

20 Pharma Congress 11 Production & Technology Duesseldorf, 22-23 March 2011



Prefilled Syringes – Trends



Prefilled Syringes –
Decontamination



Barrier Systems – RABS



Barrier Systems – Isolators



Current Aseptic
Technologies

www.pharma-kongress.com

Conferences 22 March 2011

- ECA Conference Prefilled Syringes:
New Trends
- ECA Barrier Systems Conference: RABS

Conferences 23 March 2011

- ECA Conference Prefilled Syringes:
Decontamination Technologies
- ECA Barrier Systems Conference:
Isolators
- ECA Conference Current Aseptic
Technologies

Speakers

From Industry:

Boehringer Ingelheim
CILAG
Crucell
Ferring
F. Hoffmann-La Roche
Genentech
GlaxoSmithKline Biologicals
Hameln Pharmaceuticals
Lilly
Novartis
Schering-Plough
Vetter Pharma-Fertigung

From Authorities:

Regierungspräsidium Tübingen
and others

CONCEPT
HEIDELBERG

Pharmaceutical Quality
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Greeting



Dear Colleagues,

On 22/23 March 2011 the 13th Pharma Congress will be conducted in Düsseldorf, Germany. It has almost become a tradition already that industry professionals get together at this event.

During the Congress many international projects will be introduced that are marked through current developments and innovations. The Congress will also be accompanied by an exhibition with more than 80 exhibitors. This event's goal is to present projects as technical implementations – “from operators for operators” – with a very high level of practical relevance and demonstrations of the current state of technology.

At the same time this event will be the ideal platform for exchanging information and experience. This exchange between experts will further offer the opportunity to find solutions for the one or the other problem.

Due to globalisation we are also all dependent on “good and productive” networks to be on top of developments and trends and to find interesting and sustainable solutions in this versatile field of pharma technology.

I look forward to welcoming you at the Pharma Congress – it will most certainly be an interesting event.

Yours,
 Franz Maier
Prof. Dipl. Ing. Franz Maier
Director Operations International Engineering, NYCOMED GmbH

The Pharma Congress Overview

Pharma Congress – Overview			
Conference	<u>One Day Ticket 490,- EUR</u>	22 March 9:15 am – 6:00 pm*	23 March 9:00 am – 5:00 pm*
ECA Conference Prefilled Syringes: New Trends Decontamination Technologies		✓	✓
ECA Barrier Systems Conference: RABS Isolators		✓	✓
ECA Conference Current Aseptic Technologies			✓
Exhibition	<u>One Day Ticket 90,- EUR</u>	✓	✓

* For individual conference times and updates please see agenda on congress website at www.pharma-kongress.com.



