Program

Integrated Continuous Biomanufacturing

A New ECI Conference

October 20-24, 2013

Gran Hotel Rey Don Jaime
Castelldefels, Spain

Conference Co-Chairs
Konstantin Konstantinov, Genzyme-Sanofi
Chetan Goudar, Amgen Inc.
Nigel Titchener-Hooker, University College London
Gran Hotel Rey Don Jaime
Avda. del Hotel, 22
08860 Castelldefels, Spain
donjaime@grup-soteras.com
www.grup-soteras.com
Tel: +34 93 665 13 00
Fax: +34 93 664 51 51
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.

ECI BOARD MEMBERS

Barry C. Buckland, President  
Peter Gray  
Michael King  
Raymond McCabe  
David Robinson  
William Sachs  
Eugene Schaefer  
P. Somasundaran  
Deborah Wiley

Chair of ECI Conferences Committee: William Sachs  
ECI Technical Liaison for this conference: Barry Buckland

ECI Executive Director: Barbara K. Hickernell  
ECI Associate Director: Kevin M. Korpics

©Engineering Conferences International
Conference Sponsors

Amgen
Bayer Healthcare
Bayer Technology Services
Biotechnology and Bioengineering (Wiley)
Boehringer Ingelheim
Broadley-James Corporation
CRB
DSM
EMD Millipore
Gallus Biopharmaceuticals LLC
GE Healthcare Bio-Sciences
Genzyme
Groupe Novasep
Lilly
Novo Nordisk
Pall Corporation
Refine Technology
Regeneron
Sanofi Aventis R & D
Sartorius Stedim Biotech GmbH
ThermoFisher Scientific


**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 Zydny, 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: Biologics 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
Tuesday, October 22, 2013 (continued)

**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

16:30 – 17:00  
**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 Borchart, 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