

*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**



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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*



**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 Sigantoria, 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