



Continuous Biomanufacturing: Achievements and Challenges for Commercial Implementation

Lady Margaret Hall,
University of Oxford, Oxford, UK
20th-22nd June, 2018

www.subramanian.org.uk



A WARM INVITATION TO COME AND JOIN US IN OXFORD

I invite you to join us at the fifth annual international conference on Continuous Biomanufacturing which will be held at Lady Margaret Hall, University of Oxford, Oxford, UK. On 20th- 22nd June 2018. Continuous biomanufacturing requires the ability to think laterally and have a proactive mindset across the entire team from development to production. Today Biopharma industries accept Continuous Manufacturing Process as a novel approach to efficiently and economically produce a therapeutic product. However there are some bottlenecks still to overcome. Single use continuous processing has yet to tick all the boxes from the industry's viewpoint. Over the last few years interest in continuous bioprocessing has grown considerably due to the ongoing developments of technologies and advancing their application to meet the needs of the manufacturers. Such is the interest that several leading Biopharma companies together with vendors and academics are developing the technologies to apply in their manufacturing process. The conference is enhanced by the participation of 32 leading industrial technologists, scientific vendors and also leading academics from Europe and USA. They have come forward to share their experience and knowledge to provide a better understanding of the current technologies and their application in continuous biomanufacturing. There are also two plenary lectures, an invited lecture and case studies and workshops by distinguished scientists.

By joining us you will also benefit from access to unpublished data. This meeting will address several advancements and their successful application with data, and project to the future direction of the industry. By joining with us you can benefit from the current state-of-the-art advancements in continuous manufacturing and also learn about the successful organisations that are developing these methods in-house. Together we will drive change, innovate growth and pioneer smarter technologies to ensure they reach their full potential.

I look forward to welcoming you at Lady Margaret Hall with beautiful surroundings in the historic city of Oxford.

Dr G.Subramanian

Sponsored by



* The life science business of Merck KGaA, Darmstadt, Germany operates as MilliporeSigma in the U.S. and Canada.

WEDNESDAY 20TH JUNE

12.00 Noon

Registration and Canopy reception

Plenary Lecture

Chairman Dr G Subramanian

12.30pm

“Review of achievements, future opportunities and critical implementation aspects with integrated continuous biomanufacturing”

Dr Guenter Jagschies, GE Healthcare Life Sciences, Germany.

1.15pm

**Next generation bioprocessing
Evolution to intensified mAb processing:
enabling technologies, gaps and digital
integration**

Dr. Mike Felo, Merck, Bedford, MA, USA.

Upstream

Materials and Equipment

Chairman Dr Christopher Gillespie

1.45pm

Progress on perfusion culture CD media

Dr. Bill Whitford, Strategic Solutions Leader Cell Culture, Bioprocess, GE Healthcare, USA.

2.15pm

Mini Perfusion-SUB for mammalian cell retention in a fully single-use setup

Per Stobbe, PerfuseCell, Malmlosevej, Denmark.

2.45pm

Analytical approaches for design and control in continuous biomanufacturing”

Dr. Ganesh V. Kaundinya, Co-founder and CSO, Momenta Pharmaceuticals Inc., USA.

3.15pm

Refreshments and Networking

Upstream

Process monitoring and control

3.45pm

Process modeling considerations for process intensification and continuous processing

Dr. Mike Phillips, Merck, Bedford, MA, USA.

4.15pm

Enabling continuous upstream bioprocessing using tunable promoters and model predictive control

Dr Slouka Christoph, Vienna University of Technology, Institute of Chemical Environmental and Biological Engineering, A-1060 Wien, Austria.

4.45pm

Online dielectric spectroscopy for PAT monitoring of viable cell culture in continuous biomanufacturing

David Anderson, European Sales Manager, Aber Instruments Ltd., UK.

Downstream

Materials and Equipment

Chairman Dr Parrish Galliher

5.15pm

Case studies of implementation of TFF and ATF in continuous and intensified processes

Shashi Kudugunti M.S., PhD, Sr. Application Scientist, Repligen Corporation, USA.

