



Driving Value Through Intensified Bioprocessing

Lady Margaret Hall,
University of Oxford, Oxford, UK
26th-28th June, 2019

www.subramanian.org.uk



A WARM INVITATION TO COME AND JOIN US IN OXFORD

It is my great pleasure to invite you to the Sixth annual international conference on Continuous Biomanufacturing: Driving Value Through Intensified Bioprocessing; which will be held at Lady Margaret Hall, University of Oxford, Oxford, UK on June 26-28.2019.

Continuous Bioprocessing has seen a resurgence of interest for continuous manufacturing of biopharmaceuticals, resulting in several small, medium and large biotechnology industries in evaluating the available technology to assess their real potential and benefits in producing clinical products at an affordable cost. Today Biopharma industries accept Continuous Manufacturing Process as a novel approach to efficiently and economically producing a therapeutic product. However there are some bottlenecks still to overcome.

New up-and-down-stream manufacturing procedures and technologies, single-use equipment and modular facility design, as well as localized manufacturing or materials supply can all support a more highly intensified biomanufacturing process.

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.

The conference is enhanced by the participation of leading industrial technologists, scientists, vendors and also distinguished academics from Europe and the 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.

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 through the industrial case studies and workshops. 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 its beautiful surroundings in the historic city of Oxford.

Dr G.Subramanian

Sponsored by



WEDNESDAY 26TH JUNE

12.30

Registration and canapé reception

1.20pm

Welcome: *Dr G Subramanian*

Intensified bioproduction

Chairman: **Dr Joseph Shultz**

1.30pm

Intensification of preparative protein purification by polishing chromatography

Kosma Jurlewicz, Chris Wayne, and Ajoy Velayudhan; Department of Biochemical Engineering; University College London.

2.00pm

Intensified Seed Expansion and Simplified Clarification of Fed-batch Cultures Using the XCellTM ATF System

Dr Shashi Kudugunti ; Sr. Scientist; Repligen Corporation, Waltham-MA, USA

2.30pm

Novel Commercially available tools and services for cost efficient process

Dr Zerben Zijlstra, Global Technical consultant Intensified Biomanufacturing, Sartorius-Sdtedim biotech, GmbH.

3.00pm

Implementation and Development of continuous processing, challenges and lessons learned the story so far.

Andrew Falconbridge, Snr, Director Process Technology, Alvotech; Iceland.

3.30pm

Refreshments and Networking

4.00pm

Transformation to new intensified process platform

Dr Jonathan Souquet, Head of GD&L Technology and Innovation, Merckhealthcare/Global Manufacturing and Supply, Switzerland

4.30pm

Process Intensification

Dr Thomas Flouquet, Novasep, Lyon, France

5.00pm

Digitalization of bioprocess development

Professor Dr Peter Neubauer; Technische Universität Berlin (TU Berlin), Germany

5.30pm

Chairman: **Miriam Monge**

How will the adoption of single-use and intensified processing in cGMP commercial manufacturing change the industry landscape? Key points to consider

Miriam Monge, Head of Segment Marketing mAb/ RecProtein /intensified bioprocessing; Bioprocess solution; Sartorius Stedim Biotech

Industry 4.0 meets continuous

Chairman: **Dr Michael Butler**

6.15pm

Accelerating Biologics Manufacturing by Process Modelling

Axel Schmidt; Institute of Separation and process Technology, Technische Universität Clausthal, Clausthal University of Technology. Germany.

8.00pm

Gala Dinner - Denke Dining Room

THURSDAY 27TH JUNE

8.00am

Enabling Industry 4.0 - Data Management and Analysis of Digitalized and Automated Bioprocessing.

Dr Michael Sokolov, COO and Co-founder pf Datahow, Scientist and Lecturer at ETH, Switzerland

8.30am

Integrated Digital Twins for Intensified Bioprocess Life Cycling

Professor Dr Christoph Herwig, ICEBE, Research Area Biochemical Engineering, TU Wien, Austria.

9.00am

On line Biomass Monitoring: What's really going on in your reactor

Dr Rachel Crossley and David Anderson, Aber instruments; United Kingdom

9.30am

Digitising bioprocessing towards automated analytics and next generation PAT for advanced bioprocess understanding and control

Dr Markus Gershter, Chief Scientific Officer, Synthace Ltd, United Kingdom

10.00am

Cell Density – Viable Tool on your Online Measurements

Jochen Uhlenkuken, Hamilton

10.30am

Refreshments and Networking

Downstream developments

Chairman: Britta Manser

11.00am

Meeting cost and facility utilization targets through single-batch use of convective membranes for chromatographic capture steps.

Hemanth Kaliogota, Volkmar Thom, Patrick Adametz, Ame Blima, Thomas Edenberger, Kathryn Schnorf, Jacques Clements, Sartorius-Stedim

11.30am

Model-assisted process characterisation and validation for a continuous two-column protein A capture process

Daniel Baur¹, James M Angelo¹, Srinivas Chollangi¹, Thomas Müller-Späth³, Xuankuo Xu¹, Sanchayita Ghose¹, Zheng Jian Li², Massimo Morbidelli¹

1 Biologics Process Development, Bristol-Myers Squibb, Devens, MA, USA

2 Department of Chemistry and Applied Biosciences, ETH Zürich, Zürich, Switzerland

3 ChromaCon AG, Zürich, Switzerland

12.00 noon

Efficient single-pass tangential flow diafiltration for continuous processing

Dr Alexander Helling, Ceren Gencoglu and Martin Leuthold

Sartorius Stedim Biotech GmbH, Goettingen, Germany

12.30pm

Lunch

2.00pm

Design Protein A resins for continuous chromatography

Marck Hicks, Hans J. Joansson, Patrick Gilbert; PuroLite, Wales, United Kingdom

2.30pm

Continuous Protein A Chromatography development and implementation using a next generation resin.

