

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



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Current Aseptic Technologies

10 March 2010

Highlights

- Recent trends in sterile manufacturing technologies
- Closed Vial Technology: how to improve sterility assurance level thanks to a closed container
- Track and Trace for the aseptic filling process
- Capping und grade A?!: The Merck solution
- Advanced Aseptic Technology: Aseptic Filling with Blow-Fill-Seal-Technology
- Inspection of Aseptic Operations – Where could your inspector focus on when assessing your operations?

Speakers

- Dr Martin Haerer
Holopack Verpackungstechnik GmbH
- Dr. Jean-Denis Mallet
International Committee Red Cross
- Dr. Ingo Presser
Boehringer Ingelheim Pharma GmbH & Co. KG
- Benoît Verjans
Aseptic Technologies S.A.
- Hartmut Schaz
NNE Pharmaplan GmbH
- Dr Christian Schröter
Merck KGaA

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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

- **Dr Martin Haerer**, *Holopack Verpackungstechnik GmbH, Abtsgemünd-Untergröningen*
Martin Haerer is Director Pharmaceutical Affairs and Qualified Person. He is responsible for Development, Transfer of BFS Products and pharmaceutical customer relationship.
- **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.
- **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 Christian Schröter**, *Merck KGaA*
Dr Schröter is currently Director of Liquid Manufacturing responsible for making, filling and packaging of sterile and nonsterile liquids.
- **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.

Dates

Current Aseptic Technologies

Wednesday, 10 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.

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. Charges are payable after receipt of invoice.

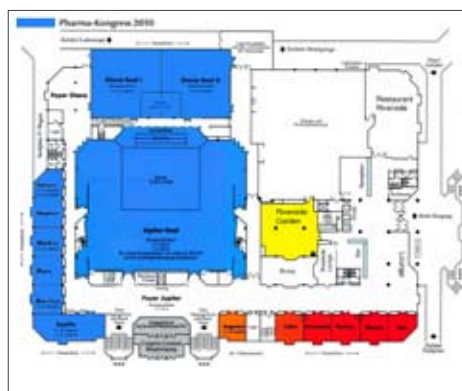
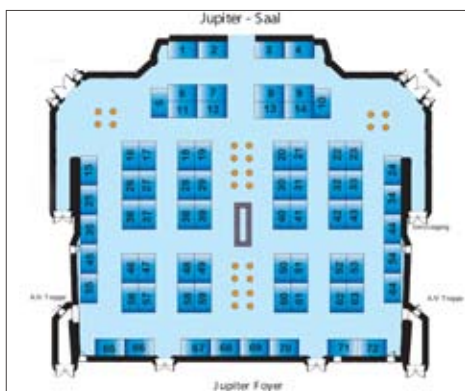
Location

Swissôtel Congress Centrum Düsseldorf / Neuss
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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! There will be no reservations via Concept Heidelberg. Charges are payable after receipt of the invoice.

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.

Easy Registration

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The Organiser



The conference „Current Aseptic Technologies“ 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.

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PLEASE NOTE!

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Registration

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

Reservation Form (Please complete in full)

Current Aseptic Technologies
10 March 2010, Düsseldorf, Germany

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