Trends in Barrier Systems & Robotics

Part of PharmaCongress 2024

19/20 March 2024
Wiesbaden, Germany

Highlights

- Barrier Systems and the New EU GMP Annex 1 Requirements
- Robotics Technology in Pharmaceutical Manufacturing
- Case studies from:
  - Cilag / Janssen
  - GSK Vaccines
  - Lonza
  - Roche Diagnostics
  - PSM
  - Vetter Pharma-Fertigung

Speakers

Dr Annika Bernsdorf | GlaxoSmithKline Biologicals, Germany

Pasquale Cataldo | Roche Diagnostics, Germany

Dr Göran Crucius | Cilag/Janssen, Switzerland

Dennis Dürr | Roche Diagnostics, Germany

Thorsten Häfner | PSM, Germany

Kenan Kanmaz | Metall+Plastic, Germany,

Harald Kiesel | Skan, Switzerland

Didier Meyer | DMCompliance, France

Dr Daniel Müller | Local GMP Authority of Baden Württemberg, Germany

Julian Petersen | groninger & co., Germany

Katharina Schlereth | Labor LS, Germany

Dr Arne Schröder | Vetter Pharma-Fertigung, Germany

Antoine Toussaint | GSK Vaccines, Belgium

Patrick Wieland | Bausch+Ströbel, Germany

Dr Florian Witte | Boehringer Ingelheim Pharma, Germany

GMP-PHARMA CONGRESS

This conference is part of PharmaCongress 2024

ECA Academy
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GMP–PHARMA CONGRESS

TRENDS IN BARRIER SYSTEMS & ROBOTICS

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 Isolators, RABS systems and Robots.
- You will discuss the current state of the art and new technological developments in Barrier Systems and Pharmaceutical Robotics Technology.
- You will get to know first-hand the new EU-GMP Annex 1 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 stricter 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. Another consequence of the separation of operator and production process is the increased introduction of Robot Technology in the aseptic environment.

PROGRAMME 19 March 2024

Isolator / RABS: What is really new in Annex 1

Florian Witte, *Boehringer Ingelheim*

- Classification by the authorities and in the current Annex 1
- What is suitable for whom?
- Advantages and disadvantages of isolators and RABS
- What is new about the classic cleanroom?

Tackling Annex 1 Requirements by Robotics: On the Way to zero human Interaction in Lyo Vial Filling

Dr Arne Schröder, *Vetter Pharma-Fertigung*

- Cleanroom layout and processes for zero human interaction in lyo vial filling
- Replacement of manual processes by robots
- Challenges of implementing robots
- Lessons learned during the first years of commercial use

Robotics and Automation – The Enabler for a higher Quality and Annex 1 CCS Compliance

Thorsten Häfner, *PSM*

Julian Petersen, *groninger & co*

- Current Annex 1 requirements and the reduction or elimination of human intervention within the ISO 5 environment
- How the usage of automation and robotics can support CCS
- Applying robotics in the pharmaceutical environment based on executed applications within aseptic environments
- Details about how to completely remove an operator from the aseptic environment

Aseptic Process Simulation in a Robotic Filling Line

Dennis Dürr, *Roche Diagnostics*

- Short introduction/Oversight into APS and Robotic filling line
- Aseptic process simulations in robotic vs. conventional lines
- Thoughts and Rationales for APS in robotic filling line
- Insights into APS-concept for a robotic filling line

APS with a Gloveless Robotic Filling Line – Best Practices and Lessons learned

Thorsten Häfner, *PSM*

- How to execute an APS for gloveless filling lines
- Challenges to overcome regarding the new Annex 1
- Is monitoring necessary in closed systems?
- Lessons learned in discussions with authorities

Barrier Systems – Current GMP Requirements

Dr Daniel Müller, *Local GMP Authority of Baden-Württemberg, Germany*

- Regulatory overview: most important guidelines for barriers/ isolators
- Revised Annex 1 section "barrier technologies" - changes and current requirements
- Annex 1 – fit for future now?

