2014 PHARMA CONGRESS

14 Production & Technology

DÜSSELDORF, 25 - 26 MARCH 2014

network. experience. benefit.

Early Bird Rebate: the first 100 one day tickets for just € 590,- instead € 690,-

With more than 60 Speakers...

Regulatory Presentations from:

Scott Aldrich, USA
Member of the 2010-2015
USP Dosage Forms Expert Committee

Dr Ajaz S. Hussain, USA
Former FDA Deputy Director

Klaus Feuerhelm, Regierungspräsidium Tübingen
GMP Inspektor

Dr Jean-Denis Mallet
Former Head of the Pharmaceutical
Inspection Dpt. AFSSAPS

Dr Daniel Müller, Regierungspräsidium Tübingen
GMP Inspector

Dr Stephen Langille, USA *(invited)*
FDA

Industry Case Studies from e.g.:

Dr Friedrich Haefele, Boehringer Ingelheim
Vice President Biopharma Operations

Dr Helmut Gaus, Rentschler Biotechnologie
Vice President Quality Control

Dr Sanjit Singh Lamba, Eisai India
Managing Director of Eisai Knowledge Centre,
Head – Global Procurement Strategy

Dr Barthold Piening, Takeda Pharmaceuticals
Head of Global Operations

Philip Schneider, F. Hoffmann-La Roche
Head of Sterile Drug Product Manufacturing
Kaiseraugst

Patrick Vanhecke, GlaxoSmithKline
Senior Manager at GlaxoSmithKline Biologicals

Dr Helmut Vigenschow, TEVA – Merckle
Head of Quality Assurance in Germany

Jörg Zimmermann, Vetter Pharma-Fertigung
Director Process Development and
Implementation

- ECA Conference Curreant Aseptic Technologies
- ECA Conference Polymer-based Prefilled Syringes
- ECA Conference Single-Use Disposables
- ECA Conference Manufacture of Oral Solid Dosage Forms
- ECA Conference Isolator Technology
- ECA Conference Particles in Parenterals

CONCEPT HEIDELBERG

Pharmaceutical Quality
Training. Conferences. Services.

The Steering Committee

For the Pharma Congress 2014 Steering Committee we were able to win leading experts from the pharmaceutical industry with extended knowlegde in production and technology. Their support allows us to develop a programme that is even closer to what you're dealing with in your daily routine.

The Steering Committee is comprised of the following members:


Dr Friedrich Haefele, Boehringer Ingelheim
Vice President Biopharma Operations


Dr Rainer Schmidt, F. Hoffmann-La Roche
Site Manager Kaiseraugst


Jörg Zimmermann, Vetter Pharma-Fertigung
Director Process Development and Implementation


Dr Johannes Krämer, CSL Behring
Manager Engineering


Prof Franz Maier
Former Manager Technology, Nycomed


Roland Szymoniak, Sanofi
Manager Industrial Engineering & Transfer


Dr Tobias Lücke, M+W Process Industrie
General Manager


Gert Moelgaard, NNE Pharmaplan
Vice President Strategy Development


Frank Studt, Chemgineering Business Design
General Manager


Günter Körblein
Senior Consultant, Pharmaceutical Technology

The Pharma Congress Overview

Pharma Congress – Overview

Key Notes on 25 March 2014


Impact of QbD and PAT - technological aspects & regulatory trends
Dr Ajaz Hussain, Former FDA Deputy Director


Trends in sterile manufacture
Dr Friedrich Haefele, Boehringer Ingelheim – Vice President Biopharma Operations

Conferences (One day ticket 690,- EUR)	25 March	26 March
ECA Conference Current Aseptic Technologies	✓	
ECA Conference Polymer-based Prefilled Syringes	✓	
ECA Conference Single-Use Disposables		✓
ECA Conference Manufacture of Oral Solid Dosage Forms		✓
ECA Conference Isolator Technology		✓
ECA Conference Particles in Parenterals		✓
Exhibition PharmaTechnica	✓	✓

The exact times for the single conferences as well as updates are available in the agenda in the back of the programme and on the Congress website at www.pharma-kongress.com.

Live Demos

The Pharma Congress 2014 will be even more practical. For that purpose we integrated Live Demos in some of the conferences for the first time. That way you will not only be introduced to technology in the conferences, but you will be able to touch and experience it. Get to know new concepts and technology – directly from leading companies. Questions are deinitely welcome!

