

Program

Integrated Continuous Biomanufacturing II

November 1-5, 2015

**Claremont Hotel
Berkeley, CA**

Conference Co-Chairs

Chetan Goudar (Amgen Inc.)

Suzanne Farid (University College London)

Christopher Hwang (Genzyme-Sanofi)

Karol Lacki (Novo Nordisk)



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Previous conference in this series

Integrated Continuous Biomanufacturing

October 20-24, 2013

Castelldefels, Spain

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Sunday, November 1, 2015

14:00 – 16:15	Conference Check-in (Claremont Ballroom)
16:15 – 16:30	Welcome – Conference Chairs and ECI Liaison
16:30 – 17:15	<u>Keynote Lecture 1</u> Evolution of biopharmaceutical manufacturing: From discrete to the continuous paradigm Alison Moore, Amgen, USA
17:15 – 18:45	Workshops (2 in parallel) <u>Workshop 1: Business Case for Integrated Continuous Bioprocessing</u> (Sponsored by Pall Life Sciences) (Napa Room) Chairs: Suzanne Farid, University College London, United Kingdom Christopher Hwang, Genzyme, a Sanofi company, USA <u>Workshop 3: Standardization of Continuous Bioprocessing Terminology</u> (Sponsored by Lonza Biologics) (Sonoma Room) Chairs: Alois Jungbauer, University of Natural Resources and Life Sciences, Austria Veena Warikoo, Genzyme, a Sanofi company, USA
19:30 – 21:30	Dinner (Claremont Ballroom)
21:30 – 23:00	Social Hour (Sonoma Room)

NOTES

- Technical Sessions will be held in Empire Ballroom.
- Poster Sessions will be held in the Claremont Ballroom.
- Workshops 1 and 2 will be in the Napa Room. Workshops 3 and 4 will be in the Sonoma Room.
- The ECI office will be the Alumni Room.
- The Lanai and Monterey rooms will be available during the week for *ad hoc* meetings. A sign up sheet will be available to reserve the rooms.
- Meals on Monday, Tuesday and Wednesday will be in the Sonoma and Monterey Rooms. Breakfast on Thursday will be in the Empire Ballroom.
- Audiotaping, videotaping and photography of presentations are prohibited.
- Speakers – Please leave at least 5 minutes for questions and discussion.
- Please do not smoke at any conference functions.
- Turn your cellular telephones to vibrate or off during technical sessions.
- After the conference, ECI will send an updated participant list to all participants. Please check your listing now and if it needs updating, you may correct it at any time by logging into your ECI account.
- Please do not smoke at any conference functions.
- Please write your name in the front of this program booklet so it can be returned if misplaced.

Monday, November 2, 2015

07:30 – 09:00 Breakfast (Sonoma and Monterey Rooms)

09:00 – 09:45 **Keynote Lecture 2**
Introducing new technology in pharmaceutical manufacturing
Janet Woodcock, CDER, FDA, USA

09:45 – 10:15 Coffee / Networking Break

Session 1: Upstream Processing **(Sponsored by Amgen)**

Chairs: Paula Alves, IBET, Portugal
Thierry Ziegler, Sanofi, France

10:15 – 10:40 **Delivering steady-state product quality with an intensified and integrated perfusion cell culture process**
Jason Walther, Genzyme, a Sanofi company, USA

10:40 – 11:05 **Exometabolome characterization of high cell density culture perfusion and optimization of the cell specific perfusion rate**
Veronique Chotteau, KTH, Sweden

11:05 – 11:30 **Development of a first generation perfusion process and medium for continuous processing based on existing fed-batch platform media**
Henry Lin, Boehringer Ingelheim, USA

11:30 – 11:55 **Medium optimization case study for continuous upstream process**
Alan Gilbert, Biogen, USA

11:55 – 12:20 **Upstream perfusion process: Back to the future**
Jean-Marc Bielser, EMD Serono, Switzerland

12:20 – 13:45 Lunch (Sonoma and Monterey Rooms)

Session 2: Downstream Processing **(Sponsored by GE Healthcare)**

Chairs: Jens Vogel, Boehringer Ingelheim Pharma, USA
Dan Bracewell, University College London, United Kingdom

13:45 – 14:10 **Integration of continuous ethanol precipitation and flocculation into manufacturing of antibodies**
Alois Jungbauer, University of Natural Resources and Life Sciences, Austria

