Program

Integrated Continuous Biomanufacturing

A New ECI Conference

October 20-24, 2013

Gran Hotel Rey Don Jaime
Castelldefels, Spain

Conference Co-Chairs
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**Sunday, October 20, 2013**

15:00 – 16:45  Conference Check-in
16:45 – 17:00  Welcome – Conference Chairs and ECI Liaison

**Session 1: Continuous Processing: Learning from Related Industries**
Session Chairs: Nigel Titchener-Hooker (University College London)
Chetan Goudar (Amgen Inc.)

17:00 – 17:30  **The amazing ability of continuous chromatography to adapt to a moving environment**  
*Roger-Marc Nicoud, Founder of Novasep, Consultant*

17:30 – 18:00  **Semi-continuous manufacturing of personal care liquids**  
*Peter Divone, Unilever*

18:00 – 18:45  **Keynote Lecture:** The promise of continuous bioprocessing  
*Konstantin Konstantinov, Genzyme-Sanofi*

19:00 – 20:00  Welcome reception
20:00 – 21:30  Dinner

**NOTES**

- Please do not smoke at any conference functions.
- Turn your mobile telephones to vibrate or off during technical sessions.
- Technical sessions will be in the Auditorium in the Conference Center.
- Poster sessions will be in the Conference Center lobby.
- Meals will be in the hotel restaurant.
- Be sure to check your contact information on the Participant List in this program and make any corrections to your name/contact information online. A corrected copy will be sent to all participants after the conference.
Monday, October 21, 2013

07:00 – 08:30 Breakfast

Session 2: Upstream Processing
Session Chairs: Veronique Chotteau (Royal Institute of Technology)
               Gerben Zijlstra (DSM Biologics B.V.)

08:30 – 09:00 Desiccated cellular composites could enable modular continuous upstream
biomanufacturing
Michael C. Flickinger, North Carolina State University

09:00 – 09:20 Continuous and semi-continuous cell culture for production of blood clotting
factors
Sunil Desai, Pfizer

09:20 – 09:50 Upstream process development, control, and scale-up of steady-state, high cell
density, perfusion processes for continuous manufacturing
Timothy Johnson, Genzyme-Sanofi

09:50 – 10:10 Coffee Break
Sponsored by Regeneron

10:10 – 10:40 Multiplicity of steady states in continuous culture of mammalian cells
Wei-Shou Hu, University of Minnesota

10:40 – 11:00 Case study: Challenges and learning in implementing ATF perfusion process
Jarno Robin, Novo Nordisk

11:00 – 13:00 Free Time for discussion / leisure

13:00 – 14:00 Lunch

Session 3: Downstream Processing
Sponsored by Sanofi
Session Chairs: Alois Jungbauer (University of Natural Resources and Life
Sciences)
               Brian Hubbard (Amgen Inc.)

14:00 – 14:30 Twin column CaptureSMB: A novel cyclic process to increase the capacity
utilization in protein A chromatography
Massimo Morbidelli, ETH Zurich

14:30 – 14:50 Continuous chromatography: Disruptive technology for downstream processing
Fabien Rousset, Novasep

14:50 – 15:10 A process for next generation antibody production: Cold ethanol precipitation and
calcium-phosphate flocculation of recombinant antibodies
Nikolaus Hammerschmidt, University of Natural Resources and Life Sciences Vienna

15:10 – 15:30 Coffee break

15:30 – 15:50 Continuous antibody capture with protein A countercurrent tangential
chromatography: A new column-free approach for antibody purification
Andrew Zydney, Pennsylvania State University
Monday, October 21, 2013 (continued)

15:50 – 16:10 Nanofibres for high productivity downstream processing
Oliver Hardick, Puridify

16:10 – 16:30 A new, integrated, continuous purification process template for monoclonal antibodies
Alex Xenopolos, EMD Millipore

