ECA Academy
Your GMP/GDP Information Source

Speakers

Prof Dr Regine Eibl
Zürcher University of Applied Science

Dr Felix Oehme
Bayer

Maarten Pennings
BiosanaPharma

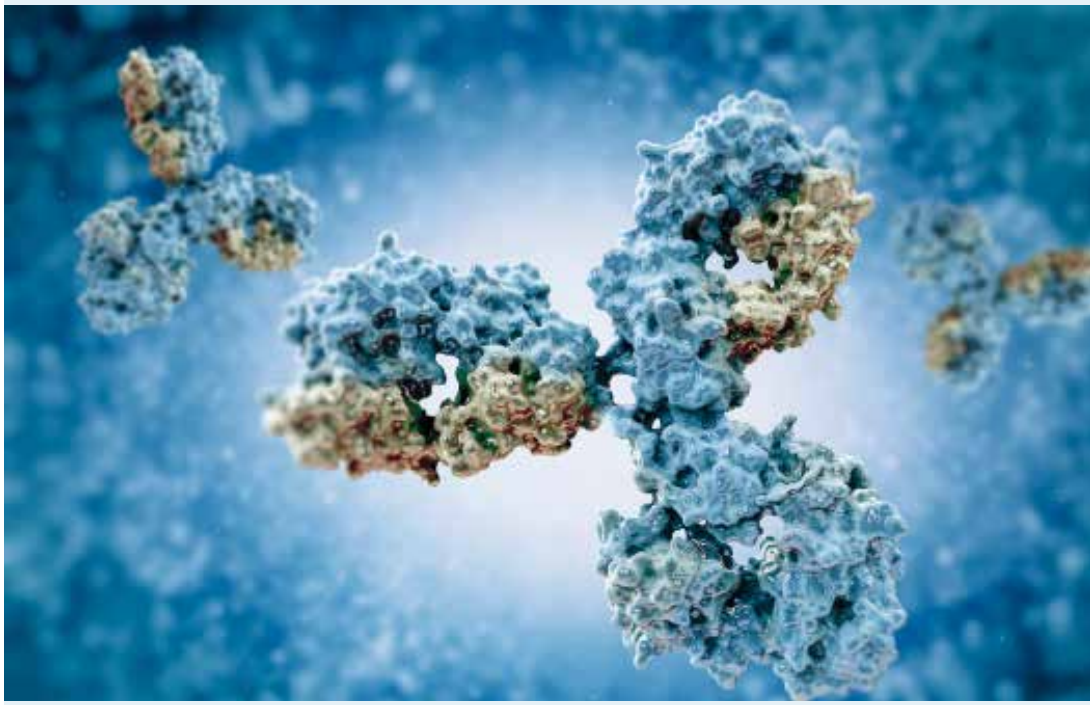
Dr Daniel Müller
Local GMP Authority of Baden Württemberg

Dr Bernd Renger
Immediate Past Chair of the European QP Association

Continuous Bioprocessing

Part of Pharma Congress 2020

15 September 2020 | Düsseldorf/Neuss, Germany



Highlights

- Technological Overview: Available Equipment for continuous USP and DSP
- A GMP inspector's view on continuous Biomanufacturing
- BiosanaPharma: Continuous Manufacturing of biosimilar antibodies
- Development of an integrated continuous downstream process
- Bayer: Continuous DSP for protein therapeutics
- Live Demo: Various continuous processing systems

This conference is part of
2020 PHARMA CONGRESS Production & Technology

Objective

This conference provides an overview of the concepts of continuous processing and its level of adoption in the biopharmaceutical industry. Besides technological challenges, GMP questions related to continuous processing are discussed.

Background

Continuous processing could be the next step for process intensification in the evolution of biopharmaceuticals. The biopharmaceutical industry is facing several challenges due to an increasing number of biosimilars and multiple therapies targeting the same indication which increases the costs but also reduces the required batch sizes. In addition, the expression levels for monoclonal antibodies could be increased by one order of magnitude which shifts the bottleneck further downstream, requiring an intensified operation in downstream processing.