14:10 – 14:35 **Towards continuous aqueous two-phase extraction (CATPE)**
Andreas S. Bommarius, Georgia Institute of Technology, USA

14:35 – 15:00 **Considerations for an incubation chamber for continuous viral inactivation**
Raquel Orozco, Boehringer Ingelheim, USA

15:00 – 15:25 **Robust design and operation of quasi-continuous adenovirus purification by two-column, simulated moving-bed, size-exclusion chromatography**
José P. B. Mota, Universidade Nova de Lisboa, Portugal

15:25 – 15:50 **Continuous downstream process or connected batch process: Which one makes most sense for Biogen?**
John Pieracci, Biogen, USA

Monday, November 2, 2015 (continued)

15:50 – 16:20 Coffee / Networking Break

Session 3: Clinical and Commercial Facility Design
(Sponsored by Sartorius Stedim Biotech)

Chairs: Thomas Daszkowski, Bayer Technology Services GmbH, Germany
Patrick Sheehy, Janssen, Ireland

16:20 – 16:45 **What is holding the industry back from implementing CBP (Continuous Bioprocessing) more broadly?**
Morten Munk, NNE Pharmaplan, Denmark

16:45 – 17:10 **Evaluating facility design and capacity planning decisions for clinical and commercial supply with hybrid continuous processes**
Suzanne S. Farid, University College London, United Kingdom

17:10 – 17:35 **What are the facility design requirements to fit biologics pipeline demands?**
Thomas Sauer, Sanofi, Germany

17:35 – 18:00 **A biomanufacturing facility based on continuous processing and single use technology**
Jorgen Magnus, Bayer Technology Services, Germany

18:00 – 18:25 **Impact of closed and continuous processing on biopharmaceutical facility layouts**
Marc Pelletier, CRB, USA

18:25 – 19:00 Coffee / Networking Break

19:00 – 20:15 **Poster Snapshot Session**

Chairs: Haleh Ahmadian, Novo Nordisk, Denmark
Sa Ho, Pfizer Global R&D, USA
Chris Love, Massachusetts Institute of Technology, USA
Todd Przybycien, Carnegie Mellon University, USA

Monitoring intracellular component pools to identify steady state in mammalian cell perfusion culture (Poster 21)
Daniel Karst, ETH Zurich, Switzerland

Designing a microbial cultivation platform for continuous biopharmaceutical production (Poster 37)
Nicholas J. Mozdierz, Massachusetts Institute of Technology, USA

Continuous production of viral vaccines with a two-stage bioreactor system (Poster 32)
Felipe Tapia, Max Planck Institute Magdeburg, Germany

Mathematical modeling of a bioreactor producing Epo-hr operating in perfusion mode (Poster 30)
Osmán Fernández, Center of Molecular Immunology, Cuba

Alternating flow filtration as an alternative to internal spin filter based perfusion process: Impact on productivity and product quality (Poster 45)
Guillermina Forno, Universidad Nacional Del Litoral, Argentina

Monday, November 2, 2015 (continued)

Comparison of bioreactor systems operated at high bacterial cell density for the production of lactic acid: Batch – CSTR – CSTR cascade – Tubular reactor
(Poster 27)

Ulrich Kulozik, Technische Universität München, Germany

Continuous countercurrent tangential chromatography for purification of high value therapeutic proteins (Poster 19)

Andrew Zydney, The Pennsylvania State University, USA

Evaluation of a continuous chromatography process through process modeling and resin characterization (Poster 26)

Ketki Behere, University of Mass Lowell, USA

Design of a continuous precipitation operation for protein capture (Poster 41)

Todd Przybycien, Carnegie Mellon University, USA

Biopharmaceutical capacity planning for batch and semi-continuous bioprocesses under various strategic criteria (Poster 42)

Cyrus Siganporia, University College London, United Kingdom

Optical enzymatic sensors for continuous monitoring of bioreactors (Poster 5)

Kenneth F. Reardon, Colorado State University, USA

Advanced computational tools to enhance continuous monoclonal antibody production (Poster 4)

Maria M. Papathanasiou, Imperial College London, United Kingdom

Spectral deconvolution of chromatograms without offline analytics (Poster 1)

Matthias Rüdert, Karlsruhe Institute of Technology, Germany

20:15 – 21:45

Dinner (Sonoma and Monterey Rooms)

21:45 – 23:00

Poster Session with dessert and Social Hour

Tuesday, November 3, 2015

07:30 – 08:30 Breakfast (Sonoma and Monterey Rooms)