Speakers

- **Dr Dieter Bachmann**, *Cilag AG, Schaffhausen, Switzerland*
 Since 2005 he is Associate Director of the Qualification & Validation department.
- **Frank Bamberg**, *SCHOTT Forma Vitrum AG, St. Gallen, Switzerland*
 Since 2008 Head of Product Management Syringes.
- **Dr Karoline Bechtold-Peters**, *Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach, Germany*
 Dr Bechtold-Peters is currently Associate Director Clinical Supplies & Process Transfer, Biopharmaceuticals/ Cell Culture and Drug Product.
- **Dr Simone Dahlmans**, *hameln pharmaceuticals GmbH, Hameln, Germany*
 Head of Technical Pharmaceutics in charge of the departments Production and Packaging, Technical Services, Product Compliance Service and Qualification/Validation.
- **James Drinkwater**, *Bioquell UK Ltd., Andover UK*
 Process and Compliance Director for Bioquell UK together with being the Chairman of the PHSS – Pharmaceutical and Healthcare sciences society and leader of the PHSS RABS special interest group.
- **Hans-Christian Gath**, *Groninger & Co. GmbH, Crailsheim, Germany*
 Hans-Christian Gath is regional sales director for the Asian market, and director of cleanroom technology.
- **Dr Friedrich Haefele**, *Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach, Germany*
 In May 2006 Dr Haefele joined Boehringer-Ingelheim Pharma as VP in the business domain Biopharmaceuticals.
- **Hartwig Hönerloh**, *Ferring GmbH, Kiel, Germany*
 Associate Director of the group Technology Service and Validation since June 2006.
- **Alexander Jaksch**, *Safety Syringes, Inc., Carlsbad, US*
 He joined Safety Syringes in 2006. Since 2009 he is responsible for Business Development and Marketing.
- **Philippe Jérôme**, *SKAN AG, Allschwil, Switzerland*
 Philippe Jérôme is responsible for the french speaking countries for the industrial division and in charge of filling line projects and key account manager.
- **Dr Jörg Lümekemann**, *F. Hoffmann-La Roche AG, Basel, Switzerland*
 Since 2001 in the development of parenterals and in charge of the implementation of new technologies in this area.
- **Gert Moelgaard**, *NNE Pharmaplan, Søborg, Denmark*
 Gert Moelgaard is Vice President for Innovation & Business Development in NNE Pharmaplan.
- **Dr Daniel Müller**, *Regierungspräsidium Tübingen, Germany*
 In 2001 he joined a German inspectorate and has been working as a GMP-Inspector with focus on biotechnological active ingredients and sterile drug products since that time.
- **Patrizia Muscas**, *Eli Lilly Italia SPA, Sesto Fiorentino, Italy*
 Actually she is the expert for isolator validation and VHP decontamination for the Italian site and is part of the Lilly global network experts in this field.
- **Claudia Petersen**, *Gerresheimer Bünde GmbH, Bünde, Germany*
 Since December 2007 she is working as Director Business Development for the Tubular Glass Division.
- **Alain Pralong**, *Crucell Holland B.V., Leiden, Netherlands*
 Since 2008 „Head of Global Process Development Department“.
- **Dr Ingo Presser**, *Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach, Germany*
 Since 2007 he is Head of an aseptic filling and freeze drying unit within the department of Biopharmaceutical production.
- **Dr Johannes Rauschnabel**, *Robert Bosch GmbH, Crailsheim Germany*
 Dr Rauschnabel is Director Process Engineering at Robert Bosch GmbH, Packaging Technology Pharma.
- **Dr Lars Restetzki**, *F. Hoffmann- La Roche AG, Basel, Switzerland*
 In the department of Global Technical Development he is responsible for the clinical supply of parenteral dosage forms for late-stage clinical studies in Basel.
- **Seán Ruddy**, *Schering-Plough (Brinny) Co., Ireland*
 Technical Services Coordinator involved in continuous improvement projects associated with an aseptic vial filling operation.
- **Dr Mike Schäfers**, *West Pharmaceutical Services Deutschland GmbH & Co. KG, Eschweiler, Germany*
 Director Marketing Europe responsible for Marketing and Technical Customer Services.
- **Klaus Ullherr**, *Robert Bosch GmbH, Crailsheim, Germany*
 Klaus Ullherr is working as a Product Manager for the business fields syringes and cartridges.
- **Bruno van der Aa**, *GlaxoSmithKline Biologicals, Rixensart, Belgium*
 QA Manager for filling, responsible for Quality system, calibration and metrology, training and continuous improvement
- **Benoît Verjans**, *Aseptic Technologies S.A., Les Isnes, Belgium*
 He is currently Commercial Director of Aseptic Technologies, responsible of developing the sales of the closed vial technology worldwide.
- **Dr Christian Vogt**, *Novartis Pharma Stein AG, Stein/Basle, Switzerland*
 Dr Vogt is responsible for sterility testing and microbiological QA and QC at the site in Stein, Switzerland.
- **Sokhorn Yim**, *Genentech, Inc., San Francisco, USA*
 She has been at Genentech for 8 years and is currently working in Process Development Engineering.
- **Thomas Zelmer**, *Groninger & Co. GmbH, Crailsheim, Germany*
 Thomas Zelmer is Senior Sales & Project Manager, responsible for the UK & Ireland.
- **Jörg Zimmermann**, *Vetter Pharma-Fertigung GmbH & Co. KG, Ravensburg, Germany*
 Jörg Zimmermann is Director Process Development and Implementation.
- **Thomas Zinn**, *Novartis Pharma AG, Stein, Switzerland*
 Supervises the manufacture of prefilled syringes since 2008, including product launches from that isolator line.

Objectives

This is why you should attend this conference:

- You will get first hand information on modern application systems.
- You will get an overview about current trends and developments in the manufacture of prefilled syringes from the perspective of pharmaceutical manufacturers, packaging suppliers and mechanical engineering.
- What GMP aspects have to be considered for prefilled syringes; what new questions arise due to new technologies and the increased supplier involvement? You will get an update from the perspective of involved parties.

Background

Prefilled syringes are a modern, but complex application system which gains in importance in the pharmaceutical and biotechnological environment. They are comprised of many – in particular cases critical – single components. For that reason the various aspects of packaging, process control and controls need to be examined carefully and are in the centre of attention of this conference.



