

20 Pharma Congress 10 Production & Technology Dusseldorf, 9-10 March 2010



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D a y 1
Barrier Systems Conference

D a y 2
Current Aseptic Technologies Conference

**CONCEPT
HEIDELBERG**

Pharmaceutical Quality
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Daily Tickets for € 490,- only!

Objectives

- You get to know the current state of the art as well as future technological developments in the field of RABSs and isolators
- You can evaluate the advantages and disadvantages of the systems with regard to their use in your companies
- How can the different requirements for high-potent aseptic products be solved technologically?
- Which are the weak points of the individual systems – which operational experience has been gathered?
- Which points have not yet been managed satisfactorily or need to be improved?

Background

Especially in connection with sterile medicinal products produced by aseptic processing, protection against microbial contamination increases in importance. In case of new facilities, today the classical cleanroom cannot be considered as the state of the art any longer. In addition, there is a growing number of high-potent / toxic products that are filled under aseptic conditions. This is another reason why the supervisory authorities require a stricter separation between staff and product in the form of an access barrier – RABS (Restricted Access Barrier System) or isolator. The level of contamination safety as well as that of personnel protection is clearly higher in both systems. Topical questions on barrier systems are discussed in detail from the perspective of pharmaceutical operators, planners and engineers.



Image: Skan

Target Audience

The event is directed at decision-makers from pharmaceutical production, development and quality assurance/control, at engineers and planners who need to be well informed about current developments in the field of RABSs and isolators.

Programme

Technical aspects during design and engineering of isolator systems

- How reasonable is a Isolator system as production equipment
- Isolator as process equipment – what has to be known
- Examples of technical solutions
- How individual is each single project?
- Validation process knowledge vs. confusion

How lessons learned can help to advance design and operatability of Isolators

- Lessons learned from previous Isolator
- Changes for new Isolator
- Design and project execution
- Start-up, Commissioning and Qualification
- Comparison between old and new Isolator
- Operation improvements

Advanced Barrier Technologies: ISOLATOR and RABS Systems

- Regulatory Aspects
- Where we come from...
- Isolator Definition, ISPE, 2007
- RABS Technical Monograph no. 15, PHSS, 2009, rev.7.1.
- BI-Syringe Filling Unit as an a-RABS
- BI-Isolator for Sterility Testing
- BI-Isolator Project: Aseptic Processing Unit 5
- PROs and CONS: RABS vs. ISOLATOR
- Which Technique to be used for different Process Scenarios?
- Summary

Case Study: RABS and Isolators in the new Hoffmann-La Roche Parenteral Production Facility

- Basic concepts
- Decisions to use RABS or Isolator technology for the individual lines
- First experiences
- Lessons learnt

Case Study: RABS from the User's Point of View

- Regulatory requirements
- Process design: Isolator, RABS, conventional clean room
- Operation of a RABS line
- Strategies for process automation
- Case study: Vetter Langenargen, Line VLA3

Rapid Transfer Port: the key element for barrier systems

- RTPs existing on the market
- Validated systems of reference today
- Transfer of solids and liquids: safety & flexibility are required
- Applications for aseptic and or toxic production
- Use of RTPs for containment

Case Study: Manufacturing of a Parenteral from Manufacturing of a high potent Drug Substance to the final Drug Product by using Isolator technology

- Basic Design: Use of isolators for employment & environment protection and sterile manufacturing
- Comparison of requirements: Isolators for the manufacturing of high potential API and parenterals
- Case study: Demonstration of GMP-compliance while routine production
- Lessons learnt

Objectives

Three good reasons to attend this conference:

- You are informed about the latest technological developments in sterile manufacture
- You learn how current GMP and production requirements have to be implemented technologically in sterile manufacture
- Afterwards you will know what has to be taken into account in the introduction and during the operation of new technologies from a GMP auditor's point of view

Background

GMP regulations only define general requirements on equipment – it has to be suitable for the intended work process, easy to clean and without any negative influence on the product quality. The questions of 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 the focus of this event. Speakers from the pharmaceutical industry, from planning and engineering firms deal with pivotal developments in the field of sterile manufacture:

- **Increasing contamination safety through new technologies**
- **Implementation of new regulatory requirements**
– Capping / Track and Trace



Target Audience

The event is directed at specialists from the pharmaceutical industry, at engineers and planners who have to deal with current aseptic technologies in clean areas in their daily practice.

