20 YEARS ECA Academy Your GMP/GDP Information Source

Aseptic Processing

Current Aseptic Technologies

RABS & Isolators

This conference is part of the

2019 PHARMA CONGRESS Production & Technology
DÜSSELDORF, 9 - 10 APRIL 2019

www.pharma-congress.com

9/10 April 2019, Düsseldorf/Neuss, Germany

SPEAKERS

DR ABDULAZIZ AWAD
Saudi Biotechnology Manufacturing Company

STEFAN BIELER
IDT-Biologika

KLAUS EICHMÜLLER
Wolnzach, c/o Regional Council Darmstadt, GMP Inspectorate, Germany

SANDRINE FAVRE
Octapharma

DR FRIEDRICH HAEFELE
Boehringer Ingelheim Pharma

KIERAN KEANEY
Abbvie Ireland

DIDIER MEYER
DMCompliance

GERT MOELGAARD
ECA Validation Group

THOMAS PAGE
FUJIFILM Diosynth Biotechnologies

THOMAS REINER
Berndt+Partner

PROF FARSHID SADEGHIPOUR
Lausanne University Hospital

DR UTE SCHLEYER
Vetter Pharma-Fertigung

PATRICK VANHECKE
GSK Vaccines

HIGHLIGHTS:

- Innovative therapeutic options – a challenge to aseptic technologies
- The evolution of current aseptic technologies
- Case studies from:
  - Abbvie Ireland
  - GSK Vaccines
  - IDT-Biologika
  - Octapharma
  - Saudi Biotechnology Manufacturing Company
  - Vetter Pharma-Fertigung
- Live Demos from:
  - Bausch + Ströbel
  - Bosch
  - Ellab
  - Metall + Plastics
  - MK-Versuchsanlagen und Laborbedarf
  - Steriline

Current Aseptic Technologies 9 April 2019

Objectives

Reasons to attend this conference:

- You will be informed on new regulatory and technological developments in sterile / aseptic manufacture.
- You will learn how current GMP and production requirements have to be implemented technologically in sterile manufacture.
- 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 manufacture.

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

GERT MOELGAARD, *ECA Validation Group*

Social Event

The Social Event at the Pharma Congress is already a tradition, and is networking and relaxation at the same time.

On the evening of the first congress day, on 9 April 2019, 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 9 April 2019

Pharmaceutical industry in digital change

- Changes in the value chains
- Opportunities and risks for production processes
- What can and will change for packaging?
- Strategies to benefit from change

THOMAS REINER, *CEO, Berndt+Partner*

Innovative therapeutic options – a challenge to aseptic technologies

The landscape of pharmaceutical products and production is changing fast at the moment. The next generation of treatments becomes a reality and raises significant challenges to production, facilities and technologies of the future. New therapies are making significant progress and the pharmaceutical manufacturing is starting to adapt to the challenges.
GERT MOELGAARD, *ECA Validation Group*

The evolution of current aseptic technologies

Today's aseptic production and regulations holds many interesting possibilities, mainly due to new process improvements such as biotech titer improvements, single use technology and flexible aseptic production technologies and 100% inline controls. The new regulations on EU Annex 1 on Sterile Products and Annex 17 on Real Time Release Testing and Parametric Release give new challenges and opportunities for practical production.
DR FRIEDRICH HAEFELE, *Boehringer Ingelheim Pharma*

Delivery of a Flexible Aseptic Filling Facility to a CMO

- Platforms Modular Aseptic Solutions (MAS) for new facility design
- Flexibility in design options
- Off-site construction
- Flexibility of filling in pre-sterilized containers
- Flexibility formulating in different batch sizes
- Flexibility of adding lyophilization of mAb products

DR ABDULAZIZ AWAD, *Saudi Biotechnology Manufacturing Company*

Live Demos

Bosch PreVAS Single-Use Dosing System
PreVAS means: - PreValidated / - PreAssembled / PreSterilized

Ease of use and reduced change-over

- Special benefit in clinical phase (many different products per time, only a few that will go in commercial production)
- Minimized risk of cross contamination for multi purpose & small batch
- Operator protection (no cleaning necessary), especially for high potent drugs
- No CIP/SIP necessary, no cleaning validation
- Reduced downtimes, utilities and labour

ROBERT BOSCH

Sterilizer validation / qualification made easy

The demo will show you how easy and efficient a validation / qualification can be with Ellab equipment.