Image: Gerresheimer Bünde

Target Audience

This conference targets staff in the pharmaceutical industry, packaging suppliers and engineering firms familiar with the issue prefilled syringes. Addressed will be particularly the areas

- Packaging development
- Production
- Quality Assurance
- Engineering / Technology

Moderator

- Klaus Ullherr, *Robert Bosch*

Programme

Introduction – “The prefilled Syringes in a Nutshell”

☞ Frank Bamberg, *SCHOTT Forma Vitrum*

- A short overview on applications, processes, formats and categories.
- What's new: requests and solutions coming into market soon?

Glass Syringe Barrel Siliconisation – Trends/Methods/Analytical Tools

☞ Claudia Petersen, *Gerresheimer Bünde*

- Overview siliconization technologies (different nozzle types/ oily vs. baked on siliconization)
- Optimized siliconization with regard to product requirements, autoinjector compatibility, general syringe performance
- Standard and high end methods capabilities to examine qualitative and quantitative syringe barrel siliconization – from Zinc oxide to Zebrasciences

Implementation of prefilled Double-Chamber Cartridge Technology – a Case Study

☞ Dr. Karoline Bechtold-Peters, *Boehringer Ingelheim*

- Construction of an innovative modular pilot scale filling machine
- Development of a suitable transfer system to load/unload the lyophilizer
- Development of the suitable siliconization parameters for the double chamber cartridges
- Challenges as regards silicone/protein interactions and subvisible particle generation for biotech products
- Functionality testing of the cartridges
- Selection of an appropriate pen system
- Scale-up to commercial scale and design of a commercial double-chamber cartridge production unit

Small Batch Filling Applications

☞ Klaus Ullherr, *Robert Bosch*

- Filling of high potent drugs
- Disposable filling systems including introduction into the cleanroom area
- Process improvement fill/finish
- Automation of critical process steps
- Barrier Systems including mock-up
- Innovative fill/finish concepts for new pre-sterilized containers

Next Generation Syringe Components and Systems

☞ Dr. Mike Schäfers, *West Pharmaceutical Services Deutschland*

- Recent quality requirements
- Next generation production process for components
- Inspection technologies for syringe components
- Innovative syringe systems through Quality by Design

Injection Options for Prefilled Glass Syringes: Requirements & Trends

☞ Alexander Jaksch, *Safety Syringes*

- Injection Devices: Current & Future Trends
- Patient & Healthcare Professional Perspective
- Legislation & Regulations as Additional Design Drivers
- Influence of Future Drug Pipelines

Prefilled Syringes: Assembly of Components & Devices

☞ Thomas Zinn, *Novartis*

- Overview (Introduction)
- Plunger rod assembly
- Safety Device assembly
- Outlook (e.g. Auto Injector assembly)

The Success Factors of the Glass Syringe for the Scope of Auto Injectors

☞ Frank Bamberg, *SCHOTT Forma Vitrum*

- Dimension control – which are the critical factors like Needle exposure
- Probability of Breakage – determine of the glass syringe geometry, glass forming process, FF and LC breakage
- Siliconization – homogeneous distribution of silicone oil and new IPC controls

Objectives

This is why you should attend this conference:

- You will get first hand information on different decontamination systems for prefilled syringe tubs.
- You become familiar with the critical process steps that have to be clarified within the framework of the qualification and validation of these systems.
- In case studies you can share your colleagues' first-hand experiences.
- You discuss the pros and cons of using these systems with experts from industry, authority and science.

Background

Within the group of prefillable syringes, there is a clear trend towards ready-to-use syringes (Ready-to-fill - RTF; Ready-to-Use - RTU; Sterile clean filling - SCF).

The ready-to-use syringes in tubs are sterilised at the syringe manufacturer's site and distributed in bags. Still, when they are introduced into the barrier system (isolator / RABS), certain microbiological risks arise for the filling process. For this reason, after having been unwrapped, the tub is introduced into the isolator / RABS through a decontamination system like E-Beam / plasma / H₂O₂ in order to ensure the outer sterilisation of the tub.