This conference will focus on current questions of barrier systems and robotics 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, automation, 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 and robotics.

MODERATORS

Didier Meyer, *DMCompliance*
Dr Florian Witte, *Boehringer Ingelheim Pharma*

PROGRAMME 20 March 2024

Case Study on Management of Indirect Products Contact Parts in an Isolator

Antoine Toussaint, *GlaxoSmithKline Vaccines*

- Definition of indirect product contact part
- Regulation's requirement
- Example of implementation along the all lifecycle of indirect product contact parts

Meeting EU GMP Annex 1 Requirements: Sterilization of indirect Product Contact Parts in Filling Lines using Sterilization Container

Dr Annika Bernsdorf, *GlaxoSmithKline Biologicals*

- Overview of the design of the current filling isolators at a GSK Vaccines manufacturing site and the challenges linked to traditional sterilization methods for parts indirectly in contact with the product
- Explanation of the features and benefits of sterilization containers as a compliant solution
- Customization of the containers to accommodate larger parts, such as the stopper bowl and stopper hopper
- Development of an improved line setup with enhanced contamination control

Upgrade of H_2O_2 Dcontamination System for Production of RABS Vial Filling Line

Pasquale Cataldo, *Roche Diagnostics*
Kenan Kanmaz, *Metall+Plastic*

- Current process, why this upgrade – Annex 1
- Project challenge – timeline & installation vs. production
- Production shutdown and realization
- Risk and other key tasks of upgrading
- Results of project, cycles development and benefits
- Key features and advanced technologies of DECOpulse® – effective H_2O_2 Bio-decontamination system

Case Study Janssen: Flexible fill & finish Equipment for Multi-Product Manufacturing Processes

Dr Göran Crucius, *Cilag / Janssen*
Patrick Wieland, *Bausch+Ströbel*

- Flexible multi-product fill and finish lines in pharmaceutical manufacturing offer several benefits that can help pharmaceutical companies improve their efficiency, flexibility and overall productivity
- Case Study of Janssens flexible pharma production to meet varying market demands and maintain product quality

Modern Sterile Test Isolators – Safe, Compliant, Efficient, Versatile

Katharina Schlereth, *Labor LS*
Harald Kiesel, *Skan*

- Components of a modern Sterile Test Isolator
- Safe for operator and process
- Compliant during all aspects of use
- Efficient by adaptable to required processes
- Versatile in handling options

SPEAKERS

Dr Annika Bernsdorf
GlaxoSmithKline Biologicals, Dresden, Germany
Pharmacist, PhD, joined GSK in 2007, different positions in aseptic manufacturing and Quality Assurance, wealth of experience in vaccines manufacturing with focus on aseptic processes and sterility assurance.

Pasquale Cataldo
Roche Diagnostics, Mannheim, Germany
Pasquale Cataldo is an expert for sterile manufacturing and lab lead of the Sterile Drug Product Manufacturing (SDPM) Innovation Lab since 2019 at Roche Diagnostics GmbH in Mannheim / Germany.

Dr Göran Crucius
Cilag/Janssen – Pharmaceutical Company of Johnson & Johnson, Schaffhausen, Switzerland
Responsible for execution of strategical projects within BU Parenterals. Lead of Operational Readiness Team for new aseptic filling technologies and related topics.

Dennis Dürr
Roche Diagnostics, Mannheim, Germany
After several stations within Roche Diagnostics GmbH, Dennis is currently working as process validation engineer with main emphasis on aseptic process simulations.

Thorsten Häfner
PSM, Schiffweiler, Germany
From 2017-2022 Director Business Development, Product Management and Marketing at groninger & co. gmbh. Vice President of Business Development at PSM GmbH since 2022.

Kenan Kanmaz
Metall+Plastic, Radolfzell, Germany
Kenan Kanmaz has been working for more than 12 years as technical engineer in the clean room section. Currently he works as Technical Sales Manager for METALL+PLASTIC GmbH (since 2016).

