

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



**Engineering Conferences International
32 Broadway, Suite 314
New York, NY 10004, USA
Phone: 1-212-514-6760, Fax: 1-212-514-6030
www.engconfintl.org – info@engconfintl.org**

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

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 Zydney, Pennsylvania State University

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

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
- 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 Borchert, 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 Zydny, The Pennsylvania State University