Image: Skan

Target Audience

This conference targets staff in the pharmaceutical industry, packaging suppliers and engineering firms familiar with the issue prefilled syringes. Addressed will particularly the areas

- Packaging development
- Production
- Quality Assurance
- Engineering / Technology

Moderator

- **Hans-Christian Gath**, *Groninger & Co.*

Programme

Decontamination Technologies from the Inspector's Point of View

☞ **Dr Daniel Müller**, *Regierungspräsidium Tübingen*

- Regulatory framework & guidelines on aseptic processing
- Current aseptic decontamination techniques – a regulatory comparison (manual disinfection & automated decontamination processes)
- Inspector's experience
- Typical inspection observations

Plasma Technology: An alternative Method to existing outside Decontamination Technologies

☞ **Thomas Zelmer**, *Groninger & Co.*

- Pro and cons of existing decontamination methods
- Description of a new method to achieve regulatory "desires"
- Explaining the capabilities of plasma technology
- Showing equipment already installed or designed to industrial needs

Surface Sterilisation using ionising Radiation (E-Beam)

☞ **Thomas Zinn**, *Novartis*

- Functional principle (Introduction)
- Qualification
- Using E-Beam in routine production
- Process monitoring

Case Study Cilag: E-beam in SCF Manufacturing – a daily Routine Experience Report

☞ **Dr Dieter Bachmann**, *Cilag*

- E-beam decontamination
- Practical experiences

Decontamination of Prefilled Syringe Tubs for High Speed Filling Lines and Pilot Plants

☞ **Philippe Jérôme**, *Skan*

- E-beam technology
- Hydrogenperoxide technology
- Residuals in the sterilized syringes after E-beam and H₂O₂ treatment
- Example Layouts for high speed filling and pilot plants
- Investment costs

Presterilized Syringe Introduction: Alternatives to E-Beam

☞ **Jörg Zimmermann**, *Vetter Pharma-Fertigung*

- Aseptic challenges in introduction of presterilized syringes into the cleanroom
- Methods used: double-wraps, automatized opening, e-beams, plasma-decontamination
- Introduction to a new method
- IQ, OQ, PQ of the system
- Lessons learnt

Objectives

- Case studies from various pharmaceutical companies show implementation examples
- You get to know the current state of the art as well as future technological developments in the field of RABS
- You can evaluate the advantages and disadvantages of the different RABS systems
- 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 for sterile manufacturing, the classical cleanroom cannot be considered as the state of the art any longer. Today the supervisory authorities require a more strict 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. On this conference day topical questions on RABS will be discussed in detail from the perspective of pharmaceutical operators, planners and engineers.



Image: Bosch

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 RABS.

Moderator

- **Jörg Zimmermann**, *Vetter Pharma-Fertigung*

Programme

Developments in Restricted Access Barrier Systems- RABS

☞ **James Drinkwater**, *Bioquell UK*

- Differences between RABS and Isolators and relative advantages
- Regulatory expectations in modern aseptic processing and application of RABS
- Overview of the harmonized PHSS RABS definition and specification, reviewed with the UK-MHRA and USA-FDA
- Risk hierarchy for Interventions; 1. Process interventions. 2. Set-up interventions. 3. Inherent and Corrective interventions
- Hierarchy of decontamination processes related to RABS and introduction of Gaseous vapour phase decontamination
- Transfer devices and procedures: types and key requirements related to contamination control in transfer steps

Integration of filling lines into RABS

☞ **Hans- Christian Gath**, *Groninger & Co*

- Possibilities and limitations
- Clean air supply concepts
- Project planning
- Cleaning and decontamination
- Product and material transfer
- Monitoring

Flexible RABS Application for the Filling of small-scale clinical Material

☞ **Jörg Zimmermann**, *Vetter Pharma-Fertigung*

Case Study: Equipment Transfer as Chance for integrating RABS Technology – filling Station as an Example

☞ **Dr Simone Dahlmans**, *hameln pharmaceuticals*

- Initial situation and scope of the project
- Concept and realisation
- Agenda and costs
- Lessons learnt

RABS Retrofit: Installation of a RABS on an existing vial filling line

☞ **Seán Ruddy**, *Schering-Plough (Brinny)*

- Background – why RABS?
- RABS design and filling line upgrade
- Installation and qualification
- Further retrofits

RABS-Technology for aseptic manufacture of lyophilised products

☞ **Hartwig Hönerloh**, *Ferring*

- Production process
- Concept for clean rooms
- HVAC technology
- Restricted Access Barrier System
- Engineering, realisation, qualification and operation

Case Study: Implementation of RABS technology for vaccines formulation

☞ **Bruno van der Aa**, *GlaxoSmithKline Biologicals*

- How we passed from an idea to real life
- Difficulties encountered
- Current benefits

Objectives

- Case studies from various pharmaceutical companies deal with the implementation and qualification of isolators
- You get to know the current state of the art as well as future technological developments in the field of Isolator
- Which are the weak points of the 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 for sterile manufacturing, the classical cleanroom cannot be considered as the state of the art any longer. Today the supervisory authorities require a more strict 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. This conference day focus on topical questions on isolators 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 isolators.