The Exhibition

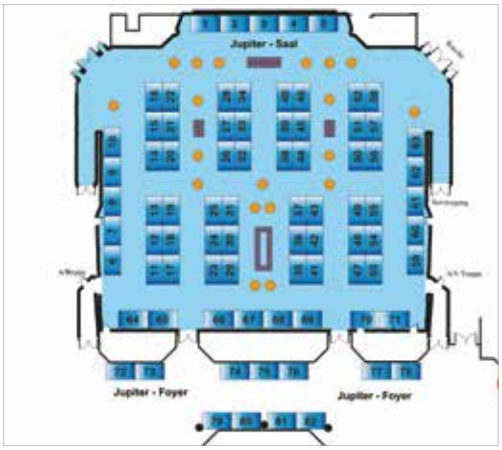
2014 PHARMA CONGRESS
PharmaTechnica
DÜSSELDORF, 25 - 26 MARCH 2014

Parallel to the Pharma Congress on 25 and 26 March there will also be taking place the large trade show PharmaTechnica. 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 that purpose the exhibitors will be waiting for you with Live Demos for the first time. For the current exhibitor list please see below or visit the website at www.pharma-kongress.com.

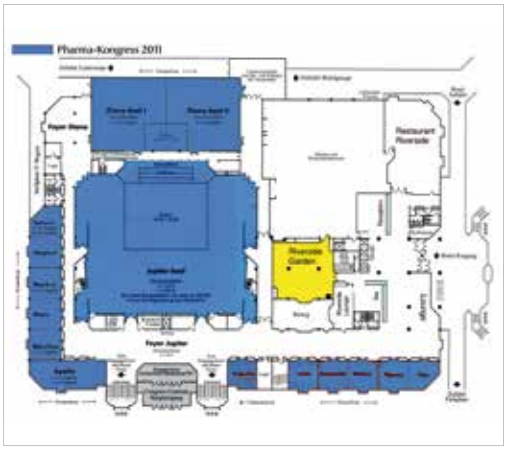
PLEASE NOTE

The PharmaTechnica is also open for visitors who do not want to participate in any of the conferences. However, please note that you will need to register for the free of charge visit of the trade show. The online registration on the website will be active in December 2013. The free visit of the PharmaTechnica does not entitle you to attend any of the conferences.

The PharmaTechnica



The Conferences



The Exhibitors (as of Sept. 2013)

Company	Stand
Bausch & Ströbel	1
Belimed	34
Bilfinger Industrietechnik	70
Borer	46
Charge Point Technology ProSys Sampling Systems	9
Concept	49
DEC Deutschland	19
Dockweiler	26
Ellab	24
Esau & Hüber	36
Extract Technology	44
FEDEGARI	13
Fette Compacting	5
Finesse Solutions	46
Franz Ziel	41
GEMÜ	14
Gerresheimer	17
Glatt	4
Groninger	40
Harro Höfliger	2
Harter	38
HENKEL Beiz- und Elektropolietechnik	69
Herding	6
HEUFT SYSTEMTECHNIK	17
Invensys Systems >EUROTHERM<	63
io-consultants	27
Kiesel Steriltechnik	31

Company	Stand
Laetus	67
Letzner	12
Lighthouse Instruments	32
Mankenberg	25
Marchesini	48
Matthews Kodiersysteme	29
multivac Sepp Haggenmüller	18
NNE Pharmaplan	30
OPAL Associates	42
OPTIMA pharma	22
Pall	68
Particle Measuring Systems	38
PMT Partikel-Messtechnik	53
pharmaserv	66
rap.ID Particle Systems	58
Robert Bosch	20
Rota Verpackungstechnik	37
rotan	50
SCHOTT	35
Skan	62
SPC France	10
Telstar Life Sciences	21
Steriline	47
Uhlmann	3
VITRONIC	65
West	51
WILCO	22

The 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 € 690,- 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 first congress day (one day ticket for the 25 March). Charges are payable after receipt of invoice.

The Location

Swissôtel Congress Centrum Düsseldorf / Neuss
Rheinallee 1
41460 Neuss
Germany
Phone: +49 (0) 2131 77 - 00
Fax: +49 (0) 2131 77 - 1367
Emailus@swissotel-duesseldorf.de

PLEASE NOTE

There will be no room 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.