Session 4: Integrated Continuous Processing **(Sponsored by Pfizer)**

Chairs: Nigel Titchener-Hooker, University College London, United Kingdom
Jon Coffman, Boehringer Ingelheim Pharma, USA

08:30 – 08:55 **Innovations in bioreactor operational modes – Hybrid semi-continuous processes to push beyond the limits of conventional fed-batch cultures**
Gregory Hiller, Pfizer, Inc., USA

08:55 – 09:20 **Development of functionally closed downstream operations for continuous biomanufacturing of recombinant therapeutic proteins**
Rohan Patil, Genzyme, a Sanofi company, USA

09:20 – 09:45 **Integrated continuous bioprocessing – opportunities and challenges**
Mats Åkesson & Peter Tiainen, Novo Nordisk A/S, Denmark

09:45 – 10:15 Coffee / Networking Break

10:15 – 10:40 **Design and control of chromatography step in an integrated column sequence**
Bernt Nilsson, Lund University, Sweden

10:40 – 11:05 **Integrated continuous processing for the manufacture of monoclonal antibodies**
Massimo Morbidelli, ETH Zurich, Switzerland

11:05 – 11:30 **Continuous culture and downstream processing of algae with recycle: An integrated large-scale approach for production of renewable crude oil**
Matt Croughan, Keck Graduate Institute, USA

11:30 – 12:00 Coffee / Networking Break

12:00 – 12:45 **Keynote Lecture 3**
Continuous beer production methods: A review of chances and risks
Konrad Mueller-Auffermann, Kronos AG, Germany

12:45 – 21:00 Boxed Lunch & Free Time / Excursion (early dinner on your own before returning to hotel)
Boxed lunches can be picked up outside the hotel main entrance by the valet/shuttle area.

21:00 – 23:00 **Poster Session** with dessert and Social Hour
Chairs: Haleh Ahmadian, Novo Nordisk, Denmark
Sa Ho, Pfizer Global R&D, USA
Chris Love, Massachusetts Institute of Technology, USA
Todd Przybycien, Carnegie Mellon University, USA

Wednesday, November 4, 2015

07:00 – 08:30 Breakfast (Sonoma and Monterey Rooms)

09:00 – 10:30 **Workshops** (2 in parallel)

Workshop 2: Strategic Considerations for Technology Development in USP & DSP
(Sponsored by Biomarin)

(Napa Room)

Chairs: Art Hewig, Amgen, USA

Jim Michaels, BioMarin, USA

Workshop 4: Scale-up/Scale-down and QbD Challenges

(Sonoma Room)

Chairs: Ajoy Velayudhan, University College London, United Kingdom

Chun Zhang, Shire, USA

10:30 – 11:00 Coffee / Networking Break

Session 5: PAT, Monitoring and Control
(Sponsored by LEWA Process Technologies)

Chairs: Marcel Ottens, Delft University, The Netherlands

John Pieracci, Biogen Idec, USA

11:00 – 11:25 **Monitoring and control of reproducibility in quasi-continuous integrated production processes of Active Pharmaceutical Ingredients**

Reiner Luttmann, Hamburg University of Applied Sciences, Germany

11:25 – 11:50 **Protein Refinery Operations Lab (PRO Lab): A sandbox for continuous protein production & advanced process control**

Mark Brower, Merck & Co., Inc., USA

11:50 – 12:15 **The use of dynamic control in periodic counter current chromatography**

Hans Blom, GE Healthcare, Sweden

12:15 – 12:40 **Leveraging large data sets in continuous chromatography applications: Monitoring critical process parameters using MVDA**

Marc Bisschops, Pall Corporation, The Netherlands

12:40 – 13:05 **PAT concepts for chromatography: Real-time monitoring, real-time control, and cause of error diagnostics**

Nina Brestrich, Karlsruhe Institute of Technology, Germany

13:05 – 14:45 Lunch (Sonoma and Monterey Rooms)

Session 6: Vaccine and Cell Therapy Processing
(Sponsored by the Bill & Melinda Gates Foundation)

Chairs: James Piret, University of British Columbia, Canada

Barry Buckland, University College London, United Kingdom

14:45 – 15:05 **Dynamic oncolytic measles virus production**

Tanja A. Grein, Institute of Bioprocess Engineering and Pharmaceutical Technology, Germany

15:05 – 15:30 **How continuous-like processes improve affordability for viral vaccines - Example of LAIV**