Today's standard batch manufacturing is comprised of a cascade of processes where the product is routed through one unit operation at a time and is collected in hold containers in between. This can limit both facility utilization and productivity.

Integrated processing on the other hand includes the use of continuous unit operations where product moves through a series of unit operations without interruption. This design allows reducing the size of unit operations which translates into buffer, resin and consumable savings. Further advantages of continuous manufacturing are seen in unprecedented control over product quality, better agility and flexibility as well as reduced risks of scale-up through smaller equipment and facilities.

Several pharmaceutical companies have shown successful examples for both fully integrated and hybrid processing platforms and first steps towards regulatory approval have been taken. However, the decision for continuous processing has to be made on a case-to-case basis. It is recommended to perform risk assessments for the platform, the connections and the automation to meet the GMP requirements.

Target Audience

This conference is directed at executives from development, engineering, production and QA responsible for the implementation of continuous biomanufacturing.

Moderator

Prof Dr Regine Eibl, Zürcher University of Applied Science

Programme

Keynote
Annex 1 Revision – the long and winding road
Dr Bernd Renger, Immediate Past Chairman, European QP Association

- The drivers of change
- New paradigms and concepts
- Contamination Control und Quality Risk Management
- Stakeholder consultation
- New expectations to Media Fills and Lyophilisation
- The big challenges – CCIT and PUPSIT

Technological overview: Single-use technologies for intensified and continuous bioprocesses (USP & DSP)
Prof Dr Regine Eibl , Zürcher University of Applied Science

- Continuous USP
  - High cell density and large volume cell banks
  - N-1 perfusion
  - Production in perfusion mode
  - Clarification
- Continuous DSP
  - Bind-elute chromatography
  - Virus inactivation
  - Flow-through chromatography
  - Virus filtration
  - Final ultra- and diafiltration

Live Demo
Pall: Intensified Downstream Processing through Continuous Manufacture
Britta Manser, Pall

Continuous processing is seen as the next step in process intensification of biopharmaceutical products. Thereby, a combination of different unit operations from chromatography through virus inactivation and concentration or diafiltration can be integrated into one harmonized platform.
This demonstration introduces the concepts of continuous operation and presents various continuous processing systems. Participants will gain an understanding of the design principles of intensified downstream processes and see where these steps can be implemented in modern protein purification platforms.

Speakers

Continuous Biomanufacturing - a GMP inspector‘s view
Dr Daniel Müller, Local Government, Germany

- Regulatory guidance
- General requirements
- Application of single-use systems
- Control & validation strategy
- Challenges and discussion points

Case Studies

Biosana: Continuous Manufacturing of biosimilar antibodies: a small company’s journey to phase 1 clinical studies
Maarten Pennings, Biosana

In 2018 the first clinical study was performed with a Mab that was manufactured with a continuous process from bioreactor to bulk drug substance. In this talk an overview of the purification process, a number of design aspects, automation control and virus safety will be presented.

- Conversion to a fully continuous manufacturing process and run for weeks under GMP to produce Clinical Trial Material
- Design choices in the frequency of exchanging single use components impact manufacturability
- Challenges in downscaling to an appropriate model for viral clearance validation were addressed.

Bayer: Continuous Downstream Processing for manufacturing of protein therapeutics
Dr Felix Oehme, Bayer

- Challenges and benefits of continuous manufacturing for biologics
- Case study: Comparison of process parameters and product quality in batch and continuous manufacturing
- Control strategy and regulatory aspects

Prof Dr Regine Eibl, Zürcher University of Applied Science

Prof Regine Eibl is a professor at the Zurich University of Applied Sciences, where she lectures in biotechnology and cell cultivation techniques. She is the platform leader for “Single-use technology” of the Swiss Biotechnet and a member of the DECHEMA (Society for Chemical Engineering and Biotechnology).