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 25 March 2014, 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:
ECA Conferences Manufacture of Oral Solid Dosage Forms / Particles in Parenterals:
Dr Robert Eicher (Operations Director), Phone +49 (0)6221 84 44 12,
E-Mail: eicher@concept-heidelberg.de.

ECA Conferences Current Aseptic Technologies / Single-Use Disposables / Polymer-based Prefilled Syringes / Isolator Technology:
Dr Andreas Mangel (Operations Director), Phone +49 (0)6221 84 44 41,
E-Mail: mangel@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation, exhibition etc.:
Detlef Benesch (Organisaton Manager), Phone +49 (0)6221 84 44 45,
E-Mail: benesch@concept-heidelberg.de.

The Organiser

CONCEPT HEIDELBERG – On behalf of the European Compliance Academy (ECA)
P.O. Box 10 17 64
D-69007 Heidelberg
Telefon 0 62 21/84 44-0
Telefax 0 62 21/84 44 34
E-Mail: info@concept-heidelberg.de
www.gmp-navigator.com

ECA
European Compliance Academy

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.

With Speakers from Industry, Academia and Authorities (as of Sept. 2013)

Scott Aldrich	**USP, Ultramikro LLC, USA** Scott is an active member of the 2010-2015 USP Dosage Forms Expert Committee, principally for Injections; USP chapters <1>, <788>, <789> and several others.
Dr Gregor Dudziak	**io-consultants GmbH & Co. KG** Head of Business Unit Pharma & Food.
Dr Helmut Gaus	**Rentschler Biotechnologie GmbH** Qualified Person and Vice President Quality Control.
Dr Friedrich Haefele	**Boehringer Ingelheim Pharma GmbH & C. KG** Vice President Biopharma Operations.
Dr Ajaz S. Hussain	**Former FDA Deputy Director; Insight - Advice & Solutions, LLC, USA** Former FDA Deputy Director Office of Pharmaceutical Science. Now Founder and Consultant of Insight, Advice & Solutions, LLC.
Andreas Kerschbaumer	**Fresenius Kabi Austria GmbH, Austria** Responsible for building up a centre of competence for pre-filled syringes.
Dr Sanjit Singh Lamba	**Eisai India** Managing Director Eisai Knowledge Centre, President - Global Brands Unit, Head - Global Procurement Strategy.
Dr Stephen Langille	**FDA, Center for Drug Evaluation and Research (CDER), USA (*invited*)** Senior Reviewer with the Center for Drug Evaluation and Research.
Terri Love	**Merck Millipore Ireland Ltd., Ireland** BioManufacturing Engineer.
Prof. Dipl.-Ing. Franz Maier	**Zuletzt Nycomed** Zuletzt Leiter der Hauptabteilung Technik. Professor an der FH Albstadt-Sigmaringen, Studiengang Pharmatechnik.
Dr Jean-Denis Mallet	**NNE Pharmaplan, France** Former Head of the French Pharmaceutical Inspection Dpt. AFSSAPS.
Dr André Mang	**Roche Diagnostics GmbH** Leader of the disposable bag implementation project (RDG innovation prize 2010).
Gert Moelgaard	**NNE Pharmaplan A/S, Denmark** Vice President for Strategic Development.
Dr Daniel Müller	**Regierungspräsidium Tübingen** GMP Inspector.
Dr Wenzel Novak	**groninger & co. gmbH** Responsible for pharmaceutical research and development.
Henrik Oberle	**Vetter Pharma-Fertigung GmbH & Co. KG** Team leader of Customer Project Management group.
Dr Susanne Pauly	**Vetter Pharma-Fertigung GmbH & Co. KG** Project manager for customer projects.
Dr Barthold Piening	**MBA, Takeda Pharmaceuticals International** Head of Global Operations.
Dr Tobias Posset	**Roche Diagnostics GmbH** Head of the support unit in Mannheim.
Dr Ingo Presser	**Boehringer Ingelheim Pharma GmbH & Co. KG** In charge of the clinical trial supply and process transfer unit with the Process Science Department.
Dr Bernd Renger	**Immediate Past Chair of the European QP Association; Renger Consulting** Member of ECA Foundation Advisory Board and former Chairman of the European QP Association.
Philip Schneider	**F. Hoffmann-La Roche Ltd., Switzerland** Head of Sterile Drug Product Manufacturing.
Dr Harald Stahl	**GEA Pharma Systems** Senior Pharmaceutical Technologist.
Stefanie Trudel	**Boehringer Ingelheim Pharma GmbH & Co. KG** Head of the new isolator filling line Biopharmaceutical Manufacturing.
Laure Valognes	**Merck Millipore, France** Head of Bio Production.
Patrick Vanhecke	**GlaxoSmithKline Biologicals S.A., Belgium** In charge of Isolator and Aseptic Filling Technologies projects.
Benoît Verjans	**Aseptic Technologies S.A., Belgium** Commercial Director.
Dr Helmut Vigenschow	**TEVA – Merckle GmbH** Head of Quality Assurance in Germany.
Jörg Zimmermann	**Vetter Pharma-Fertigung GmbH & Co. KG** Director Process Development and Implementation.