5.45pm

Batch versus continuous chromatography at 100-gram scale: Protein A affinity purifications of CHO expressed monoclonal antibody

Anthony C. Grabski, Ph.D. Director of R&D, Semba Biosciences, Inc. USA.

6.15pm

“Using SPTFF to intensify downstream processing such as chromatography steps”

Herb Lutz, Merck, Bedford, MA, USA.

6.45pm

Chairman Helena Nordvarg

GEHealthcare

Workshop: Obstacles preventing taking the next step towards ICB

8.00pm

Dinner - Monson Room

THURSDAY 21ST JUNE

Plenary Lecture

Chairman Dr G Subrmanian

8.00am

Continuous Integrated Manufacture of Therapeutic Proteins

Prof Dr Massimo Morbidelli, Institute for Chemical and Bioengineering ETH Zurich, Switzerland.

Downstream

Process monitoring and control

Chairman Dr Parrish Galliher

8.45am

Enabling integrated continuous DSP by PAT approach

Dejan Arzenšek, PhD, Novartis Technical Operations - BTDM Menges, Lek Pharmaceuticals d.d. Scientist, DSP Development, Slovenia.

9.15am

Process Development of an all flow-through mAb polishing process

Dr Christopher Gillespie, R&D Manager, Next Generation Processing, MilliporeSigma USA.

9.45am

Dynamic process control for continuous countercurrent twin-column chromatography

Dr. Lars Aumann, Chromacon, Switzerland.

10.15am

Networking and refreshments.

11.00am

Scale up design and optimization for an intensified downstream process utilizing multi-column operations

Dr James M Angelo, Biologics Process Development, Bristol-Myers Squibb, Devens, MA, USA.

Integrated Continuous Biomanufacturing

Chairman Dr Jean-Francois Hamel

11.30am

Continuous DSP solutions for perfusion-based mAb processes

Dr Britta Badertscher, pall. Switzerland.

12.00 Noon

The SMART Factory: end-to-end, modular automation for multiple processing platform

Dr. John Moys, Bioproduction Systems Business Development, Thermo Fisher Scientific.

12.30pm

Digitalisation Platform, Advanced Online Monitoring and Hybrid Modeling for intensified Continuous Bioprocessing

Dr. Michael Sokolov, Postdoctoral fellow and Lecturer at ETH Zurich, COO and Co-founder of DataHow AG, Switzerland.

1.00pm

Lunch Monson Room

2.00pm

Scalable Multi-parallel development tools for reducing time to market of Intensified and Continuous Processes

Dr. Gerben Zijlstra, Sartorius-Stedim. France.

Continuous Viral and Vaccine Activities

Chairman Dr Britta Badertscher

2.30pm

Considerations for in-line viral inactivation

Dr. Christopher Gillespie, R&D Manager, Next Generation Processing, MilliporeSigma USA.

3.00pm

Bioreactor concepts for enabling continuous vaccine production

Dr Felipe Tapia, Bioprocess Engineering, Max Planck Institute for Dynamics of Complex Technical Systems, Germany.

3.30pm

Networking and Refreshments

4.00pm

Impact of continuous/intensified production towards a cost-effective Malaria vaccine

Dr. Wian de YANG, CSO, Expres2ion, Denmark.

4.30pm

Chairman: Linda Mathiasson

GEHealthcare

Workshop: Effects of Integrated Continuous Bioprocessing on Process Development

5:15pm

High-Density Vero Cell Perfusion Culture in Packed-Bed Bioreactors

Joerg Schwinde, Eppendorf, Germany.

7.30pm

Gala Dinner - Denke Dining Room

FRIDAY 22ND JUNE

Invited Lecture Invited

Chairman Dr G Subramanian

8.15am

Educating tomorrow's industrial workers in continuous bioprocessing?

Jean-François P. Hamel, PhD, Director, Undergraduate Teaching Laboratories, MIT, USA.

Financial, Regulatory and Quality

Chairman Dr. Gerben Zijlstra

9.00am

Biosafety in continuous bioprocessing

Dr. Marc Bisschops, Director, Biopharm SLS - Continuous Bioprocessing, Pall Life Sciences.