Dr Felix Oehme, Bayer

Dr Oehme has been working for Bayer since 1999 in various positions in research and process development. Since 2016 he is leader of the Biological Development at the site in Wuppertal.

Maarten Pennings, BiosanaPharma

Maarten Pennings has a M.Sc. in Bioprocess Technology and has 20 years of experience in the development of biopharmaceuticals. He has been working on the development of continuous manufacturing in biopharma since 1999 and is a co-inventor of the BioSMB®. For the past 4 years he has been in charge of process development and manufacturing for BiosanaPharma.

Dr Daniel Müller, Local GMP Authority of Baden Württemberg

Currently Daniel Müller is head of the GMP inspectorate (local competent authority) in Tuebingen, Germany. Since 2001 he has been working as GMDP inspector, conducting national inspections as well as EMA and overseas inspections. Before joining the authority Dr Müller was working in pharmaceutical industry, also as Qualified Person for sterile drug products. He is member of German expert groups ‘biotechnology & tissue’ and ‘quality assurance’.

Dr Bernd Renger, Immediate Past Chair of the European QP Association

Dr Bernd Renger has been Immediate Past Chair of the European QP Association. He was VP of Quality Control at Vetter Pharma-Fertigung and had several management positions at Mundipharma, Byk Gulen and Baxter BioScience. Since 2011 he is running his own consultancy business.

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Reservation Form (Please complete in full)

Continuous Bioprocessing, 15 September 2020, Düsseldorf/Neuss

Part of the Pharma Congress Production & Technology, 15/16 September 2020 – I would like to register for the following days:

☐ *Continuous Bioprocessing only – 15 September 2020 (EUR 690.- plus VAT)*

☐ *Both days of the Pharma Congress – 15/16 September 2020 (EUR 1,380.- plus VAT)*

☐ *I would also like to participate in the Social Event on 15 September 2020*

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

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If you cannot attend the conference you have two options:
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2. If you have to cancel entirely we must charge the following processing fees:
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- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week prior to the conference 100 %.

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In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012).
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Date
Tuesday, 15 September 2020, 09.00 – 17.45 h
Registration:
Monday, 14 September 2020, 19.00 – 20.30 h,
Tuesday, 15 September 2020, 08.00 – 09.00 h

Venue
Crowne Plaza Düsseldorf / Neuss
Rheinallee 1
D-41460 Neuss, Germany
Phone: +49 (0) 2131 77 - 00
E-mail: emailus@cphotelduesseldorfneuss.com

Fees
EUR 690.- per delegate and day plus VAT
(due to the special congress fees, ECA membership discounts are not applicable, and participation does not entail ECA membership).
The conference fee is payable in advance after receipt of invoice and includes lunch on that day day, beverages during the event and during breaks as well as the Social Event on 15 September. VAT is reclaimable.

Registration
Via the reservation form, by e-mail or by fax message.
Or you register online at www.pharma-congress.com.

Your registration also entitles you to participate in all other Pharma Congress conferences on the day of your registration. For the other Pharma Congress conferences on 15/16 September 2020 please visit www.pharma-congress.com.

Please note
There will be no print-outs at the Pharma Congress. All documentation will be provided prior to the Congress in a download are and via the Pharma Congress app.
There will be no room reservations via Concept Heidelberg. Please book your hotel room directly with the reservation form which you will receive together with your confirmation/invoice! Charges are payable after receipt of the invoice.

Conference language
The official conference language will be English.

Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this event.

CONCEPT HEIDELBERG
P.O. Box 10 17 64 | D-69007 Heidelberg
Phone +49(0) 62 21/84 44-0 | Fax 49(0) 62 21/84 44 34
E-Mail: info@concept-heidelberg.de
www.gmp-navigator.com

For questions regarding content:
Dr Robert Eicher (Operations Director) at
+49-62 21/84 44 12, or per e-mail at
eicher@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc. please contact:
Ronny Strohwald (Organisation Manager) at
+49-62 21/84 44 51, or per e-mail at
strohwald@concept-heidelberg.de.