Moderator

- **Dr Friedrich Haefele**, *Boehringer Ingelheim*

Programme

BI-Isolator Project: Aseptic Processing Unit 5 – A modular Concept for Capacity Expansion

☉ **Dr Friedrich Haefele**, *Boehringer Ingelheim*

- Regulatory Aspects
- Isolator Definition ISPE, 2007
- Where we come from...
- Project Rationale, Scope and Timelines
- Phase I: supporting process areas
 - Bulk formulation
 - Liquid/Lyo vial filling
 - Freeze drying
- Phase II – options for capacity/technology extension

Interface Isolator / Filling Line

☉ **Philippe Jérôme**, *Skanska*

- Automated, aseptic filling machines under isolator technology
- Good engineering
- Easy integration on site

Qualification of an Isolator on a high Speed Cartridge Filling Line

☉ **Patrizia Muscas**, *Eli Lilly Italia*

- Cycle development strategies
- Routine monitoring
- Lessons learnt

Microbiology in Filling and Sterility Test Isolators

☉ **Dr Christian Vogt**, *Novartis*

- Get the microbiology in an isolator under control
- Decontamination
- Environmental monitoring
- Media Fills
- Integrity of Isolators
- Microbiological „problems“ in isolators
- Case studies

Hole Science and Glove Practice – Studies and Procedures with Barrier System Gloves

☉ **Dr Johannes Rauschnabel**, *Robert Bosch*

- Regulatory expectation
- Glove testing
- Microbial relevance of holes
- Life time of gloves
- Glove materials and Hypalon™

Detecting Low Levels Vapor Phase Hydrogen Peroxide (VHP) and Protecting Biotech Products

☉ **Sokhorn Yim**, *Genentech*

- The three main concerns for using isolators
- Time required to aerate the residual VHP atmosphere concentration down to 10 ppb in vapour phase
- The amount of VHP dissolved in the liquid filled vial
- The different detection methods

Biological Indicators in VHP Decontamination

☉ **Dr Dieter Bachmann**, *Cilag*

- Detection of false positive results
- Interpretation of positive results
- Distinguish between real and false positive results

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
- You will get the interpretation of new guidelines and requirements from a GMP inspector'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 – Disposables / Lyophilisation – Close Vial Technology**
- **Interpretation and Implementation of new regulatory requirements – EU-GMP-Guide Annex 1 Capping**



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

- Gert Moelgaard, *NNE Pharmaplan*

Programme

Aseptic Manufacturing in the Future Pharmaceutical Industry

☞ Gert Moelgaard, *NNE Pharmaplan*

- Trends in the new pharmaceutical industry
- Aseptic technology from a business perspective
- Challenges and opportunities for the future

Laser Spectroscopy as a Tool to control freeze Drying Cycles

☞ Dr Jörg Lümke, *F. Hoffmann-La Roche*

- Advantages and Disadvantages of the current Endpoint-Determination Methods
- Requirements for a “new”-Endpoint-Determination Method
- Tunable Diode Laser Spectroscopy in lyophilization
- Strategies to control freeze drying cycles
- Experimental results and outlook

Advanced Closed Vial Technology

☞ Benoît Verjans, *Aseptic Technologies*

- Introduction of the Closed Vial Technology
- Lyophilization in Closed Vial
 - Process description
 - Results of tests made with biological products
- Particle inspection of the closed vial
- Key advantages of the Closed Vial Technology both for liquid and lyo products

Clinical manufacturing of injection solutions of highly active substances in a new multiple purpose facility using isolator technology

☞ Dr Lars Restetzki, *F. Hoffmann-La Roche*

- Clinical supply building: conventional clean room & highly active suite
- Multiple purpose concept of highly active facility in clinical supply
- Qualification of isolators & process validation
- Decision tree: facility use depending on health hazard categorization of API
- Case study: material and personal flow

Main Focus Topics: New Annex 1 Requirements for Capping

Strategies to ensure Container Closure Integrity for Capping in Grade C under Laminar Flow

☞ Dr Ingo Presser, *Boehringer Ingelheim*

- Risk assessment for the aseptic filling process
- Define the parameters for “tightness”
- Implementation of new test methods
- Requirements and selection of suitable packaging combinations
- Implementation of a monitoring system

