2014 PHARMA CONGRESS

14 Production & Technology

DÜSSELDORF, 25 - 26 MARCH 2014

network. experience. benefit.

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 BP Fill & Finish Germany

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 Current Aseptic Technologies**
- **ECA Conference Polymer-based Prefilled Syringes**
- **ECA Conference Isolator Technology**
- **ECA Conference Single-Use Disposables**
- **ECA Conference Manufacture of Oral Solid Dosage Forms**
- **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 allowed 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 BP Fill & Finish Germany


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 BP Fill & Finish Germany

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

The exact times for the single conferences as well as updates will be available on the Congress website at www.pharma-kongress.com at a later point in time.

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 definitely welcome!

The Exhibition

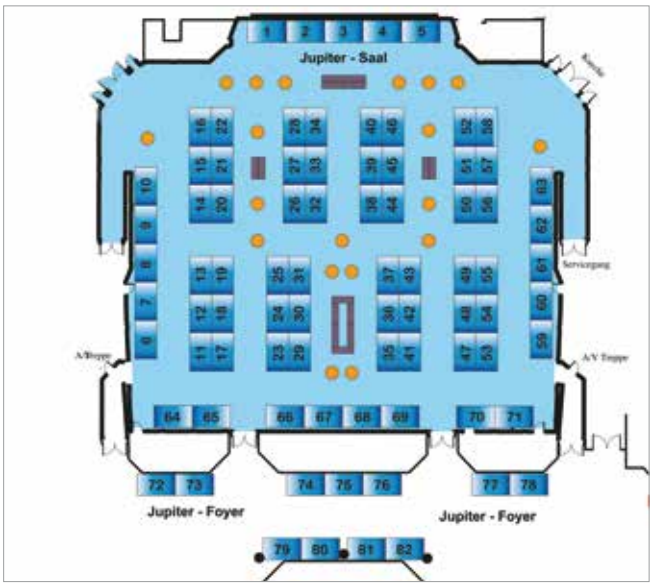
2014 PHARMA CONGRESS
PharmaTechnica
DÜSSELDORF, 25 - 26 MARCH 2014

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.

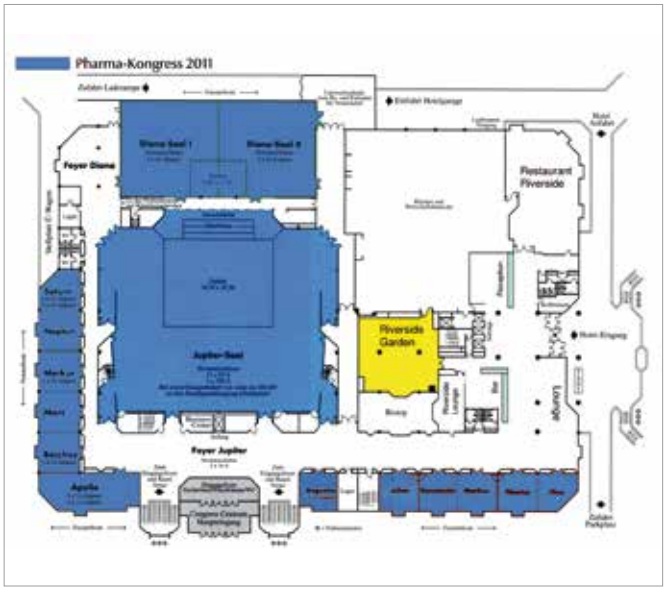
PLEASE NOTE

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 Oct. 2013)

2014 PHARMA CONGRESS
PharmaTechnica
DÜSSELDORF, 25 - 26 MARCH 2014

Company	Stand
Bausch & Ströbel	1
Belimed	34
Bilfinger Industrietechnik	70
Borer	28
CAS Clean-Air-Service	59
Charge Point Technology ProSys Sampling Systems	9
Concept	49
DEC Deutschland	19
Dockweiler	26
Ellab	35
Esau & Hüber	36
Extract Technology	45
FEDEGARI	13
Fette Compacting	5
Finesse Solutions	46
Franz Ziel	41
GEMÜ	37
Gerresheimer	24
Glatt	4
Groninger	40
Harro Höfliger	2
Harter	38
HENKEL Beiz- und Elektropolietechnik	69
Herding	6
HEUFT SYSTEMTECHNIK	17
International Packaging Systems	56
Invensys Systems >EUROTHERM<	63
io-consultants	27
Kiesel Steriltechnik	31
Laetus	67
Letzner	18

Company	Stand
Levitronix	82
Lighthouse Instruments	32
Mankenberg	25
Marchesini	48
Matthews Kodiersysteme	29
Mediseal	57
multivac Sepp Haggenmüller	33
NNE Pharmaplan	23
OPAL Associates	42
OPTIMA pharma	52
Pall	68
Particle Measuring Systems	30
PMT Partikel-Messtechnik	44
pharmaserv	66
rap.ID Particle Systems	58
Robert Bosch	20
Rota Verpackungstechnik	43
rotan	50
SCHOTT	39
Skan	62
SPC Manufacturing	10
Telstar Life Sciences	21
Steriline	47
Uhlmann	3
Vaisala	11
VITRONIC	65
VTU Engineerung	8
West	51
WILCO	22