ECA Academy Conference

Current Aseptic Technologies

25 March 2014

Objectives

Reasons to attend this conference:

- You are informed about the latest technological developments in sterile / aseptic manufacture
- You learn how current GMP and production requirements have to be implemented technologically in sterile manufacture
- You will get case studies from pharmaceutical companies
- Live Demos will show you how technologies perform

Background

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

Moderator

Gert Moelgaard, *NNE Pharmaplan*

Target Audience

The event is directed at specialists from the pharmaceutical industry as well as at engineers and planners who have to deal with current aseptic technologies in clean areas in their daily practice. It particularly addresses the departments:

- Production
- Quality assurance
- Engineering / technology

Programme

Current aseptic technologies today – and tomorrow
Gert Moelgaard, NNE Pharmaplan

Case Study GlaxoSmithKline:

H_2O_2 Dryfog process for room and RABS decontamination
Patrick Vanhecke, GlaxoSmithKline Biologicals

Case Study Aseptic Technologies:

Use of the Closed Vial Technology for aseptic filling of biological products
Benoît Verjans, Aseptic Technologies

Case Study Boehringer Ingelheim:

Ready to fill vials for aseptic filling
Dr Ingo Presser, Boehringer Ingelheim Pharma

Case Study:
Evaluation of Media Fills by Laser Spectroscopy
NN

LIVE DEMOS

In the practical part of the conference, suppliers will show you new technologies and solutions for aseptic manufacture. You will come in contact with new equipment and you have the chance to discuss your questions immediately with technology experts.

100% Container Closure Integrity Testing, In Process Monitoring of headspace oxygen, Rapid Media Fill Readout, and other Headspace Applications for Sterile Pharmaceutical Product
➲ **Lighthouse Instruments**

Closed Vial Technology
➲ **Aseptic Technologies**

Image: Lighthouse Instruments

ECA Academy Conference

Polymer-based Prefilled Syringes

25 March 2014

Objectives

This is why you should attend this conference:

- You will get first hand information on a new and modern application system.
- You will get an overview about current trends and developments in the manufacture of polymer-based prefilled syringes from the perspective of pharmaceutical manufacturers, packaging suppliers and mechanical engineering.
- You will get case studies from pharmaceutical companies who still fill polymer-based syringes.
- Hot and critical topics in the use of polymer-based packaging materials will be discussed with the most important suppliers.

Background

Prefilled syringes are a modern, but complex application system which gains in importance in both the pharmaceutical and in the bio-technological environment. The most used material for syringes in Europe and in the US is glass. But glass is being questioned more and more due to particles and other glass related issues. Can polymer-based syringes be an alternative? They have advantages but also some disadvantages. For that reason the various aspects of polymer-based prefilled syringes in regard to packaging material, filling process and process controls are in the centre of attention of this conference.

Moderator

Jörg Zimmermann, *Vetter Pharma-Fertigung*

Target Audience

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

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

Programme

Case Study Vetter Pharma-Fertigung:

Daikyo Crystal Zenith®: System Offers, Update on the Filling Capability Development
Jörg Zimmermann, Vetter Pharma-Fertigung

Case Study Vetter Pharma-Fertigung:

Project life cycle of a polymer syringe introduction within a product life cycle management for the Japanese market
Henrik Oberle, Vetter Pharma-Fertigung

Filling equipment for Polymer-based syringes
Dr Wenzel Novak, groninger

Pharmaceutical development: Requirements for polymer-based syringes
NN

Case Study Fresenius Kabi:

