complex biologics: A CBER perspective*

Manuel Osorio, FDA/CBER, USA

17:15 – 17:45 Coffee Break

17:45 – 19:15 **Workshop 1: Regulatory Gaps in Continuous Processing**

Chairs: Andrew Sinclair, BioPharm Services, United Kingdom
Karen Sitney, Boehringer Ingelheim, USA

**Workshop 2: High-throughput Methodologies for ICB**

Chairs: Marcel Ottens, TU Delft, Netherlands
Rohan Patill, 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

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**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.
- Speakers – Please have your presentation loaded onto the conference computer prior to the session start (preferably the day before).
- Speakers – Please leave discussion time as previously directed by your session chair.
- Please do not smoke at any conference functions.
- Turn your mobile telephones to vibrate or off during technical sessions.
- Please write your name on your program so that it can be returned to you if lost or misplaced.
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- Emergency Contact Information: Because of privacy concerns, ECI does not collect or maintain emergency contact information for conference participants. If you would like to have this information available in case of emergency, please use the reverse side of your name badge.
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  
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  
Benjamin Maiser, Bayer AG, Germany

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

09:45 – 10:10 Integrated continuous bioprocessing: Costs of goods versus cost of development  
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  
Raquel Orozco, Boehringer Ingelheim, USA

11:15 – 12:00 Keynote  
Development and future manufacturing of live biologicals  
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?  
Joseph Shultz, Novartis, Switzerland

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

14:20 – 14:45 Design of a periodic counter-current chromatography process for efficient oncolytic virus purification  
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
Marc Hein, Max Plank Magdeburg, Germany

15:10 – 15:35  Towards continuous bioprocessing of lentiviral vectors
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
Matt Shields, Sanofi, USA

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

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

09:45 – 10:10 Developing a flexible automated continuous downstream processing system for research to clinical supply
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
Robert E. Kottmeier, Pfizer, USA

11:15 – 12:00 Keynote
Application of continuous processing in cell and gene therapy: Current state and future opportunities
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  
Rick St. John, Genentech, USA

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

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

09:45 – 10:10  
Development of scalable semi-continuous downstream processes  
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  
Huanchun Cui, Novartis Pharma AG, Switzerland

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

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

12:30 – 12:55  
Viral clearance validation for a fully continuous manufacturing process for phase 1 studies  
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  
Veronique Chotteau, KTH Royal Institute of Technology, Sweden
**Wednesday, October 9, 2019 (continued)**

14:20 – 14:45  **Process characterization for dynamic design space development: An intensified design of experiment method**  
Rui Manuel Freitas Oliveira, New University of Lisbon, Portugal

14:45 – 15:10  **High density perfused batch: Robustness and scalability of perfusion processes from lab scale to commercial scale**  
David Garcia, Novartis, Switzerland

15:10 – 15:35  **Successful scale up of an intensified perfusion process to clinical and commercial scales**  
Charles Budde, Sanofi, USA

15:35 – 16:00  **Tailor-made aqueous two-phase systems for application in continuous separation of potent biomolecules**  
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**  
Chairs: Jessica Molek, GSK, USA  
Daisie Ogawa, Boehringer Ingelheim Pharma, USA

**Workshop 4: Big Data Analytics for Continuous Manufacturing**  
*Sponsored by MilliporeSigma*  
Chairs: Christian Airiau, Sanofi, USA  
Christoph 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**  
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

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**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
Poster Presentations

1 Exploring metabolic demands of high density CHO-cell cultures
   Matthias Noebel, University of Queensland, Australia

2 Modeling the residence time distribution of an end to end integrated biomanufacturing process
   Jure Senčar, University of Natural Resources and Life Sciences, Vienna (BOKU), Austria

3 Experimental design and small-scale model for high-performing perfusion media and processes scalable to 50 L bioreactors
   Andreas Castan, GE Healthcare, Sweden

4 Elution profile from periodic counter current capture step as an on-line monitoring and control tool for perfusion bioreactors
   Daniel Komuczki, University of Natural Resources and Life Sciences Vienna (BOKU), Austria

5 Straight-through process development of up and downstream integration of monoclonal antibodies production using flocculation, AEX and one pass TFF
   Rimenys J. Carvalho, Federal University of Rio de Janeiro (UFRJ), Brazil

6 Hydrocyclones for single-use perfusion application
   Andreas Castan, GE Healthcare, Sweden

7 Flow-through chromatography as a continuous and integrated purification method
   Shuichi Yamamoto, Yamaguchi University, Japan

8 Development of integrated continuous bioprocessing using Continuous Countercurrent Tangential Chromatography (CCTC) platform for capture and polishing of monoclonal antibodies
   Oleg Shinkazh, Chromatan, USA

9 Intensifying the manufacture of hiPSC therapy products through metabolic and process understanding
   Margarida Serra, iBET, Portugal

10 Inclined plate settlers with novel receiver section as a unit operation for complex continuous solid-liquid separation problems
    Hannah Engelmaier, ACIB GmbH, Austria

11 Perfusion microbioreactor with integrated cell retention device
    Amer Al-Lozi, MilliporeSigma, USA

12 Decreasing drug development timeline via upstream process intensification
    Daisie Ogawa, Boehringer Ingelheim, USA

13 Virus reduction filtration in continuous bioprocessing: Critical flux concept for virus breakthrough
    Dharmesh Kanani, Teva Branded Pharmaceutical Products R&D, Inc, USA

14 Novel periodic alternating tangential filtration harvest approach provides increased volumetric productivity
    Sean Cole, Amgen, USA
15 **Manipulations of antibody galactosylation in a fed-batch adapted perfusion process**  
Mao-shih Liang, Teva Pharmaceuticals, USA