It particularly aims at the departments:

- Production
- Quality assurance
- Engineering / technology

Moderator

- Hartmut Schaz

Programme

Recent trends in sterile manufacturing technologies

- Recent Regulatory News
 - EU and US FDA Legislation
- Technology Trends
 - Filling Equipment / Barrier Systems
 - Freeze Dryer Loading & Unloading Technology
 - Sterilisation Technology
 - Rubber Stopper Process Technology
 - Equipment Cleaning Technology

Closed Vial Technology: how to improve sterility assurance level thanks to a closed container

- Introduction on the technology
- Main validation results obtained
- Feasibility of Lyophilization
- Perception of the technology by healthcare professionals
- Key advantages over the classical glass
- Approval by EMEA of a first GMP manufacturing site

Track and Trace for the aseptic filling process

- Mark each unit with a unique identifier
- Process surveillance for each unit
- New opportunities for process optimizations and troubleshooting
- Synergies regarding serialization and anti-counterfeiting

Capping und „grade A“: The Merck Solution

- Introduction: Layout and design of the vial filling line
- Design of the capping station
- Evaluation of the new requirements
- Conclusion

Advanced Aseptic Technology: Aseptic Filling with Blow-Fill-Seal-Technology

- Basics of BFS-Technology
- Comparison BFS-Technology with other Advanced Filling Technologies and conventional filling.
- New possibilities with BFS-Technology: Container for special applications
- Optimized container material: CoExtrusion

Inspection of Aseptic Operations - Where could your inspector focus on when assessing your operations?

- A compiling of GMP requirements: can your inspector ask for more than EU-GMP?
- Three main „conventional“ types of processes: cleanrooms, isolators, blow-fill-seal.
- The approach of audit/inspection in relation with the specific points of these processes
- The real question: Media-Fill-Tests, ideal situation or routine simulation?
- Decontamination or sterilization of the aseptic core (filling point)
- Aseptic fluids: Air & Gases, Water & Clean steam

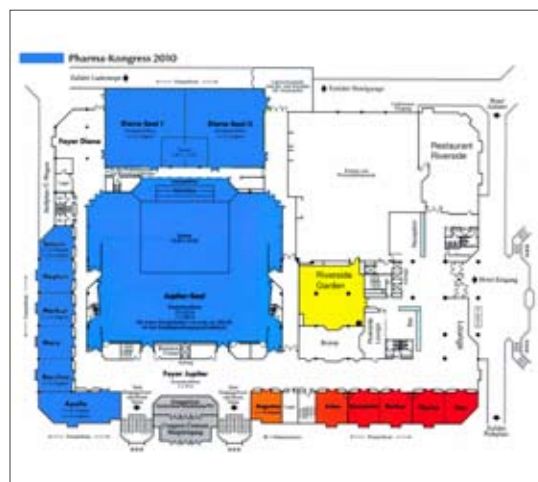
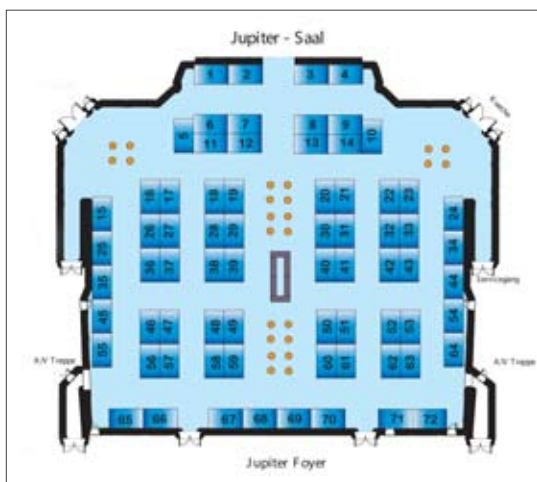
Speakers

