

Speakers



Hesham Elrayes
B.Braun



Fabio Gentilini
BSP Pharmaceuticals



Dr Friedrich Haeefe
Formerly Boehringer
Ingelheim Pharma



Dr Martin Haerer
Rommelag CMO



Dr Markus Lesch
Vetter Pharma-Fertigung



Ronan McGarvey
AbbVie



Gert Moelgaard
ECA Validation Interest
Group



Dermot O'Riordan
EirGen



Dr Rolf Ratke
AbbVie



Dr Bernd Renger
Immediate Past Chair
European QP Association



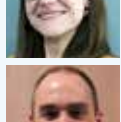
Dr Beate Reutter
Landesamt für soziale
Dienste Schleswig-
Holstein, Kiel, Germany
Dr Gabriele Sabine Roidl
Lonza



Dr Martin Schwab
Vetter Pharma-Fertigung



Dr Sofia Venceslau
Genibet
Biopharmaceuticals



Patrice Wery
GSK Vaccines



Jörg Zimmermann
Vetter Pharma-Fertigung

Aseptic Processing

Part of Pharma Congress 2020

15/16 September 2020 | Düsseldorf/Neuss, Germany



Highlights

- Innovative therapeutic options – a challenge to aseptic technologies
- The evolution of current aseptic technologies
- Case studies from:
 - BSP Pharmaceuticals
 - EirGen
 - Genibet Biopharmaceuticals
 - Lonza
 - Vetter Pharma-Fertigung
- Live Demos from:
 - Bausch + Ströbel
 - Metall + Plastic / Castus
 - Steriline

This conference is part of



Objective

Reasons to attend this conference:

- You will be informed on new technological developments in sterile / aseptic manufacturing
- You will learn how current GMP and production requirements have to be implemented technologically in sterile manufacturing
- You will get case studies from pharmaceutical companies
- Live Demos will show you how technologies perform

Background

GMP regulations only define general requirements for equipment – it has to be suitable for the intended work process, easy to clean and without any negative influence on the product quality. Questions like how these general requirements have to be fulfilled concretely in sterile manufacture, which points call for special attention and which new technologies will be used in the future are in this conference's focus. Speakers from the pharmaceutical industry and from planning and engineering companies deal with pivotal developments in the field of sterile manufacturing.

Target Audience

The event is directed at specialists from the pharmaceutical industry as well as at engineers and planners who have to deal with current aseptic technologies in clean areas in their daily practice. It particularly addresses the departments:

- Production
- Quality assurance
- Engineering / Technology

Moderator

Gerd Moelgaard, ECA Validation Interest Group
Jörg Zimmermann, Vetter Pharma-Fertigung



Social Event

On the evening of the first congress day, on 15 September 2020, all congress delegates and speakers are invited to a „Get together“ in the Congress Center. Take advantage of this opportunity for an information exchange and enjoy the laid-back atmosphere and the entertainment programme.

Programme



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

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

The Evolution of Aseptic Technologies

Dr Friedrich Haefele, formerly Boehringer Ingelheim Pharma

- Technological trends in the development of biotechnology APIs
- Galenic challenges
- Technical trends in API production and production of finished dosage forms
- Regulations – do they make it harder or easier?

Challenges in Manufacturing high Value lyophilized Oncologics – a Case Study

Fabio Gentilini, BSP Pharmaceuticals

- BSP's requirements for a flexible CMO sterile suite with space constrains for high value oncological products containing solvents under isolation technology
- Suppliers provided solutions including:
 - Reduced foot-print equipment
 - Innovative loading/unloading system (including cold shelf loading)
 - PAT tools (including nucleation)

From Design to Construction of a new integrated Fill&Finish Facility – Combination of proven and new Technologies

Dr Gabriele Sabine Roidl, Lonza

- Installation of a new drug production line
- Using modern and innovative technologies
- Vial filling line with isolator technology and 2 lyophilizers



Live Demos

B+S Multi Dosing System - 3 in 1!
Bausch + Ströbel

Collaborative Robots
Steriline

Isolator Technology & RTP Transfer Systems
Metall + Plastic / Castus

Case Study: Cycle Development & Validation of automated AHP Decontamination Processes for Cleanrooms

Dr Markus Lesch, Vetter Pharma-Fertigung

- Design of decontamination system & cleanroom
- Optimization of aerosolized amount of H₂O₂
- Selection of positions to be challenged with indicators
- Optimization of relative humidity
- Optimization of decontamination time
- Value of chemical indicators for validation of AHP processes

EirGen Pharma– How state-of-the-art Fill & Finish Equipment Flexibility supports CMO Business

Dermot O’Riordan, EirGen

- Possibilities and challenges when processing various RTU packaging components
- Challenges of filling non- to high-potent products
- Flexibility in aseptic filling processes
- Challenges of manufacturing different products with different batch sizes



Image: Groninger

Objective

Reasons to attend this conference:

- You will be informed on the current status of EU Annex 1 revision
- You will learn how current GMP and production requirements have to be implemented in sterile manufacture
- You will get case studies from pharmaceutical companies

Background

EU GMP Annex 1 on sterile medicinal products is currently under revision. A first public draft from 2017 was intensively discussed. What are the consequences of this discussion and what are the next steps to a final document will be explained in this conference.