Harald Kiesel
Skan, Allschwil, Switzerland
Harald Kiesel Dipl.-Ing, MBA is strategic Product Manager at Skan and responsible for the portfolio of sterile test isolator. In this position he is mainly working for shaping the offering of Skan isolators to meet market needs.

Didier Meyer
DMCompliance, France
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 GMP Authority of Baden Württemberg, Germany
Currently Daniel Müller is head of GMP inspectorate (local competent authority) at Tuebingen, Germany. Since 2001 he has been working as GMDP inspector, conducting national inspections as well as EMA- and overseas inspections.

Julian Petersen
groninger & co., Germany
After a short timeout in the semiconductor/metrology business Julian returned to the pharmaceutical fill&finish business as a Sales Director responsible for the DACH market. Now leading the Business Development and Product management.

Katharina Schlereth
Labor LS, Bad Bocklet, Germany
Katharina studied Biology at the University Würzburg. 2009 she joined Labor LS AG in Bad Bocklet, Germany, where she is responsible for sterility testing. Her current position is Division Head, Microbiological Testing of Sterile Products.

Dr Arne Schröder
Vetter Pharma Fertigung, Ravensburg, Germany
Arne Schröder, Ph.D., joined Vetter in 2016. Since 2017 he is working as Head of Production in the area of manufacturing and filling of sterile drug products, which includes various vial, single/dual-chamber cartridge and SCF syringe filling lines.

Antoine Toussaint
GSK Vaccines, Wavre, Belgium
12 years of experience in GSK vaccines in several roles: Manager in QC department in Environmental monitoring / Sterility Assurance Manager for primary and secondary operations / Global Sterility Assurance Lead on Technology Barrier, Facility Design, HVAC & Disinfectant.

Patrick Wieland
Bausch+Ströbel, Germany
Patrick Wieland is a senior sales professional with more than 10 years of working experience in the pharmaceutical industry.

Dr Florian Witte
Boehringer Ingelheim Pharma, Ingelheim, Germany
For more than 20 years in different positions at Boehringer Ingelheim. Florian Witte has headed the quality assurance unit for device development since 2021.

The guiding theme of the GMP PharmaCongress 2024 on 19/20 March will be „users sharing challenges and solutions in practice". Therefore, benefit from your colleagues' experience and from the direct information exchange at the GMP PharmaCongress & GMP PharmaTechnica 2024.

The Conference Tracks

As a participant you can switch between any of the **11 conference tracks** any time and also visit the PharmaTechnica Expo with more than 110 international exhibitors.

The GMP PharmaCongress Conference Tracks	19 March 2024	20 March 2024
Non-Sterile Products – Challenges in Manufacturing & Quality	✓	n.a.
GMP – Green or Good Manufacturing Practice?	✓	n.a.
Packaging/Packaging Materials – Challenges & Solutions	n.a.	✓
European Aseptic Conference – Technology	✓	✓
Trends in Barrier Systems & Robotics	✓	✓
Modern Cleanroom Technology	✓	✓
Digitalisation & Artificial Intelligence	✓	✓
GMP for Pre-Filled Syringes (PFS)	✓	✓
Lyophilization – Modern Techniques & New Requirements	✓	✓
ATMPs – Hurdles & Achievements in Quality and Safety	✓	✓
Vaccines – Advantages & Challenges in Manufacturing	✓	✓
GMP PharmaTechnica Expo	✓	✓

Keynote on 19 March 2024

The CEPI Project – 40 Countries – 1 Billion Euros for Vaccines

Dr Guido Dietrich, *CEPI*

Do you know the worldwide importance of CEPI? And why is this so important for everyone working in pharmaceutical production?
Our first keynote will address a very important new development. More than 40 countries, several non-governmental organizations and the European Commission are involved in the **Coalition for Epidemic Preparedness Innovations (CEPI)**.

What is the goal?
The goal of CEPI is to develop, produce and distribute a vaccine as quickly as possible in the event of the next global pandemic, i.e. within 100 days.