- **Christoph Bohn**, *Holopack Verpackungstechnik GmbH, Abtsgemünd-Untergröningen*
Christoph Bohn is working as Technical Plant Manager at Holopack Verpackungstechnik GmbH.
- **Dr Friedrich Haefele**, *Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach*
In May 2006 Dr Haefele joined Boehringer-Ingelheim Pharma as Vice President in the business domain Biopharmaceuticals.
- **Brigitte Lechiffre**, *GETINGE LA Calhene, Vendôme*
As Sales Area Manager responsible for Sales of all DPTE® configurations to Integrators and OEM companies and the support for transfer applications.
- **Dr. Jean-Denis Mallet**, *International Committee Red Cross, Geneva*
He is currently a GMP auditor within the ICRC. He was previously Head of the Pharmaceutical Inspection Department at the French Health Products Regulatory Agency.
- **Herwig Muehleider**, *Wyeth BioPharma, Dublin, Ireland*
Project engineer and leader in realising Wyeth's second Syringe Filling Line with new Skan E-Beam System at Grange Castle near Dublin.
- **Dr. Michael Pfeil**, *Merz Pharma GmbH & Co. KGaA, Reinheim*
Head of Production (Biologics), Merz Group Services GmbH, Site Dessau.
- **Dr. Ingo Presser**, *Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach*
Since 2007 he has been Head of an Aseptic Filling and Freeze Drying Unit within the department of biopharmaceutical production.
- **Hartmut Schaz**, *NNE Pharmaplan GmbH, Bad Homburg*
He is working with NNE Pharmaplan as a Senior Expert for Small Volume Parenteral Products and is a Director of the Board of NNE Pharmaplan India.
- **Dr. Rainer Schmidt**, *F. Hoffmann-La Roche AG*
Dr Rainer Schmidt is the project owner for building a new parenterals facility for F. Hoffmann-La Roche in Kaiseraugst, Switzerland.
- **Dr Christian Schröter**, *Merck KGaA*
Dr Schröter is currently Director of Liquid Manufacturing responsible for making, filling and packaging of sterile and nonsterile liquids.
- **Volker Sigwarth**, *Skan AG, Allschwil*
As Director Business Development, he headed the engineering and development department; since 2009 he has been CEO of Skan AG.
- **Benoît Verjans**, *Aseptic Technologies S.A., Les Isnes, Belgien*
He is currently Commercial Director of Aseptic Technologies, responsible for developing the sales of the closed vial technology worldwide.
- **Jörg Zimmermann**, *Vetter Pharma-Fertigung GmbH & Co. KG, Ravensburg*
Since 2001, he has been Head of Production at the Langenargen site, where he is in charge of the aseptically prefilled syringes.

The Exhibition

The Exhibition taking place together with the Pharma Congress provides you with the opportunity to get the latest information – more than 70 internationally oriented companies will present new technologies, products and services. To get the current exhibitor list please visit www.pharma-kongress.com. Visiting the exhibition is free of charge.

The Exhibition: Floor Plans



Dates

Barrier Systems Conference

Tuesday, 9 March 2010, from 09.00 - 18.00 h
(Registration and coffee 08.30 - 09.00 h)

Current Aseptic Technologies Conference

Wednesday, 10 March 2010, from 9.00 - 18.00 h
(Registration and coffee 08.30 - 09.00 h)

Parallel to these conferences there will also be taking place five German language conferences, which delegates are also free to attend. To find out more about these conferences, please visit the congress website at www.pharma-kongress.com.

Fees

Daily tickets will enable you to visit the congress either only on day 1 or only on day 2 or attend on both days. Charges for the daily tickets are € 490,- plus VAT. They include a lunch and beverages during the conferences and in breaks as well as the social event on the evening of the 1. congress day (9 March 2010). Charges are payable after receipt of invoice.

Location

Swissôtel Congress Centrum Düsseldorf / Neuss
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41460 Düsseldorf/Neuss, Germany
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Fax: +49 (0) 2131 77 - 1367
Email: swissotel-duesseldorf.de

Room Reservation

Please book your **hotel room directly with the reservation form** which you can find on the congress website at www.pharma-kongress.com! There will be no reservations via Concept Heidelberg. Charges are payable after receipt of the invoice.

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 March 2010, all congress delegates, speakers and exhibition visitors 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.

Contact

For questions regarding content:

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For questions regarding reservation, hotel, organisation etc.:


Detlef Benesch (Organisation Manager),
Tel. +49 6221 84 44 45, E-Mail: benesch@concept-heidelberg.de.

Easy Registration

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69007 Heidelberg
Germany

 Reservation Form:
+ 49 6221 84 44 34

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The Organiser



The two conferences „Barrier Systems Conference“ and „Current Aseptic Technologies“ are organised by CONCEPT HEIDELBERG on behalf of the European Compliance Academy (ECA) as part of the Pharma Congress 2010.

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PLEASE NOTE!

Please note that congress materials will not be available as print outs in a folder. Instead all lectures will be made available prior to the congress for download. In addition, all congress delegates (excluding exhibition and Forum visitors) will receive the presentations of all conferences on site on a USB stick.

**Daily Tickets
for € 490,- only !**

Registration

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

Reservation Form (Please complete in full)

Please mark the conference(s) you would like to attend!

- Barrier Systems Conference (Day 1; 9 March 2010)
 Current Aseptic Technologies Conference (Day 2; 10 March 2010)
 Yes, I would also like to participate in the Social Event (9 March 2010)
- Mr Ms Dr

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

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GERMANY

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 %
 - until 1 weeks prior to the conference 50 %
 - 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 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)!