Jose Castillo, Univercells, Belgium

Wednesday, November 4, 2015 (continued)

- 15:30 – 15:55 **Small-scale platform for rapid on-demand manufacturing of recombinant proteins**
J. Christopher Love, Koch Institute at MIT, USA
- 15:55 – 16:20 **Exploring continuous and integrated strategies for the up- and downstream processing of human mesenchymal stem cells**
Paula M. Alves, iBET/ITQB-UNL, Portugal
- 16:20 – 16:50 Coffee / Networking Break
- Session 7: Regulatory Considerations**
 (Sponsored by Sanofi)
 Chairs: Mark Heintzelman, Genzyme, a Sanofi company, USA
 Kurt Brorson, Food and Drug Administration, USA
- 16:50 – 17:15 **CDER's emerging technology team**
Kurt Brorson, CDER, FDA, USA
- 17:15 – 17:40 **Quality systems for continuous manufacturing**
Ron Branning, RBC LLC, Quality Systems Consulting, USA
- 17:40 – 18:05 **Regulatory challenges of continuous biomanufacturing**
Andrew N. Papas, NSF Health Sciences Pharma Biotech Consulting, USA
- 18:05 – 18:30 **A regulatory perspective on continuous perfusion production of rFVIII**
Robert Kozak, Bayer HealthCare, USA
- 18:30 – 19:00 Coffee / Networking Break
- 19:00 – 19:45 **Keynote Lecture 4**
 Transforming the present into the future with uncertainty and imprecision
Charles Cooney, Massachusetts Institute of Technology, USA
- 20:30 – 22:30 Conference Banquet and Poster Awards (Sonoma and Monterey Rooms)
- 22:30 – 23:30 Social Hour

Thursday, November 5, 2015

07:00 – 09:30 Breakfast (Empire Ballroom) and departures

WORKSHOP SESSIONS

Workshop 1: Business Case for Integrated Continuous Bioprocessing **(Sponsored by Pall Life Sciences)**

Chairs: Suzanne Farid, University College London, United Kingdom
Christopher Hwang, Genzyme, a Sanofi company, USA

There is a growing interest in exploring and developing integrated continuous bioprocesses (ICB) for the production of biologics as evident by a significant increase in the number of companies and academic labs working on it over the past few years. Among the many strategic advantages of ICB, many cite lowering costs (capital expenditure and/or operating expenses), flexible capacity management, operational flexibility, minimizing tech transfer risks, and enhanced product quality as primary drivers for ICB.

In this workshop, we would like to explore these and other business drivers for implementing ICB. We will be tapping into your experiences on these two core themes and insights to answer questions such as:

Theme 1: Drivers for integrated continuous bioprocessing

1. What business and operational drivers are important to you and why?
(e.g., COG, cost of development, overall lifecycle profitability, development timeline, risk, flexibility)
2. How would you rank these drivers for ICB implementation for early phase versus commercial manufacture? How would this influence your recommendation?
3. How do you envisage ICB impacting development timeline drivers (process development, tech transfer, process characterization, PV/PPQ batches)?
4. What kind of decision-making tools do you use to measure the impact of ICB on key business and operational drivers?

Theme 2: Developing a business case for integrated continuous bioprocessing

1. How do you develop a business case that captures the key drivers for ICB so as to convince senior management?
2. What challenges have you faced in convincing senior management to adopt ICB? Can you share lessons learnt on building a business case?
3. How do you capture intangible benefits such as “flexibility” when operating multiproduct facilities into your business case?
4. How might a business case for ICB differ between a small and a large company?

Our goal is to facilitate a lively and interactive discussion where we encourage open dialogue and sharing of experiences from all participants. Please feel free to forward comments to us for additional suggestions and prioritization of topics for the group to tackle ahead of the meeting.

Workshop 2: Strategic Considerations for Technology Development in USP and DSP **(Sponsored by Biomarin)**

Chairs: Art Hewig, Amgen, USA

Jim Michaels, BioMarin, USA

Implementation of continuous manufacturing in the biopharmaceutical industry will require the development of key technologies in upstream and downstream processing. One important aspect is defining strategic goals to determine which key enabling technologies to invest in. Without a clear strategy it is difficult to refine technology development efforts and this can result in diluted efforts and limited progress. Two examples of key strategic considerations include facility constraints (footprint, capital investment, liquid handling, staffing/automation) and portfolio mix (predicted mass needs per program, number of programs, new modalities). These types of strategic considerations help to focus efforts put into specific mass output, bioreactor perfusion rates, continuous purification adoption, as well as the level of process and automation complexity employed. The aim of this workshop is to showcase, discuss, and explore how specific technology development efforts in upstream and downstream can help fulfill these specific strategic goals.