Improve medication safety in Hospital Care environment with Polymer Prefillable Syringes in combination with syringe pumps
Andreas Kerschbaumer, Fresenius Kabi

PANEL DISCUSSION

- Plastic syringes: leachables and extractables?
- What kinds of rubber components are used?
- Differences in appearance in comparison to glass syringes
- Visual inspection of syringes
- Plastic as a gas barrier: how to handle oxygen sensitive products
- Container closure integrity challenges
- Processing of plastic syringes: vacuum stoppering? Processing aids like silicone oil?
- Handling of syringes to avoid scratches?
- PENs and autoinjectors for plastic syringes?
- How will users be trained on the systems?
- What will be the price per system compared to glass? Will it ever be competitive?

➲ **Nicolas Brandes, West Pharmaceutical Services Deutschland**
➲ **William Dierick, TERUMO EUROPE**
➲ **Anil Kumar Busimi, Schott Pharmaceutical Packaging**
➲ **Bernd Zeiss, Gerresheimer Bünde**

ECA Academy Conference

Single-Use Disposables

26 March 2014

Objectives

Reasons to attend this conference:

- You will get an overview on the current state of single use technologies and a prospect on new developments
- You will get first hand information on how to design and implement a robust and efficient single use technology
- You will get case studies from pharmaceutical companies about the use of single use technology in development and production

Background

The use of single use technology increases in many biotechnological processes as well as in sterile filling processes. There are different reasons for this development, i.e.

- Avoiding cleaning and cleaning validation
- Reducing time to market by omitted construction activities
- Simplified scale-up procedures

On the other side – especially in comparison to stainless steel – new questions arise like

- How to qualify and validate the technology?
- What is the relevance of extractables and leachables?
- What are the consequences for approval activities?

These questions will be discussed during the conference by experts from pharmaceutical companies and leading suppliers.

Moderator

Dr Gregor Dudziak, *io-consultants*

Target Audience

The event is directed at decision-makers from pharmaceutical industry and suppliers from

- production
- research & development
- quality assurance/control
- engineering

who need to be well informed about current developments in the field of Single use technology.

Programme

Single Use Systems in pharmaceutical applications – GMP inspector's view
Dr Daniel Müller, Regierungspräsidium Tübingen

Single-Use Technology: Designing and Implementing for Robust and Efficient Manufacturing
Dr Gregor Dudziak, io-consultants

Case Study Roche Diagnostics:

Single-Use-Disposables for Pharma-Parenteral-Drug-Production
Dr André Mang, Roche Diagnostics

Case Study Merck Biodevelopment:

Process development and manufacturing: Single Use versus Glass and Stainless Steel
Laure Valognes, Merck Biodevelopment

Case Study Merck Millipore:

Adoption of single use final filtration assembly in a production facility
Terri Love, Merck Millipore

Case Study Vetter Pharma-Fertigung:

Usage of Disposable Bags for Bulk-Solution during Fill-Finish
Dr Susanne Pauly, Vetter Pharma-Fertigung

LIVE DEMOS

In the practical part of the conference, suppliers will show you different components and solutions in relation to single use equipment. You will come in contact with the equipment and you have the chance to discuss your questions immediately with technology experts.

SmartSystems for a sustainable Single-Use Technology in Upstream Processing
➲ **Finesse**

Image: Finesse

PreVAS – Single-use filling systems
➲ **Bosch**

Image: Bosch

Production chain – mixer / redundant filtration / final filling
➲ **Merck Millipore**

Downstream-Processes: Automation of Single-Use Processing
➲ **Pall**

Image: Pall

ECA Academy Conference

Manufacture of Oral Solid Dosage Forms 26 March 2014

Objectives

This conference aims at informing about recent technologies in the manufacture of oral solid dosage forms, emphasising tableting and continuous manufacturing.

Background

Solid dosage forms are still the most common dosage form, first and foremost tablets with a portion of over 50%. Tablets are the least expensive dosage form, have a good stability and open up adjustable possibilities of drug release. Continuous processing, sourcing of production equipment and validation issues with regard to tableting which has its start in FDA's new validation guideline have become the newest topics in this industry.

This conference focuses on those hot topics: **Continuous Processing, New Validation Principles and Sourcing Strategies**. The latter is also of importance when the question arises where future production will take place.