Dr Laura Carnston, DSP Process Development Specialist, Alvotech, Iceland.

3.00pm

Parallelized DSP steps with a single skid at pilot-scale: Manufacturing strategies buffer platform and equipment integration

Nicolas-Julian Hilbold; Purification Innovation Scientist, Bioprocess Technology and Innovation; Biopharma/GMS Development and Launch Merckserano, Switzerland

3.30pm

Networking and Refreshments

4.00pm

Case Studies for Debottlenecking Existing Facilities

Significant productivity improvement using multi-column chromatography; Case studies for a new approach to a downstream fed-batch mAb process

Dr Kathleen Mihlbachler; YMC Process Technologies

4.30pm

Case Study: Sequential Pool-less Processing for downstream polishing

Dr Mary Jo Wojtusik, YMC Technologies

New directions in continuous applications

Chairman: Miriam Monge

5.00pm

Case Study: Continuous bioprocessing with E.Coli chances and drawbacks

Julian Kopp, Project assistant at TU Wien, ICEBE, Austria

5.30pm

Quality by Design for continuous Bioprocessing

Dr Marc Bisschops; Director SLS-Integrated Process-Solutions, Pall Biotech

6.00pm

Monitoring mammalian cell growth and metabolism at high densities.

Michael Butler; Distinguished Professor Emeritus (Univ. Manitoba); Adjunct Full Professor University College Dublin; Chief Scientific Officer (CSO), National Institute of Bioprocessing Research & Training (NIBRT) Dublin Ireland

8.00pm

Dinner - Monson Room

FRIDAY 28TH JUNE

8.00am

Gain efficiency and reach high-density cultures through flexible and highly customizable Single Use Bioreactor enhancements for both perfusion on suspension cells and adherent cell culture.

Camille DESROUSSEAUX; Sr Field Application Specialist SUT; Bioproduction; Life Sciences Solutions; Thermo Fisher Scientific; United Kingdom

8.30am

"Enabling the Next Generation of Biopharmaceutical Manufacturing through Integrated Processing"

Dr Joseph Shultz, Global Head of Advanced Process and Manufacturing Technologies at Novartis Pharma AG; Switzerland.

Challenges and concern for continuous biomanufacturing

Chairman: Dr Jean-Francois Hemel

9.00am

Viral Clearance Studies on a Fully Continuous Manufacturing Process for phase 1 studies

Maarten Pennings, BiosanaPharma, The Netherlands

9.30am

Is Continuous Manufacturing, Transitioning from Batch to Continuous Economics and Operational Implications

Andrew Sinclair;/Dr Yuki Abe, Biopharm Services Ltd., United Kingdom

10.00am

Implementation Challenges for Large Scale Continuous Bioprocessing Technologies

Dr Marc Bisschops, Director SLS-Integrated Process Solutions, Pall Biotech

10.30am

Refreshments and Networking

11.00am

Challenges in Biomanufacturing

Nico Oosterhuis, Celltainer Biotech BV. The Netherlands

11.30am

Integration of PAT-analysis for real-time monitoring a bioprocess: Implications for research and teaching

Dr Jean-Francois Hemel, Director, Undergraduate Teaching Laboratories, MIT, USA

12.00 noon

Workshop: Implementation challenges for Innovative Manufacturing Technologies for Process Intensification.

Marc Bisschops, Director SLS - Integrated Process Solutions; Pall Biotech, Gerben Zijlstra, Global Technical Consultant; Intensified Biomanufacturing, Sartorius Stedim Biotech GmbH and Britta Manser, Manager SLSEU Continuous Bioprocessing. Pall Biotech.

12.45pm

Conclusion

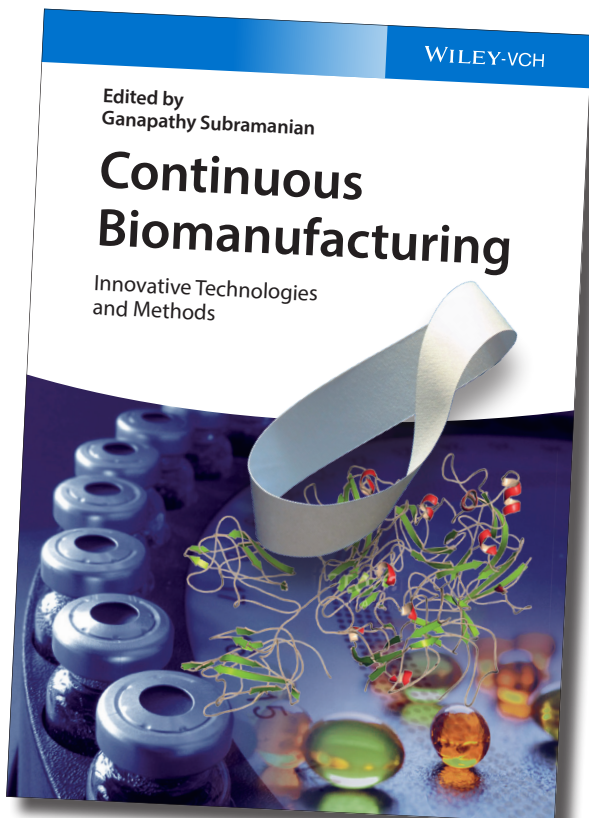
1.00pm

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 2019

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: **£875**

Attendance, all meals and no accommodation: **£725**

Payment Method:

Online at www.subramanian.org.uk/Conferences

For bank transfer please contact.

Cancellation:

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



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