The new Annex 1 Requirements for Capping from an Inspector's Point of View

☞ Dr Daniel Müller, *Regierungspräsidium Tübingen*

- Changes in Annex 1 (Version Feb. 2008)
- Regulatory interpretation of capping section
- Discussion of possible solutions to be compliant with the capping requirements
- Discussion of variety of current industry practices for existing equipment (upgrade) and new lyophilisation lines
- Inspectors experience & inspection findings

How disposable Technology changes the Biomanufacturing Landscape

☞ Alain Pralong, *Crucell Holland*

- Development over the last 10 years
- How disposable technology changes the manufacturing setup in USP and DSP
- Impact of disposable technology on timelines, CAPEX and COGS – Crucell's experience
- Remaining challenges in USP and DSP for disposable technology

Location Swissôtel Congress Centrum Düsseldorf / Neuss
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The conference hotel is located just 14 kilometers from Düsseldorf International Airport and minutes from the historic and commercial areas of Düsseldorf. More details can be found here: www.swissotel-duesseldorf.de/location-en.html

Room Reservation There will be no 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.

Fees One day tickets will enable you to visit the congress either only on day 1 or only on day 2 or on both days. Charges for the one day tickets are € 490,- plus VAT (due to the special fees for the congress, ECA membership discounts are not applicable). 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 (one day ticket for 22 March 2011). Charges are payable after receipt of invoice.

The 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 22 March 2011, 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.

Contacts

For questions regarding content:
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Tel. +49 6221 84 44 41, E-Mail: mangel@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Detlef Benesch (Organisation Manager),
Tel. +49 6221 84 44 45, E-Mail: benesch@concept-heidelberg.de.

The Organiser

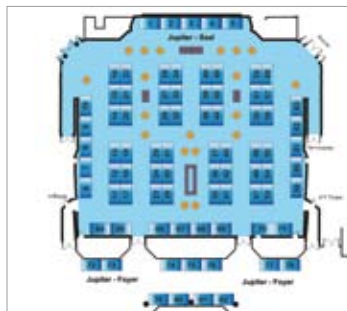
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PLEASE NOTE

Please note that there will not be any print-outs at the Congress. Instead you will receive all presentations prior to the Congress as Downloads. All Congress delegates (excluding exhibition visitors) will also receive the presentations on a USB stick at the registration center.

The Exhibition



Parallel to the Pharma Congress from 22-23 March 2011 there will also be taking place the large exhibition. This show with more than 80 internationally oriented exhibitors will allow you to get to know and to discuss new technologies, products and services as well as to network. For the current exhibitor list please visit the website at

www.pharma-kongress.com. If you are merely interested in visiting the exhibition, you will need a one day ticket for € 90,-. This ticket includes lunch on that day, beverages and coffee. The one day tickets for the 22 March 2011 also includes participation in the social event in the evening with dinner and beverages. For registering please use the form on the back of this programme.

Registration Options

Visit of the Exhibition – One Day Tickets for € 90,-

Please mark the day on which you plan on visiting the exhibition:

(Information on the exhibition is also available on the congress website at www.pharma-kongress.com.)

Day 1 (22 March 2011)

Day 2 (23 March 2011)

(Please fill in your personal data below. You will receive a confirmation/invoice for your registration for the exhibition per mail.)

Attending Conferences – One Day Tickets for € 490,-

(Includes a lunch and beverages during the conferences and in breaks as well as the social event on the evening of the 1. congress day (One Day Ticket for 22 March 2011). Please mark if you would like to attend the Social Event.)

With a one day ticket you can attend any conference offered that day. To be able to prepare the conference rooms, though, we would appreciate it if you marked the conference you are interested in addition to marking the day you plan on attending the Congress. **Please mark only one conference per day.**

I would like to attend on day 1 (22 March 2011) and I'm primarily interested in the conference:

ECA Conference Prefilled Syringes: New Trends

ECA Barrier Systems Conference: RABS

I would also like to take part in the Social Event on the evening of 22 March 2011.

I would like to attend on day 2 (23 March 2011) and I'm primarily interested in the conference:

ECA Conference Prefilled Syringes: Decontamination Technologies

ECA Barrier Systems Conference: Isolators

ECA Conference Current Aseptic Technologies

Registration

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

Reservation Form (Please complete in full)

Mr Ms Dr

 First name, Surname

 Company

 Department

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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!)