ECA Academy
Your GMP/GDP Information Source

Speakers


Dr Timo Krebsbach
HHAC Labor Dr Heusler


Quentin Majeau
Hydro-Fill


Ronan McGarvey
Abbvie


Didier Meyer
DMCompliance


Dr Daniel Müller
Local Authority of
Baden-Württemberg


Dr Rolf Ratke
Abbvie


Leslie Southam
Oxford Biomedica


Rutger Vandiest
Bavarian Nordic


Udara Yapa
MSD Animal Health
Danube Biotech

Barrier Systems

Part of Pharma Congress 2020

25 March 2020 | Düsseldorf/Neuss, Germany


Image: Skan

Highlights

- Regulatory update
- The evolution of barrier systems
- Case studies from:
  - Bavarian Nordic
  - Hydro-Fill
  - MSD Animal Health Danube Biotech
  - Oxford Biomedica

This conference is part of
2020 PHARMA CONGRESS
Production & Technology
DÜSSELDORF, 24 - 25 MARCH 2020

Objective

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

Social Event

On the evening of the first congress day, on 24 March 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
„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

Grey Field Project for Production of Large Scale Bacterial Antigen in an Aseptic Environment
Udara Yapa, MSD Animal Health Danube Biotech

- Planning, execution, commissioning and qualification and the technologies behind the vision
- Details of the Bacterial Antigen Production Line
- Challenges/complications and the complexity of the project
- Aseptic technology related to isolators will be discussed along with the single use connectors used in the process to maintain the containment of the project

Aseptic Processing and Filling of a Viral Vector for Gene and Cell Therapy
Leslie Southam, Oxford Biomedica

- An integrated solution of a state of the art small batch filler in a barrier system, designed to fit a biological production process: Freeze/thaw and time restrictions of the product lead to a special line layout where formulation and filling are combined in one barrier system
- Application of No-touch-transfer (NTT): An alternative methodology to introduce pre-sterilized product containers into the Grade A environment without in process disinfection steps
- Aseptic Containment Approach: Requirements on containment driven by cross contamination control are combined with requirements for aseptic filling and viral containment

Barrier Systems and Annex 1: GMP Inspectors's Point of View
Dr Daniel Müller, GMP Inspector Local Authority of Baden Württemberg

- Most important changes of Annex 1 – an update
- Regulatory comparison of Annex 1 version 2018 and new / intended Annex 1
- GMP inspector's comments on new / intended requirements for barriers

New-Designed Isolator for Aseptic Filling
Quentin Majeau, Hydro Fill

- Isolators : Overview
- Disposable Isolator to a Virtual-wall Isolator
- Virtual wall Isolator : containment or Class A operation
- Virtual wall Isolator : Integration on a disposable filling line

Vaccines for the World - Insights into Design and Execution of a BSL2 Fill-Finish Facility
Rutger Vandiest, Bavarian Nordic

- The fill & finish operations for viral vaccines: specific attributes to facility and equipment
- Design, construction and qualification of their new fill & finish facility in Denmark
- Filling and lyophilization of live vaccines in a BSL2 environment
- Dedicated capacity for CDMO services

Writing User Requirement Specifications (URS) for Isolator Projects
Dr Timo Krebsbach, HHAC Labor Dr Heusler

- The URS should define clearly and precisely, what the user wants the equipment to do in terms of performance characteristics, product quality metrics, and production yields. It should also define any nonfunctional requirements, constraints, and deliverables that need to be supplied with the system
- The presentation shows the lesson learned from the view of a customer
- In the future topics like automation and digitalization need more attention from the very beginning

Speakers

Dr Timo Krebsbach, HHAC Labor Dr Heusler GmbH

After completing his extra-occupational MBA studies, he moved to the HHAC Labor Dr Heusler, a medium-sized GMP contract laboratory in Germany, as its Business Development Manager in 2015. He has been the Managing Director here since October 2015.

Quentin Majeau, Hydro-Fill

He did develop, qualify and validate a complete disposable isolator for aseptic filling. We were the first team to produce a clinical batches in disposable isolators.

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.

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.

Dr Daniel Müller, Local Authority of Baden-Württemberg

Currently Daniel Müller is head of 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 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.

Leslie Southam, Oxfort Biomedica

As QA Manager for Oxford Biomedica he is the quality lead on the project for the design, construction and qualification of a new, state of the art 7200m^2 GMP manufacturing facility.

Rutger Vandiest, Bavarian Nordic

Being for more than 20 years in the biopharmaceutical industry, he is a preeminent expert in biopharmaceutical outsourcing. Gained aseptic processing experience in top-tier pharma companies and leading global sales and marketing teams in the primary component sector, he also has many years of experience in negotiating and establishing outsourcing partnerships. Rutger holds a Master in Medical Nuclear Sciences from the Limburg University in Belgium.

Udara Yapa, MSD Animal Health Danube Biotech

Responsible for managing Qualification, Validation and Re-Qualification activities.

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GERMANY

Reservation Form (Please complete in full)

Barrier Systems, 25 March 2020, Düsseldorf/Neuss

Part of the Pharma Congress Production & Technology, 24/25 March 2020 – I would like to register for the following days:

☐ *Barrier Systems – 25 March 2020 (EUR 690.- plus VAT)*
☐ *Both congress days – 24/25 March 2020 (EUR 1,380.- plus VAT)*
☐ *I would also like to participate in the Social Event on 24 March 2020*

Title, first name, surname

Department | Company

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

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

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 weeks prior to the conference 50 %
- Cancellation within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.
If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERGwill not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
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)! (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 Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see 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
Wednesday, 25 March 2020, 09.00 – 17.00 h
Registration:
Monday, 23 March 2020, 19.00 – 20.30 h,
Tuesday, 24 March 2020, 08.00 – 09.00 h
Wednesday, 25 March 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.- plus VAT (EUR 1,380.- for both congress 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 24 March. 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 area 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.

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