Target Audience

The event is directed at specialists from the pharmaceutical industry as well as at engineers and planners who have to deal with current aseptic regulations in their daily practice. It particularly addresses the departments:

- Production
- Quality assurance
- Engineering / Technology

Moderator

Gerd Moelgaard, ECA Validation Interest Group
Jörg Zimmermann, Vetter Pharma-Fertigung

Programme



Keynote

„Case Study AbbVie: The new Biologics Site in Singapore“

Dr. Rolf Ratke, AbbVie

Ronan McGarvey, AbbVie

- The Site strategy
- Products, processes & equipment
- Cooperation with EMA, blueprint to prepare for the successful pre-approval-inspection
- From start- up to realization until approval

Status of Annex 1 Revision?

*Dr Beate Reutter, Landesamt für soziale Dienste
Schleswig-Holstein, Kiel, Germany*

Environmental Monitoring in modern Biopharmaceutical DP Facilities – A Proposal for a harmonized Risk Based Approach for selecting Monitoring Points and defining Monitoring Plans

Patrice Wery, GSK Vaccines

- What about Biophorum, the group working on this Risk Assessment?
- Why do we need a harmonized Risk Assessment tool?
- Explanation of the tool in a step by step approach
- First feed-back of authorities
- A practical example to illustrate how it works

Case Study: Media Fill Design for aseptic Blow Fill Seal Filling

Dr Martin Haerer, Rommelag CMO

- General Media fill concept
- Bracketing concept
- Intervention procedure
- Operator involvement
- Evaluation

Single Use Bioreactor Platform(SUB) for microbial Fermentation in a GMP Manufacturing Facility

Dr Sofia Venceslau, Genibet

- Benefits for GMP production
- Broaden the use of SUBs to expand bacteria and yeast cells
- Main faced challenges

Challenges and Opportunities of Aseptic Manufacturing Process Transfers

Dr Martin Schwab, Vetter Pharma Fertigung

- Manufacturing Process Transfers / Clean Room Transfers: Background, Drivers, Characteristics
- Technology Transfer: Like for like, process optimization, gap- and risk-analysis, challenges
- Lessons learned and outlook

Areas of Focus for Auditors of Sterile Operations

Hesham Elrayes, B. Braun

- Areas to be focused
 - APRs (PQRs)...
 - BRs
 - Deviations/Investigations
 - Training
 - Complaints
 - Adverse Events – Signal Detection
- What should I spend some time looking at here...?
 - Batches Manufactured
 - Analytical Data & Trend Analysis
 - Qualification status of equipment
 - Quality Agreements
 - Sterilization cycles
 - Environmental Monitoring
- Assessment tools to focus on key process and environmental elements relative to audit aseptic Lyophilization process



Hesham Elrayes, B. Braun

Between 2012 and 2018 Global Auditor and Global Consultant in Novartis and Eli Lilly. Since 2018 Senior Auditor for B. Braun Group.



Fabio Gentilini, BSP Pharmaceuticals

With a Mechanical Engineering degree, he joined BSP Pharmaceuticals in 2013 as Project Engineer, working on the engineering and construction of industrial plants for the manufacturing operations. In 2018, he was assigned to lead projects as Project Manager, supporting BSP's business strategy by focusing on results delivery of capital investments.



Dr. Friedrich Haefe, Formerly Boehringer Ingelheim Pharma

Dr Haefe has been in the pharmaceutical industry for almost 20 years now. From 2006 to 2018 Dr Haefe was with Boehringer-Ingelheim Pharma, where he was responsible for the department Biopharma Fill & Finish Germany.



Dr Martin Haerer, Rommelag CMO

Dr Haerer is a pharmacist and works for Rommelag CMO. He currently is responsible for Business Development, Technology Transfer and Research and Development, and is still acting as Qualified Person.



Dr Markus Lesch, Vetter Pharma-Fertigung

Since 2016 at Vetter Pharma-Fertigung as head of Microbiological Validation responsible i.a. for Validation of sterilization / decontamination / depyrogenisation processes and microbiological clean room qualification.



Ronan McGarvey, AbbVie

Ronan McGarvey has been Director of Quality for AbbVie Operations Singapore for the past 5 years since the design phase. Prior to that he was Director of Quality and QP for AbbVie Ireland, Sligo for 5 years. He holds a BSc in Chemistry and an MSc in Industrial Pharmaceutical Science. His areas of expertise include Start-up, Technology Transfer, Process Validation and GMP Inspections. He has worked on API, BDS and OSD products.