What is the current budget?
For the first 5 years alone, a budget of one billion euros has been made available.

In the Live Demo Area in the PharmaTechnica Expo hall you will benefit from the exhibitors' demonstrations – presenting their latest technology, products and services. Take advantage of these live performances – and get to feel and experience their products. For a list of all companies exhibiting at PharmaTechnica, please see the exhibitor list and plan on the website at **www.pharma-congress.com**.

Exhibitor	Stand	Live Demo
boTec	A 7	TBN
MKVersuchsanlagen	A 12	TBN
Ellab	A 16	TBN
Bausch+Ströbel	A 33	OMNIA - Boost your processes and step closer to your pharmaceutical plant of the future.
PHARMAPLAN	A 37	Accelerated Design Decisions enabled by Digital Twins
Quascenta Pte	B 6	Using an Intelligent Lifecycle-Based Solution for Streamlined Product Tracking, Design Optimization, Collaboration, and Reporting
ZETA	B 12	TBN
IWT / Tecniplast	B 15	High pressure cleaning in pharmaceutical production. Advantages, challenges, sustainability and savings
MBV	B 20	TBN
Emerson Automation Solutions	B 22	TBN
Atec Steritec	B 28	Safe & Sterile Transfer with Minimal Operator Intervention
REA Elektronik	B 29	Experts in Printing and Code Verification of pharmaceutical and medical-device packaging (f.e.UDI/MDR)
Friedrich Sailer	B 31	Shining Solutions: Live Demo of Cutting-Edge Stainless Steel Cleanroom Equipment
Merck	B 32	Annex 1's "Specific Risks Associated with Single-Use Systems"
Particle Measuring Systems	C 7	Facility Monitoring Systems
Yokogawa	C 9	Flow Imaging using FlowCam for High Performance Products to warrant constant excellent Quality

Easy Registration

Registration Form:
CONCEPT HEIDELBERG
Rischerstraße 8
69123 Heidelberg

Registration Form:
(06221) 84 44 34

E-Mail:
info@concept-heidelberg.de

Internet:
www.pharma-congress.com

Congress Dates
Tuesday, 19 March 2024, 09.00 - 18.00 h
Wednesday 20 March 2024, 09.00 - 17.00 h
Registration
Tuesday & Wednesday, 19/20 March 2024, 08.00 - 09.00 h

Fees
The one day ticket is available for € 690,- plus VAT, both days for € 1,380.- plus VAT. It includes participation in any track on that day and the visit of the PharmaTechnica Expo. In addition, lunch and beverages during the tracks and in breaks as well as the social event on the evening of the first congress day, 19 March is included; please mark if you would like to attend the Social Event. The fee is payable in advance after receipt of invoice.

Venue
RheinMain CongressCenter (rmcc)
Friedrich-Ebert-Allee 1 | 65189 Wiesbaden
Phone: +49 (0) 611 1729-444
E-Mail: veranstaltungsservice-rmcc@wicm.de

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms close to the CongressCenter. You will receive a room reservation form when you have registered for the conference. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration
Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Presentations/Certificate
The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

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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69007 Heidelberg, Germany
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For questions regarding organisation please contact:
Mr Ronny Strohwald (Organisation Manager) at
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GERMANY

Reservation Form (Please complete in full)

Trends in Barrier Systems & Robotics

Part of PharmaCongress 2024

19/20 March 2024, Wiesbaden, Germany

☐ Day 1 & 2 (19/20 March 2024)
☐ Day 1 (19 March 2024)
☐ Day 2 (20 March 2024)

☐ Yes, I would also like to take part in the Social Event on the evening of 19 March 2024.

☐ Mr ☐ Ms ☐ Mx ☐ Dr

First name, Surname

Company

Department

Important: Please indicate your company's VAT ID Number P.O. Number (if applicable)

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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 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks 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 HEIDELBERG will 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 July 2022). 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.

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