

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



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## Barrier Systems Conference

9 March 2010

### Highlights

- Technical aspects during design and engineering of isolator systems
- How lessons learned can help to advance design and operability of Isolators
- Advanced Barrier Technologies: ISOLATOR and RABS Systems
- Case Study: RABS and Isolators in the new Hoffmann-La Roche Parenteral Production Facility
- RABS from the user's point of view
- Rapid Transfer Port: the key element for barrier systems
- Case Study: Manufacturing of a Parenteral from Manufacturing of a high potent Drug Substance to the final Drug Product by using Isolator technology

### Speakers

- Dr Friedrich Haefele  
*Boehringer Ingelheim Pharma GmbH & Co. KG*
- Brigitte Lechiffre  
*GETINGE LA Calhene*
- Herwig Muehleder  
*Wyeth BioPharma*
- Dr. Michael Pfeil  
*Merz Group Services GmbH*
- Dr. Rainer Schmidt  
*F.Hoffmann-La Roche AG*
- Volker Sigwarth  
*Skon AG*
- Jörg Zimmermann  
*Vetter Pharma-Fertigung GmbH & Co. KG*

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## 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

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- 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 operability of Isolators

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- 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

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- 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

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- 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

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- 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

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- 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

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- 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

## Speakers

- **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.
- **Herwig Muehleder**, *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. 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.
- **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.
- **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.

## Dates

### Barrier Systems Conference

Tuesday, 9 March 2010, from 09.00 - 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](http://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  
Rheinallee 1  
41460 Düsseldorf/Neuss, Germany  
Tel.: +49 (0) 2131 77 - 00  
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## Room Reservation

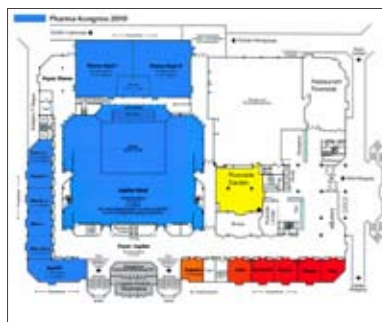
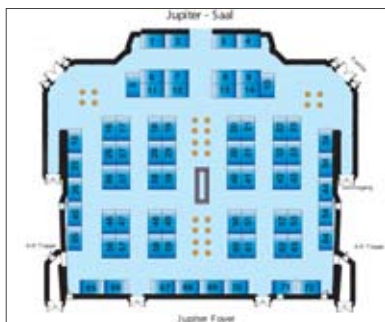
Please book your **hotel room directly with the reservation form** which you can find on the congress website at [www.pharma-kongress.com](http://www.pharma-kongress.com)! There will be no reservations via CONCEPT HEIDELBERG. Charges are payable after receipt of the invoice.

## 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.

## 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](http://www.pharma-kongress.com). Visiting the exhibition is free of charge.

## Easy Registration

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 **Internet:**  
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## The Organiser



The conference „Barrier Systems Conference“ is organised by CONCEPT HEIDELBERG on behalf of the European Compliance Academy (ECA) as part of the Pharma Congress 2010. For more information please see [www.pharma-kongress.com](http://www.pharma-kongress.com).

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## Contact

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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.

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## Registration

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Reservation Form (Please complete in full)

**Barrier Systems Conference**  
9 March 2010, Düsseldorf, Germany

Yes, I would also like to participate in the Social Event

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