Gert Moelgaard, ECA Validation Interest Group, Moelgaard Consulting

Gert Moelgaard has more than 25 years experience in the pharmaceutical and biotech industry, including several years of experience in process control, automation, computer systems validation and process validation as well as process engineering and consulting. He has previously worked in Novo Nordisk, Novo Nordisk Engineering and NNE Pharmaplan. Since 2015 he is Consultant. He is chairman of the ECA's Validation Group.



Dermot O'Riordan, EirGen

With almost 20 years' experience in the Pharmaceutical and Biopharmaceutical industries, Dermot is currently the Sterile Technical Operations Manager at EirGen Pharma. Here he has responsibility for the introduction, qualification and operation of the aseptic manufacturing facility as well as management of the fill finish product portfolio.



Dr Rolf Ratke, AbbVie

Dr Ratke is Director Biologics QA, Qualified Person/QP and authorized representative at AbbVie. He is also the head of the German QP Association.



Dr Bernd Renger, Immediate Past Chair European Qualified Person 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 (now Takeda) and Baxter BioScience in Vienna. Since 2011 he is running his own consultancy business.



Dr Beate Reutter, Landesamt für soziale Dienste Schleswig-Holstein, Kiel, Germany

After 15 years working for a quality control laboratory, in 2003 she changed to the Drug Supervision Department of Land Schleswig-Holstein.



Dr Gabriele Sabine Roidl, Lonza

Gabriele Roidl has been working at Lonza Drug Product Manufacturing since 2017. She is part of the Team designing the new facility in Visp and supports the integration of a newly acquired production site in Switzerland. Her expertise lies in sterile fill&finish manufacturing, an area she has been working in over the last 12 years.



Dr Martin Schwab, Vetter Pharma-Fertigung

He worked as Pharmaceutical Project Manager responsible for merger-driven site Transfers at MSD Animal Health. Since 2012 Dr Schwab has been Customer Project Manager / 2017 Director Customer Project Manager at Vetter Pharma-Fertigung.



Dr Sofia Venceslau, Genibet Biopharmaceuticals

At Genibet Biopharmaceuticals, Sofia is a project manager responsible for setting up the clients' projects under GMP. She is also responsible for the success of the clients' project by coordinating and assisting the production team and engaging the required departments for the success of the projects.



Patrice Wery, GSK Vaccines

Patrice is currently with GlaxoSmithKline, where he has held various positions for 14 years, including QP, Operational QA and as a Senior Site Sterility Assurance Manager. He is currently a member of GlaxoSmithKline's Manufacturing Science and Technology team, implementing CPV and new technologies in vaccines manufacturing facilities.



Jörg Zimmermann, Vetter Pharma-Fertigung

Since November 2019, Jörg Zimmermann is Vice President, Vetter Development Service, External Affairs.

If the bill-to-address deviates from the specifications on the right, please fill out here:

Reservation Form (Please complete in full)

Aseptic Processing, 15/16 September 2020, Düsseldorf/Neuss

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

- Current Aseptic Technologies – 15 September 2020 (EUR 690.- plus VAT)
- Current Aseptic Compliance – 16 September 2020 (EUR 690.- plus VAT)
- Current Aseptic Technologies and Current Aseptic Compliance – 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

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General terms and conditions

If you cannot attend the conference you have two options:

1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:

- Cancellation until 2 weeks prior to the conference 10%.

- Cancellation until 1 week prior to the conference 50%.

- Cancellation within 1 week prior to the conference 100%.

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If the event must be cancelled, registrants will be notified as soon as possible

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lation.

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invoice.

Important: This is a binding registration and above fees are due in case of can-

cellation or non-appearance. If you cannot take part, you have to inform us in

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time at which we receive your message.

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 con-

ference (receipt of payment will not be confirmed!) (As of January 2012).

German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal

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for which I hereby declare to agree that my personal data is stored and pro-

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also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I

note that I can ask for the modification, correction or deletion of my data at any

time via the contact form on this website.

Date

Current Aseptic Technologies

Tuesday, 15 September 2020, 09.00 – 17.45 h

Current Aseptic Compliance

Wednesday, 16 September 2020, 09.00 – 17.00 h

Registration

Monday, 14 September 2020, 19.00 – 20.30 h,

Tuesday, 15 September 2020, 08.00 – 09.00 h

Wednesday, 16 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 (EUR 1,380.- for both days 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/both days, beverages during the event and during breaks as well as the Social Event on 15 September. VAT is reclaimable.

Your registration also entitles you to participate in all other Pharma Congress conferences on either day of your registration. For the other conferences on both days please visit www.pharma-congress.com.

Registration

Via the reservation form, by e-mail or by fax message. Or you register online at 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 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

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