- Computer-assisted validation system (GAMP®5 & FDA 21 CFR Part 11 compliant)
- Efficient work & set up through profiles
- Combination of different measuring systems (data logger & thermocouple system)
- Automated and quick reporting /interpretation of the results

ELLAB

Fully automatic and integrated particle detection system for filters in hot air sterilization tunnels and LAF units

- Automatic integrated system
- Tracking of results and protocol systems
- Shorter validation times, therefore cost savings
- Safe and reliable system
- No influence of human faults

BAUSCH+STRÖBEL

Vial filling line VIRTUAL REALITY experience

Unique possibility to navigate inside an aseptic processing line incl.:

- General overview of the line
- Split by machine
- "I'm a vial" dedicated tour

STERLINE

Case study Vetter Pharma-Fertigung: Next steps in the development of V-CRT®; Analytical monitoring of H_2O_2 decontamination processes

- Within the Vetter Cleanroom Technology (V-CRT®) concept a batch specific H_2O_2 decontamination of the entire cleanroom mitigates the risk of microbial contamination
- To mitigate the risk of the decontamination agent on the drug product, an encompassing H_2O_2 monitoring system was established
- Whereas H_2O_2 is continuously monitored in the cleanroom, analysis of filled syringes, cartridges and vials is carried out upon customer's request
- Therefore, the advanced technology together with the comprehensive analytical approach reaches quality and safety standards well exceeding cGMP requirements

DR UTE SCHLEYER, *Vetter Pharma-Fertigung*

Substitution of formaldehyde room decontamination by hydrogen peroxide and acceleration of decontamination process by application of innovative catalyst technology for effective decomposition of hydrogen peroxide

- Required performance of the decontamination process (kill of bacterial and viral bio indicators)
- Comparison of the different decontamination processes regarding room and HVAC requirements
- Implementation of catalysts in different room and HCAV scenarios
- Acceleration of degassing process with catalyst (presenting tests results)
- Principle of heterogeneous H_2O_2 catalysis

STEFAN BIELER, *IDT-Biologika*

RABS & Isolators — 10 April 2019

Objectives

This is why you will benefit from attending this conference:

- Case studies from various pharmaceutical companies deal with the implementation, qualification and operation of Isolator and RABS systems.
- You will discuss the current state of the art and new technological developments in Barrier Systems technology.
- You will get to know first hand the new EU-GMP Annex 1 draft requirements on Barrier Systems.
- Experts from pharmaceutical companies will share their knowledge regarding operational experience.

Background

The protection against microbial contamination is the most important point for drugs produced by aseptic processes. Today the regulators require a more strict separation between operators and product in the form of an access barrier.

Two systems are on the market – RABS (Restricted Access Barrier System) and Isolators. But only isolators are referred to by the US FDA as advanced aseptic technology.
This conference will focus on current questions of barrier systems coming from FDA regulations as well as from the revised EU GMP Annex 1, and it will specifically address the subject from the perspectives of pharmaceutical operators, planners and engineers.

Target Audience

This event is directed at decision-makers from pharmaceutical production, development and quality assurance/control. It also addresses engineers and planners who need to be well informed about current developments in the field of barrier systems.

Moderator

DIDIER MEYER, *DMCompliance*

Programme

Congress Key Note

EU GMP Inspection in Sterile/Aseptic Production

- Main focus areas of inspections
- Frequently detected findings
- Data Integrity issues – where are possible weak spots?
- Possible new areas due to the revision of Annex 1 and further regulatory changes

KLAUS EICHMÜLLER, *Wolnzach, c/o Regional Council Darmstadt, GMP Inspectorate, Germany – Head of Inspectorate*

Closure Processing System for rubber stoppers: key aspects to consider to ensure process robustness in routine production

- Introduction into Octapharma project
- CPS design phase
- Cycle development and process characterization
- Learnings

SANDRINE FAVRE, *Octapharma*

Case study GSK Vaccines: Isolator decontamination by H_2O_2 nebulization process

- VHP process versus H_2O_2 nebulization process
- Cycle development for nebulization process
- Pros and Cons for both processes
- Manufacturing applications

PATRICK VANHECKE, *GSK Vaccines*

Key considerations for gene therapy manufacturing from early stage to fill-finish operations

- The importance of flexibility and high containment requirements
- Applications of closed systems in designing the manufacturing process
- Differences in facility design, qualification and validation for gloveless isolators versus conventional isolators and
- Treating facilities as pieces of equipment for advanced therapy manufacturing

THOMAS PAGE, *Fujifilm Diosynth Biotechnologies*

Live Demos

DECOpulse® – The H_2O_2 bio-decontamination system with atomization-driven evaporation

The Live-demo includes a short introduction to the innovative functional principle followed by a hands-on demonstration of the system. Come, see and feel how you can shorten your decontamination cycle times while saving H_2O_2!
METALL+PLASTICS

TBN

MK VERSUCHSANLAGEN UND LABORBEDARF

Aseptic meets high-potent – setting the stage for next level ADC processing

- General introduction into customer site
- Introduction into project scope
- Dedicated line solutions and technology
- What have been the major challenges and highlights from a client's perspective

KIERAN KEANEY, *Abbvie Ireland*

The specific case of use of isolators and biosafety cabinets type III in Hospital Pharmacy

- Isolators for Non-Toxic Aseptic preparations
- Isolators and BSC an for Cytostatic Injectable preparations
- Sterility testing
- Perspectives with ATMP
- Perspectives with automation

PROF FARSHID SADEGHIPOUR, *Lausanne University Hospital*

Speakers

DR ABDULAZIZ AWAD, *Saudi Biotechnology Manufacturing Company*
Board Member and Chief Executive Officer of Saudi Biotechnology Manufacturing Company and holding vast experience in medical administration and as senior surgeon. Member of Executive Committee, Saudi bio.