16:30 – 18:00 Workshop 1: Addressing the Process and Economic Dimensions
Workshop Chairs: Suzanne Farid (University College London)
Andrew Sinclair (BioPharm Services)

18:00 – 18:15 Stretch break

18:15 – 19:00 Keynote Lecture: Fully automated end-to-end continuous manufacturing of small molecule pharmaceuticals and implications for biologics
Bernhardt Trout, Massachusetts Institute of Technology

19:00 – 20:00 Poster viewing and/or free time

20:00 – 21:30 Dinner

21:30 – 23:00 Poster Viewing / Social Hour
Poster Chairs: Richard Biener (University of Applied Sciences, Esslingen)
James Michaels (BioMarin)
Tuesday, October 22, 2013

07:00 – 08:30  Breakfast

**Session 4: Case Studies of Integrated Continuous Processing in Practice**

*Sponsored by GE Healthcare Bio-Sciences*

Session Chairs: Bernhard Helk (Novartis Pharma AG)
Veena Warikoo (Genzyme-Sanofi)
Jens Vogel (Boehringer Ingelheim)

08:30 – 09:00  Integrated and scalable cyto-technology (InSCyT) platform for biopharmaceutical manufacturing on demand

*Chris Love, Massachusetts Institute of Technology*

09:00 – 09:20  Single-use systems supporting continuous biomanufacturing for current and “next-gen” products

*William Whitford, Thermo Fisher Scientific*

09:20 – 09:40  New approaches in continuous biomanufacturing: Continuous XD® cell cultures (At 100 million cells/mL and beyond) coupled to the Rhobust® EBA integrated clarification and purification technology

*Gerben Zijlstra, DSM Biologics B.V*

09:40 – 10:00  Platform downstream processes in the age of continuous chromatography: A case study

*Mark Brower, Merck & Co.*

10:00 – 10:20  Coffee break

*Sponsored by Bayer AG*

10:20 – 10:40  End-to-end continuous production of complex recombinant proteins integration of perfusion cultivation and automated multi-step purification

*Peter Tiainen, Novo Nordisk A/S*

10:40 – 11:00  How to purify a monoclonal antibody in one shot: continuous chromatography applied to the entire purification process

*Laure Landric-Burtin, Sanofi*

11:00 – 11:20  Continuous processing in biotech production as an alternative to a modern batch, single-use facility

*Thomas Daszkowski, Bayer Technology Services*

11:20 – 11:45  Stretch break

11:45 – 12:30  Keynote Lecture: Biologicals for global health: The case for lower cost drugs

*Stephen Hadley, Bill and Melinda Gates Foundation*

13:00 – 14:00  Lunch

14:00 – 15:00  Free time for discussion / leisure
### Session 5: PAT, Process Modeling, Monitoring and Control
Session Chairs: Thomas Scheper (University of Hannover), Reinhard Baumfalk (Sartorius Weighing Technology GmbH)

15:00 – 15:30  
**PAT for real time monitoring and control of continuous drug manufacturing process: Lessons learned**  
*Peter McDonnell, Sanofi*

15:30 – 15:50  
**Requirements for process control of continuous processes: sensorics and automation**  
*Marek Hoehse, Sartorius Stedim Biotech GmbH*

15:50 – 16:10  
**From design of experiments to closed loop control**  
*Petter Moree, Umetrics*

16:10 – 16:30  
**A label-free methodology for selective in-line quantification of co-eluting proteins in chromatography by means of spectral data**  
*Nina Brestrich, Karlsruhe Institute of Technology*

16:30 – 17:00  
Coffee Break

### Session 6: Process Validation and Regulatory Considerations
Sponsored by Amgen
Session Chairs: Chantal Cazeault (Amgen Inc.), Mark Heintzelman (Genzyme-Sanofi)

17:00 – 17:30  
**Integrated continuous biomanufacturing: Quality and regulatory considerations**  
*Chantal Cazeault, Amgen Inc.*