Workshop 3: Standardization of Continuous Bioprocessing Terminology **(Sponsored by Lonza Biologics)**

Chairs: Alois Jungbauer, University of Natural Resources and Life Sciences, Austria

Veena Warikoo, Genzyme, a Sanofi company, USA

Those who have started to have a closer look on integrated continuous biomanufacturing have pretty soon come to the question “how continuous is continuous?” To establish the technology in industry we need to communicate with different groups and stakeholders. Industry must file license applications to health agencies, vendors must sell products and processes to industry and academia must communicate new research and train new scientists and engineers. There is definitely a need to define terminology in this field. We will start from the very basic concepts of real continuous, pseudo-continuous, quasi-continuous to a more sophisticated engineering terminology including definitions of reactor types and states of reactions in continuous bioprocessing. In this workshop these terms will be openly discussed between participants from industry and academia.

Workshop 4: Scale-up/Scale-down and QbD Challenges

Chairs: Ajoy Velayudhan, University College London, United Kingdom

Chun Zhang, Shire, USA

Scalability is a critical issue for conventional batch bioprocessing, and considerable work has been done to evaluate scale-up and scale-down for various unit operations. Similar studies are needed for continuous unit-operations. This session will focus on experimental and theoretical approaches to scalability of single steps and sequences of steps relevant to bioprocessing. Since control of continuous steps is particularly important, contributions are also sought on the related issue of Quality by Design. Evaluation of critical process parameters for continuous steps is of particular interest.

Poster Presentations

Analytics & Control

1. **Spectral deconvolution of chromatograms without offline analytics**
Matthias Rüdts, Karlsruhe Institut für Technologie, Germany
2. **PAT concepts for the process monitoring and control of continuous biomanufacturing**
Eike Zimmermann, Boehringer-Ingelheim, USA
3. **Suitability of select in-line single-use sensors for PAT in continuous processing**
James Furey, PendoTECH, USA
4. **Advanced computational tools to enhance continuous monoclonal antibody production**
Maria M. Papathanasiou, Imperial College London, United Kingdom
5. **Optical enzymatic sensors for continuous monitoring of bioreactors**
Kenneth F. Reardon, Colorado State University, USA
6. **Optimal control of a continuous bioreactor for maximized beta-carotene production**
M. Nazmul Karim, Texas A&M University, USA
7. **Strategy for scaling semi-continuous downstream and integration of process analytical tools for monoclonal antibody toxicology**
Darshini Shah, Merck Research Laboratories, USA

Integrated Processes

8. **Continuous production of proteins: Integration of polishing using MCSGP**
Fabian Steinebach, ETH Zurich, Switzerland
9. **Process time and cost savings achieved through automation and islands of integration in existing facilities.**
Lynne Frick, Pall Life Sciences, United Kingdom
10. **Tools for process intensification upstream and continuous processing downstream**
James Rusche, Repligen Corporation, USA
11. **Integrated solutions for continuous processing in Mobius® bioreactor systems**
Andrew Clutterbuck, Merck Millipore, France
12. **Laboratory scale continuous linear purification as a development tool for recombinant blood protein processing, using chromatographic resins and membranes**
Rimenes J. Carvalho, Federal University of Rio De Janeiro, Brazil
13. **Integrated and single use continuous manufacturing**
Atul Mohindra, Lonza, United Kingdom
14. **Enabling technologies for integrated / continuous downstream processing of biologics**
Jeff Salm, Pfizer, USA