9.30am

Strategies, gaps and hurdles to achieve low-risk continuous bioprocessing

Dr Parrish M. Galliher, CTO Upstream and Founder, Xcellerex Inc., GE Healthcare Life Sciences, USA.

10.00am

Intensified, multi-step purification process for mAbs and Fc-fusion proteins

Dr Nicolas-Julian Hilbold, Merckgroup, Switzerland.

10.30am

Networking and Refreshments.

11.00am

Case study: Process validation for CB interlinking process characterisation with CB verification

Dr Patrick Sagmeister, CTO EXPUTEK GmbH, Vienna, Austria.

11.30am

Product quality attribute control in continuous biologics manufacturing using automated sampling and analysis

Clint Pepper, Ph.D. Director, MAST Products, Mast Lonza, USA.

12.00 Noon

Chairman, Miriam Monge

Panel discussion: Establishing the business case for the switch from fed batch to intensified/continuous processing

12.45pm

Concluding Remarks.

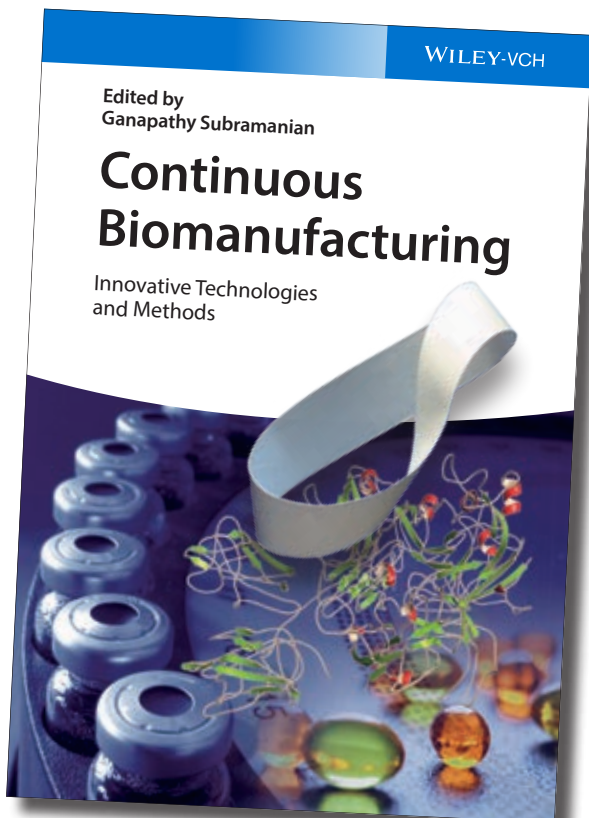
Dr William Whitford

1.00pm

Lunch - Mary O'Brien Room

NOW AVAILABLE

This is the most comprehensive treatise of this topic available, providing invaluable information on the technological and economic benefits to be gained from implementing continuous processes in the biopharmaceutical industry. Top experts from industry and academia cover the latest technical developments in the field, describing the use of single-use technologies alongside perfusion production platforms and downstream operations. Special emphasis is given to process control and monitoring, including such topics as 'quality by design' and automation. The book is supplemented by case studies that highlight the enormous potential of continuous manufacturing for biopharmaceutical production facilities. Published by Wiley-VCH and available online and at all academic bookshops.



WORLD BIOPHARM FORUM 2018

To reserve your place please complete the registration form in BLOCK LETTERS and post it with full remittance to: Dr. G. Subramanian, 44 Oaken Grove, Maidenhead, Berkshire, SL6 6HH or, email to gsub@subramanian.org.uk

Full Name:

Job Title:

Organisation:

Address:

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..... Postcode:

Country:

Tel:

Email:

Any Special Requirement (Dietary):

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Questions or Comments:

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Registration Fees:

Attendance, all meals and accommodation: **£850**

Attendance, all meals and no accommodation: **£700**

Payment Method:

- Online at www.subramanian.org.uk/Conferences
- Cheques payable to Dr G. Subramanian in Pound Sterling only and drawn on a UK based bank or direct bank transfer.

Cancellation:

Should you be unable to attend, a substitute delegate is welcomed at no extra charge.



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