17:30 – 17:50  
**A quality perspective on continuous biomanufacturing**  
*Frank Lammers, Sanofi*

17:50 – 18:10  
**Technological, regulatory, and validation considerations for single-use downstream processing**  
*Marc Bisschops, Tarpon Biosystems Europe B.V.*

18:10 – 18:30  
**A regulatory perspective on continuous perfusion production of rFVIII**  
*Robert W. Kozak, Bayer HealthCare LLC*

18:30 – 20:00  
Break

20:00 – 21:30  
Dinner

21:30 – 23:00  
Poster Viewing / Social Hour
Wednesday, October 23, 2012

07:00 – 08:30  Breakfast

Session 7: Clinical and Commercial Facility Design for Continuous Biomanufacturing
Session Chairs: Thomas Daszkowski (Bayer AG)
Marc Pelletier (CRB)

08:30 – 09:00  Operational and economic evaluation of integrated continuous biomanufacturing strategies for clinical and commercial antibody production
Suzanne S. Farid, University College London

09:00 – 09:20  Implementing process closure and continuous processing into the modern biopharmaceutical future facility
Marc Pelletier, CRB

09:20 – 09:50  Data management and control strategies for continuous bioproduction
Kjell Francois, Siemens AG

09:50 – 10:20  Coffee Break
Sponsored by Sartorius Stedim Biotech GmbH

10:20 – 10:40  Facility drivers for housing start-to-finish continuous bioprocessing: Disruptive changes in scale and operational expectations vs. traditional batch operations
Bradley E. Kosiba, BK Collaborative, LLC

10:40 – 11:00  Building a business case for fully integrated continuous biomanufacturing platform
Jason Walther, Genzyme-Sanofi

11:00 – 13:00  Free time for discussion / leisure

13:00 – 14:00  Lunch

Session 8: Continuous Processing in Vaccine Manufacturing, Stem Cells, and Microbial Cultures
Session Chairs: James Piret (University of British Columbia)
Jean-Marc Guillaume (Sanofi-Pasteur)

14:00 – 14:30  Options for continuous production of cell culture-derived viral vaccines
Udo Reichl, Max Planck Institute for Dynamics of Complex Technical Systems

14:30 – 14:50  Sequential/parallel production of potential Malaria vaccines - a fast way from single batch to quasi continuous processing
Reiner Luttmann, Hamburg University of Applied Sciences

14:50 – 15:10  Bioengineering approaches for up- and down-stream processing of human stem cells for clinical application
Margarida Serra, ITQB-UNL/IBET

15:10 – 15:30  Optimization of T cell expansion in a perfusion bioreactor
Clive Glover, GE Healthcare UK Limited

15:30 – 16:00  Coffee Break
Wednesday, October 23, 2012 (continued)

16:00 – 16:45  
**Keynote Lecture: Matching Flows: The development of continuous bioprocessing, new initiatives in the approval of bioproducts, and assurance of product quality throughout the product lifecycle**  
*Jeffrey Baker, FDA*

16:45 – 18:15  
**Workshop 2: New Modalities, Enabling Technologies and Unit Operations**  
Workshop Chairs:  
Uwe Gottschalk (Sartorius-Stedim Biotech)  
Karol Lacki (GE HealthCare)

20:00 – 22:30  
Conference Banquet and Poster Awards
Thursday, October 24, 2012

07:00 – 09:30 Breakfast and departures
Poster List

1. **Continuous matrix-assisted refolding separation of self-cleaving fusion proteins by SMB size-exclusion chromatography with buffer recycling**
   Nicole Walch, ACIB GmbH

2. **Tubespin bioreactors for rapid media optimization of a late stage perfusion cell culture process: A case study**
   Joseph Peltier, BioMarin Pharmaceutical

3. **A continuous precipitation process for high titer monoclonal antibody capture and purification**
   Todd M. Przybycien, Carnegie Mellon University