Regulating authorities, first of all the FDA, encourage the transition from batch to continuous production. They expect an increase in product safety while equipment suppliers promote a decrease of production costs. But is this really the case? Listen to companies who already did this transition and learn about advantages and disadvantages.
Process understanding plays the key role in the new validation concepts of the FDA and also in the minds of Europe's regulators. We want to talk about processes, problems occurring during routine operations and how to fix them, how a tableting process should be validated from a formal point of view in order to fulfil EU and US FDA requirements.
The third block will further deal with economic and strategic issues, focussing on where to buy production equipment. Is there a difference depending on the market a product is manufactured for? Listen to global players from Europe and India and discuss chances and risks on an upper management level.

Moderator

Dr Harald Stahl, *GEA Pharma Systems*

Target Audience

This event is designed for all managers and executives from Pharmaceutical Development, Production and Quality Assurance responsible for the development, transfer or manufacture of solid dosage forms.

Programme

Equipment Sourcing Strategies

European Perspective
Dr Barthold Piening, Takeda

Indian Perspective
Dr Sanjit Singh Lamba, Eisai, India

Tableting

FDA und EU requirements on the validation of a tableting process
Dr Helmut Vigenschow, TEVA – Merckle

Solutions for Tablet Defects - Troubeshooting
Dr Harald Stahl, GEA Pharma Systems

Continuous Manufacturing

Update on the regulatory requirements
Dr Ajaz Hussain, Former FDA Deputy Director

Case Study:
Continuous Manufacturing in the pharmaceutical industry
NN

EU Regulatory Update

Requirements from the future chapters 3 & 5 of the EU GMP Guide
Impact on the manufacture of oral solid dosage forms
Dr Jean-Denis Mallet, Former Head of the French Pharmaceutical Inspection Dpt. AFSSAPS

Isolator Technology

26 March 2014

Objectives

This is why you will benefit from attending this conference:

- Case studies from various pharmaceutical companies deal with the implementation and qualification of isolator systems.
- You will get to know the current state of the art as well as future technological developments in isolator technology.
- Which are the weak points of the systems – which operational experience has been gathered? Experts from pharmaceutical companies will share their experience.
- You will be able to share your point of view – discuss 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, the protection against microbial contamination increases in importance. The classical cleanroom cannot be considered as state of the art any longer, though – especially with regard to new facilities for sterile manufacturing. Today the supervisory authorities require a more strict separation between staff 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 advancing aseptic technology. This conference will therefore focus on the current questions with regard to isolators in detail, and it will specifically address the subject from the perspectives of pharmaceutical operators, planners and engineers.

Moderator

Dr Friedrich Haefele, *Boehringer Ingelheim Pharma*

Target Audience

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

Programme

Isolators: best practice for aseptic processing – a solution only for large product manufacturing?
Dr Friedrich Haefele, Boehringer Ingelheim Pharma

Case Study GlaxoSmithKline Biologicals:

Formulation Process under Isolator, an Enhancement of the Isolated Process Chain
Patrick Vanhecke, GlaxoSmithKline Biologicals

Case Study Boehringer Ingelheim:

H_2O_2 – lessons learned and measurement of residual concentration
Stefanie Trudel, Boehringer Ingelheim Pharma

Case Study F. Hoffmann-La Roche:

Roche Kaiseraugst: "Liquid vials and prefilled syringes filling lines with isolator technique"
Philip Schneider, F. Hoffmann-La Roche

Case Study:
Use of bioindicators for the validation of isolators
NN

Case Study:
Isolator for high potent Drugs
NN

Case Study:
Installation of a new aseptic filling line for pre-filled syringes
NN

ECA Academy Conference

Particles in Parenterals

26 March 2014

Objectives

Main topic of this conference is the detection of particles in parenterals as well as finding their origin. Besides special tests conducted during root cause analysis, routine 100% inspection of products for parenteral use will be addressed.

Background

In most cases particles found in parenteral medicines will lead to a quarantined product or even to the recall of the product – as we have seen in 2012 and 2013 in the cases of several pharmaceutical companies. Responsible staff in charge will have to start root cause analysis to find the source of the particles. There are several origins possible. Particles found can be categorised in extrinsic (not part of the process), intrinsic (part of the process) or inherent (product agglomerates). Nevertheless their source must be found and eliminated.