16 **Development of scale-down models for validation of integrated continuous virus filtrations**  
Julie Kozaili, Asahi Kasei Bioprocess, USA

17 **Continuous integrated biologics manufacturing**  
John Welsh, Pall Life Sciences, United Kingdom

18 **Perfusion process for the production of a new, VLP-based yellow fever vaccine candidate**  
Renata G. F. Alvim, Federal University of Rio de Janeiro (UFRJ), Brazil

19 **Critical quality attributes (CQAs) of a therapeutic antibody produced from integrated continuous bioprocessing**  
I-Fen Liu, Development Center for Biotechnology, Taiwan

20 **Process simulation based decisional tool to evaluate strategies for continuous downstream bioprocess implementation - A CDMO perspective**  
Kristina R. Pleitt, Patheo, USA

21 **High cell density optimization strategies for continuous bioprocesses using perfusion bioreactors**  
Jana Mahadevan, MilliporeSigma, USA

22 **Continuous process performance enhancements for 50 L to 500 L single-use bioreactors: A technical comparison of performance characterization, cell culture, and scale-up modeling**  
Tony Hsiao, Thermo Fisher Scientific, USA

23 **Apply adsorption technology to solve the UV sensor instability of dynamic control on periodic counter current purification system**  
Wei-Kuang Chi, Development Center for Biotechnology, Taiwan

24 **Acoustic Wave Separation – A non-filtration approach for continuous clarification of perfusion cell culture prior to capture chromatography**  
Peter Levison, Pall Biotech, United Kingdom

25 **Production of Zika virus-like particles (VLPs) by perfusion processes**  
Renata G. F. Alvim, Federal University of Rio de Janeiro (UFRJ), Brazil

26 **Integration of upstream and downstream for a hybrid continuous process development and manufacturing for a stable monoclonal antibody produced in CHO cell culture**  
Jianlin Xu, Bristol-Myers Squibb, USA

27 **Conversion of biomanufacturing processes from fed-batch into integrated continuous: Strategy, methods and case studies**  
Ying Jing, Novartis Pharma, Switzerland

28 **Continuous downstream process development following quality by design philosophy**  
Marc Bisschops, Pall Biotech, Netherlands

29 **Evaluation of ambr® 250 perfusion bioreactor system as a model for high-throughput perfusion cell culture process development**  
Jack Huang, Merck & Co., Inc, USA
30 **Upstream process intensification using frozen high cell density intermediates**
Luis Fernando Ayala Solares, Merck KGaA, Germany

31 **Validation aspects in the commercialization of integrated continuous biomanufacturing**
Canghai Lu, Sanofi, USA

32 **Direct inoculation of a perfusion bioreactor with a frozen intermediate seed train**
Sofie Goetschalckx, Sanofi, Belgium

33 **A Virus Harvest Unit for the continuous harvesting of lentivirus from suspension cell cultures**
Maurizio Cattaneo, Artemis Biosystems, USA

34 **Definition of a platform continuous capture scale down model and link to scale-up for monoclonal antibody clinical manufacturing**
Rebecca A. Chmielowski, Merck, USA

35 **Optimization study on periodic counter-current chromatography (PCC) integrated in a mAb downstream process**
Joaquin Gomis Fons, Lund University, Sweden

36 **Flow-velocity programmed chromatography as an alternative method for increasing the efficiency of continuous- or integrated-chromatography processes**
Chyi-Shin Chen, Yamaguchi University, Japan

37 **Continuous aqueous two-phase system extraction using oscillatory flow reactor**
Diogo Faria, Instituto Superior Técnico, Portugal

38 **Analytical and data strategy for continuous downstream manufacturing**
Mehdi Ghodbane, GlaxoSmithKline, USA

39 **Accelerated process development for integrated end-to-end biologics manufacturing**
Laura E. Crowell, Massachusetts Institute of Technology, USA

40 **The NevoLine™ manufacturing system: Intensification & integration of upstream and downstream processing in a low-footprint, automated platform for viral production**
Tania Pereira Chilima, Univercells, Belgium

41 **Integration of XCell™ ATF perfusion with single column capture chromatography for production of monoclonal antibodies**
Amit Dutta, Repligen Corporation, USA

42 **Model-based evaluation and process development of continuous chromatography**
Dong-Qiang Lin, Zhejiang University, China

43 **Developing new perfusion capabilities for ambr(R) micro and mini bioreactors**
Barney Zoro, Sartorius, United Kingdom

44 **Leveraging Sanofi intensified ICB platform to enable early process development for a labile and hard-to-express molecule**
Jiuyi Lu, Sanofi, USA

45 **Development of scale down models for perfusion bioreactor medium optimization**
Meghan E. Casey, Regeneron, USA
46 Introduction of intensified processes into the clinical supply center
   Constanze Duerr, Roche Diagnostics GmbH, Germany

47 Development of an N-1 perfusion medium to intensify seed train operation
   Luis Fernando Ayala Solares, Merck KGaA, Germany

48 A CDMO perspective toward the implementation of continuous bioprocessing stand-alone and integrated offerings
   Claudia Berdugo-Davis, Catalent Biologics, USA

49 Small-scale end-to-end mAb platform with a continuous and integrated design
   Hubert Schwarz, KTH, Sweden

50 Novel amino acid feeding strategy in perfusion cultures to enhance monoclonal antibody production
   Hubert Schwarz, KTH, Sweden

51 Continuous antibody capture step based on Magnetic Beads
   Nils Arnold Brechmann, AdBIOPRO, Competence Centre for Advanced BioProduction by Continuous Processing, Sweden

52 Implementation of an integrated continuous downstream process for a monoclonal antibody production
   Wei (Heidi) Gong, Shanghai Henlius Biotech, Inc., China