4. **Quality characterization of monoclonal antibody produced under different bioreactor processes conditions**
   Wei-Kuang Chi, Development Center for Biotechnology

5. **Connected antibody purification process with integrated low pH hold step**
   Alex Xenopoulos, EMD Millipore

6. **Twin column Capture SMB: A novel cyclic process to increase the capacity utilization in protein A chromatography**
   Monica Angarita, ETH Zürich

7. **Small scale media optimization for continuous culture - effect on cellular metabolism**
   Daniel Karst, ETH Zürich

8. **Performance comparison of multi-column countercurrent capture processes**
   Thomas Muller-Spath, ETH Zürich

9. **Perfusion cultures of BHK cells using an internal spin-filter**
   Leda R. Castilho, Federal University of Rio de Janeiro (UFRJ)

10. **Rotating cylindrical filters: CFD modeling and use in large-scale perfusion cultivations**
    Leda R. Castilho, Federal University of Rio de Janeiro (UFRJ)

11. **Predicting the conductivity of a buffer by Kohlrausch's law: Continuous bioprocessing applications**
    Roger Nordberg, GE Healthcare

12. **Continuous chromatographic technology aimed at vaccine applications using core bead chromatography for reduction of ovalbumin impurities**
    Karol Lacki, GE Healthcare Life Sciences

13. **Pseudo-continuous production of potential malaria vaccines by integration of bioreaction, expanded bed adsorption and fixed bed chromatography**
    Sven-Oliver Borchet, Hamburg University of Applied Sciences

14. **Integrated analytical proteomic tools provide new insights into human cardiac stem cells characterization throughout bioprocessing**
    Margarida Serra, IBET/ITQB
15. Challenges and solutions of continuous, scalable cultivation for anchorage dependent 
cells in single use bioreactors  
Margarida Serra, IBET/ITQB

16. A simplified micro bioreactor model to mimic perfusion culture  
David Ho, Irvine Scientific

17. Model-based integrated optimization of multi-step ion exchange chromatography  
Anna Osberghaus, Karlsruhe Institute of Technology (KIT)

18. Achievement of extreme cell densities in different perfusion systems and impact of the 
cell density  
Veronique Chotteau, KTH

19. Optical sensors for monitoring mammalian cell cultivation processes  
David Bulnes Abundis, Leibniz Universität

20. Continuous bioprocessing: A CMO's perspective  
Colin Jaques, Lonza Biologics

21. A simple strategy for continuous viral inactivation  
Mark Brower, Merck & Co Inc.

22. Bench top continuous chromatography: An enabling platform for bioprocess development  
Robert C. Mierendorf, Semba Biosciences, Inc.

23. Repeated transient transfection extends production time and increases production in HEK 
293 suspension cell cultures  
Laura Cervera, Universitat Autònoma de Barcelona

24. Process economics optimization of single-use and semi-continuous chromatography for 
FAB manufacture  
Richard Allmendinger, University College London

25. Multi-objective optimisation of biopharmaceutical production plans consisting of batch 
and semi-continuous bioprocesses  
Cyrus Siganporia, University College London

26. Robustness and regulatory considerations in the development of a continuous bioprocess 
unit-operation  
Ajoy Velayudhan, University College London

27. Continuous production of friulimicin by actinoplanes friuliensis  
Richard Biener, University of Applied Sciences Esslingen

28. Precipitation: A powerful tool for continuous purification of monoclonal antibodies  
Ralf Sommer, University of Natural Resources and Life Sciences Vienna

29. Improved quality and productivity in pseudo-perfusion cultures of 
self-degradation protein (t-PA)  
Masami Yokota, Astellas Pharma

30. Continuous bioprocessing: The factory of the future an economic perspective?  
Paul Sinclair, Biopharm Services Ltd.
31. Continuous countercurrent tangential chromatography for antibody purification
   Andrew Zydney, The Pennsylvania State University