The testing methodology in the major compendia have been harmonised with regard to subvisible particles, coming for example from agglomeration of biopharmaceutical products. But: the Pharmacopoeias do not address particles smaller than 10 µm in parenteral drugs. Despite the harmonisation of the tests concerning subvisible particles, there is confusion within the global pharmaceutical industry with regard to the requirements for testing on visible particles.

The required 100% visual inspection can be done manually, semi-automated and fully automated. Throughout the last years there has been a recognisable trend towards automated inspection machines. The challenge for pharmaceutical companies is to find a suitable machine for their products and to determine reasonable inspection parameters during qualification and validation. But also during routine process there are questions arising like the permission of re-testing and the usage of test-sets and setting AQL-Levels.
We will address those topics during the conference and discuss and answer questions on

- The compendial requirements concerning particles
- The possible origins of particles in sterile products
- QA aspects of visual inspection, statistics and AQL testing
- The qualification and validation of an automated system

Moderator

Dr Bernd Renger, *Immediate Past Chair of the European QP Association*

Target Audience

This conference is directed at specialists and executives from sterile operations, that is manufacturing, quality control and engineering. But also persons responsible for CAPAs and suppliers of primary packaging materials for sterile medicinal products are target group of this conference.

Programme

Regulatory and Compendial Requirements

Compendial requirements for particle testing
Scott Aldrich, USP, Ultramikro

FDA's thinking on particles and particle testing (US)
Dr Stephen Langille, FDA ***(invited)***

Particles – origin and root cause analysis

Sources of particulate matter in injectables
Dr Bernd Renger, Immediate Past Chair of the European QP Association

Particle levels exceeded – what to do?
Dr Bernd Renger, Immediate Past Chair of the European QP Association

Particle Detection and Inspection Systems

Quality assurance topics and statistics to be considered in visual inspection
Dr Helmut Gaus, Rentschler Biotechnologie

Implementation of an automated inspection system
Dr Tobias Posset, Roche Diagnostics

LIVE DEMOS

In the practical part of the conference, you will see testing equipment for particle detection and identification in action. Get in contact with the equipment and ask the technological experts your questions.

Parenteral inspection technologies
➲ Wilco

Particle inspection technologies for small batches
➲ Bosch

Particle identification
➲ rap.ID Particle Systems

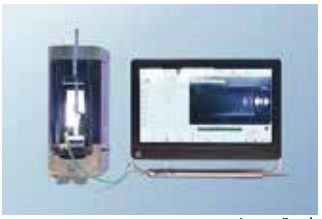


Image: Bosch

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-kongress.com

Registrations Options

Attending Conferences – One Day Tickets for € 690,-*

(Includes participation in any conference on that day and the visit of the exhibition, and, in addition, lunch and beverages during the conferences and in breaks as well as the social event on the evening of the first congress day (one day ticket for the 25 March. Please mark if you would like to attend the Social Event.)

*Early Bird Rebate: the first 100 one day tickets for just € 590,- instead € 690,-

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.

☐ **Day 1 (25 March 2014)**: I would like to attend the Congress on day 1. I'm primarily interested in the conference:
- ☐ ECA Conference Current Aseptic Technologies
- ☐ ECA Conference Polymer-based Prefilled Syringes

☐ I would also like to take part in the Social Event on the evening of 25 March 2013.

☐ **Day 2 (26 March 2014):** I would like to attend the Congress on day 2. I'm primarily interested in the conference:
- ☐ ECA Conference Single-Use Disposables
- ☐ ECA Conference Manufacture of Oral Solid Dosage Forms
- ☐ ECA Conference Isolator Technology
- ☐ ECA Conference Particles in Parenterals

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.
- There will be no room 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.

☐ Visit of the PharmaTechnica (free of charge)

2014 PHARMA CONGRESS 14+ PharmaTechnica DÜSSELDORF, 25 - 26 MARCH 2014

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 (25 March 2014) ☐ Day 2 (26 March 2014)

(Please note that the visit of the exhibition does not include the participation in the conferences. For registering please fill in your personal data below or visit www.pharma-kongress.com and complete the online registration. You will receive a confirmation/invoice for your registration for the exhibition per mail.)

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

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

Street/P.O. Box

City Zip Code

Country

Phone/Fax

E-Mail (please fill in)

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34
D-69007 Heidelberg
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)!