Process Technologies

15. **Design criteria and requirements for development of perfusion media**
Jochen B. Sieck, Merck KGaA, Germany
16. **GlycoExpress: A toolbox for the high yield production of glycooptimized fully human biopharmaceuticals in perfusion bioreactors at different scales**
Steffen Kreye, Glycotope GmbH, Germany
17. **Genomics based methodology of cell-culture media formulation for improved bio-therapeutic productivity and quality consistency**
Hemlata Bhatia, University of Massachusetts, Lowell, USA
18. **Novel compact cell settlers for continuous perfusion bioreactor cultures of microbial (and mammalian) cells**
Dhinakar Kompala, Sudhin Biopharma Company, USA
19. **Continuous countercurrent tangential chromatography for purification of high value therapeutic proteins**
Andrew Zydney, The Pennsylvania State University, USA
20. **Factors affecting the productivity of 4-Column Periodic Counter Current Chromatography (4C-PCC)**
Laura Fagan, Actavis Biologics Ltd., United Kingdom
21. **Monitoring intracellular component pools to identify steady state in mammalian cell perfusion culture**
Daniel Karst, ETH Zurich, Switzerland
22. **Simple method transfer from batch to continuous chromatography process to fit parameters to business needs**
Rene Gantier, Pall Life Sciences, USA
23. **EcoPrime twin – Scale-up of CaptureSMB to the process scale**
Kathleen Mihlbachler, LEWA Process Technologies, USA
24. **A novel plant cell culture platform for semicontinuous production of recombinant proteins: Butyrylcholinesterase as a case study**
Karen A. McDonald, University of California, Davis, USA
25. **Case study: Optimisation of a stabilised large scale atf perfusion process**
Jarno Robin, Novo Nordisk, Denmark
26. **Evaluation of a continuous chromatography process through process modeling and resin characterization**
Ketki Behere, University of Mass Lowell, USA
27. **Comparison of bioreactor systems operated at high bacterial cell density for the production of lactic acid: Batch – CSTR – CSTR cascade – Tubular reactor**
Ulrich Kulozik, Technische Universität München, Germany
28. **Scale up and implementation of a high density long-term perfusion suspension cell culture in a 250L single use bioreactor**
Weichang Zhou, WuXi AppTec Co., Ltd, China

29. **BioSC® predict simulation software: FLExibility and optimization of your multi-column process**
Fabien Rousset, Novasep, France
30. **Mathematical modeling of a bioreactor producing Epo-hr operating in perfusion mode**
Osmán Fernández, Center of Molecular Immunology, Cuba
31. **Efficient approaches for perfusion medium development**
Andreas Castan, GE Healthcare Life Sciences, Sweden
32. **Continuous production of viral vaccines with a two-stage bioreactor system**
Felipe Tapia, Max Planck Institute Magdeburg, Germany
33. **Continuous downstream processing of a monoclonal antibody using Periodic Counter Current Chromatography (PCC) and Straight Through Processing (STP)**
Hans Blom, GE Healthcare, Sweden
34. **Bioprocess economics and optimization of continuous and pre-packed disposable chromatography**
Richard Allmendinger, University College London, United Kingdom
35. **Modeling perfusion at small scale using ambr15™**
Delia Lyons, SAFC, USA
36. **Evaluation of novel CEX resin for continuous processing of MAb purification**
Takuya Muramoto, Takeda Pharmaceutical Company Limited, Japan
37. **Designing a microbial cultivation platform for continuous biopharmaceutical production**
Nicholas J. Mozdierz, Massachusetts Institute of Technology, USA
38. **Continuous purification of hepatitis C virus-like particles by multi-column chromatography**
José Mota, FCT-UNL, Portugal
39. **BHK cells physiological response to spin-filter stress condition**
Aldo Tonso, University of Sao Paulo, Brazil
40. **mAb product consistency achieved in long duration microfiltration-based CHO perfusion process**
Douglas Rank, EMD Millipore, USA
41. **Design of a continuous precipitation operation for protein capture**
Todd Przybycien, Carnegie Mellon University, USA
42. **Biopharmaceutical capacity planning for batch and semi-continuous bioprocesses under various strategic criteria**
Cyrus Siganporia, University College London, United Kingdom
43. **Salt-tolerant cation exchange HD-Sb hydrogel membrane: mAb purification performance in flowthrough mode**
Annabel Shang, Natrix Separations Inc., Canada
44. **Toward complete continuity in antibody biomanufacture: Multi-column continuous chromatography for Protein A capture and mixed mode hydroxyapatite polishing**
Anthony C. Grabski, Semba Biosciences, Inc., USA

45. **Alternating flow filtration as an alternative to internal spin filter based perfusion process: Impact on productivity and product quality**
Guillermina Forno, Universidad Nacional Del Litoral, Argentina
46. **Pilot scale hybrid fed batch and continuous processing of biologics**
Dave Sullivan, Pfizer, USA
47. **From fed-batch to perfusion: Productivity and quality considerations for a late-stage program**
Sen Xu, Merck Research Laboratories, USA