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Integrated Continuous Biomanufacturing IV

Proceedings

10-6-2019

Conference Program

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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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Engineering Conferences International (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.

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Guenter Jagschies (GE Health Sciences)
Barry Buckland (BiologicB)

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 than 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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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	<u>Keynote</u> 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 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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- Speakers – Please leave discussion time as previously directed by your session chair.
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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**
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

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



ECI 
Engineering Conferences International

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 erformance 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