STEFAN BIELER, *IDT-Biologika*
Planning, implementation and commissioning of projects such as new investments, reconstructions and extension of facilities incl. planning of maintenance activities and technical support of specific biotechnical production facilities incl. peripheries.

KLAUS EICHMÜLLER, *Wolnzach, c/o Regional Council Darmstadt, GMP Inspectorate, Germany*
He was Deputy Head of the Central Authority for Supervision of Medicinal Products in Bavaria as long as it existed and has now been Head of the Inspectorate for Drug Products, APIs, Blood Products and Tissues in Hesse since March 2014.

SANDRINE FAVRE, *Octapharma*
Currently she is Head of Corporate Pharmaceutical Production department working on process standardization and on major investment projects for the 4 manufacturing sites located in Europe. From 2010 to 2015, she was Head of Pharmaceutical Production in an Octapharma manufacturing site located in France.

DR FRIEDRICH HAEFELE, *Boehringer Ingelheim Pharma*
Dr Haefele has been in the pharmaceutical industry for almost 20 years now. In May 2006 Dr Haefele joined Boehringer-Ingelheim Pharma where he is responsible for the department Biopharma Fill & Finish Germany.

KIERAN KEANEY, *Abbvie Ireland*
Senior Engineer with more than 20 years experience in the Pharma & Bio Pharma Industry.

DIDIER MEYER, *DMCompliance*
Didier worked 7 years with Millipore Europe in various positions of sales, marketing and training. Since 1983 he has worked in the development of isolation technology in the Biopharma industry with La Calhène. Currently he is consultant at DMCompliance.

GERT MOELGAARD, *ECA Validation 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.

THOMAS PAGE, *FUJIFILM Diosynth Biotechnologies*
Vice President, Engineering & Asset Development, FUJIFILM Diosynth Biotechnologies.

THOMAS REINER, *Berndt+Partner*
Thomas Reiner is a managing partner and has been with Berndt+Partner for over 25 years. He is also Chairman of the Board of the German Packaging Institute and a member of the Board of the World Packaging Organisation.

PROF FARSHID SADEGHIPOUR, *Lausanne University Hospital*
Adjunct Professor of Hospital and Clinical Pharmacy, Geneva and Lausanne School of Pharmacy (EPGL), University of Lausanne, University of Geneva and Chief Pharmacist, University hospital of Lausanne.

DR UTE SCHLEYER, *Vetter Pharma-Fertigung*
Ute Schleyer, Ph.D. was appointed Project Manager in the Site & Plant Development department of Vetter in 2016. In this position, she is responsible for supporting projects in the field of pharmaceutical technology. Ute joined Vetter in 2007 as Manager of Aspetic Production. She was promoted to the position of Head of Production in 2008 in the area of manufacturing and filling of sterile drug products, which includes various single and dual-chamber filling lines.

PATRICK VANHECKE, *GSK Vaccines*
Patrick Vanhecke joined GSK Bio in 1992 as Aseptic Filing Manager in Rixensart (Belgium). In 2002 he joined the Parenteral Technologies team and since 2015 he joined the Global Manufacturing Science and Technologies – Manufacturing Technologies team as expert in Isolator and Aseptic Filling Technologies and Room decontamination process.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
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69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.pharma-congress.com

Date
Tuesday, 9 April 2019, 09.00 – 17.45 h
Wednesday, 10 April 2019, 09.00 – 17.00 h
(Registration: Monday, 8 April 2019, 19.00 – 20.00 h,
Tuesday, 9 April 2019 & Wednesday, 10 April 2019, 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.neu02@gchhotelgroup.com

Fee
EUR 690.- per delegate and day plus VAT (EUR 1,380.- for both days) (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 9 April. 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 below, by e-mail or by fax message. Or you register online at www.pharma-congress.com.

PLEASE NOTE
Please note that there will **not be any print-outs** at the Congress. Instead you will receive all presentations prior to the Congress as Downloads. All Congress delegates (excluding exhibition visitors) will also receive the presentations on a USB stick at the registration center.

Please further note that 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.

Organisation & Contact
ECA has entrusted Concept Heidelberg with the organisation of this event.
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Aseptic Processing (9-10 April 2019)
Part of the Pharma Congress Production & Technology 2019
Düsseldorf/Neuss, Germany, 9-10 April 2019

PLEASE NOTE:
Please book your hotel room directly with the reservation form which you will receive together with your confirmation/ invoice!

I register for:
☐ Current Aseptic Technologies (9 April 2019 – € 690)
☐ RABS & Isolators (10 April 2019 – € 690)
☐ Both days (9-10 April 2019 – € 1,380)*

☐ Yes, I would also like to participate in the Social Event on 9 April.

☐ Mr ☐ Ms

Title, first name, surname

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Department

Important: Please indicate your company's VAT ID Number

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* Please see www.pharma-congress.com for an overview of all conferences.

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2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

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Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of 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 conference (receipt of payment will not be confirmed)!
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