The Fees

Charges for the one day tickets are € 690,- plus VAT (due to the special fees for the congress, ECA membership discounts are not applicable). These tickets allow you to attend any conference offered that day (you can also switch between the conferences any time). 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

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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 BP Fill & Finish Germany.
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.
Alan Kelly	**Genzyme Ireland Ltd, Ireland**
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.
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 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 Sebastian Schneider	**F. Hoffmann-La Roche AG, Switzerland** Currently he supports commercial transfer projects with development expertise, i.a. in the transfer of freeze-drying cycles.
Dr Harald Stahl	**GEA Pharma Systems** Senior Pharmaceutical Technologist.
Dr Hayden Thomas	**Vertex, USA** Senior Director, Formulation Development
Stefanie Trudel	**Boehringer Ingelheim Pharma GmbH & Co. KG** Head of the new isolator filling line Biopharmaceutical Manufacturing.
Klaus Ullherr	**Robert Bosch GmbH** Product manager for the business fields syringes and filling systems with global product responsibility.
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 and Engineering / Technology.

Programme

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

- Increasing importance of aseptic processing
- Increasing regulatory actions towards facilities with aseptic processing
- Pressure on health care costs and the consequences for aseptic processing
- Latest trends in technologies and facilities upgrade
- Aseptic technologies of tomorrow

Case Study GlaxoSmithKline:

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

- Scope of the project / Application / Principle
- Generator
- Product
- Validation
- Process understanding / Cycle steps / Case studies

Case Study Aseptic Technologies:

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

- The Closed Vial technology has been developed for aseptic filling of injectables with the aim to improve patient safety and simplify operations
- Several products have been tested in the Closed vial technology and many of them show a better stability than in glass container
- This is particularly true for biological products like cell therapies, recombinant protein including antibodies and virus therapies
- Several container functionalities are improving product stability, safety and collection compared to the classical glass vial.

Case Study Boehringer Ingelheim:

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

- Pro/con ready to use packaging vials for aseptic filling
- Impact on invest and footprint for aseptic filling lines
- Special features to increase synergies between different formats

Case Study F. Hoffmann-La Roche:

Detection of silicone oil leakages in freeze dryers using mass spectrometry
Dr Sebastian Schneider. F. Hoffmann-La Roche

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

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 biotechnological 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 and Engineering / Technology.

Programme

Case Study Vetter Pharma-Fertigung:

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

- Introduction to the Crystal Zenith (CZ) syringe system
- Manufacturing experience and validation of CZ syringes
- Products on the market: overview
- Development of a filling operation for CZ syringes
- Product inspection and cleanliness
- Media fill approach and results
- Summary and conclusion

Processing of plastic syringes – challenges and solutions
Klaus Ullherr, Robert Bosch

- Differences glass to plastic
- Different package styles
- Big volume nested syringes
- Processing of plastic bulk syringes
- Retrofit for plastic syringes

Case Study Fresenius Kabi:

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

- Design requirements for COC prefillable syringe to the used in combination with syringe pumps
- Infusion performance due to pump specific system design
- Project challenges and the solutions found

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**
➲ **Horst Koller, Schott Pharmaceutical Packaging**
➲ **Bernd Zeiss, Gerresheimer Bünde**

ECA Academy Conference

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

- Conceptual design for an isolator dedicated to formulation
- Process to define the equipment to build / The challenges of the project / Project-, Process- and Validation- Targets
- Project Set Up between R&D and Validation
- Process Risks Analysis and corresponding Test Studies
- Test Set Up, used Equipment and Methods
- Summary and remaining Questions / Conclusion of the Project

Case Study Boehringer Ingelheim:

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

- Decontamination cycle and cycle times
- Experiences with H_2O_2 from two different suppliers
  - Impact on H_2O_2 concentration in decontamination phase / Impact on aeration time / Impact on evaporation / maintenance of evaporation unit
  - Points to consider when H_2O_2 material is changed
- Measurement of low H_2O_2 residual concentrations
- Approach for evaluation of product sensitivity to H_2O_2 residual concentration

Case Study F. Hoffmann-La Roche:

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

- Project introduction
- Start-up experience of isolator lines
- Development & Validation of isolator decontamination cycle
- Experience in routine production (i.e. capacity impact)
- Continuous process improvement measures

Case Study:

Use of bioindicators for the validation of isolators
NN

Case Study Oncotec Pharma Produktion:

Isolator for high potent Drugs
NN, Oncotec Pharma Produktion

Case Study Genzyme:

Alan Kelly, Genzyme Ireland

ECA Academy Conference

Single-Use Disposables

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

- Regulatory requirements
- Typical (bio)pharmaceutical applications
- Single-use versus multi-use systems: regulatory consequences
- Importance of cGMP supplier management
- Inspection observations

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

- Improve cost efficiency
- Manufacturing robustness
- Critical points to consider with regard to
  - Design
  - Qualification
  - Start-up and operation

Case Study Roche Diagnostics:

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

- Overview of the single-use disposable systems available in the market
- Advantages of disposable systems
- Use of disposable bags and sampling systems during manufacturing of a Biotech Roche product
  - Project motivation
  - QA-requirements/Project challenges
  - Process description (incl. pictures)

Case Study Merck Biodevelopment:

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

- Performing studies in order to evaluate the performance of Singe-Use equipment from early Process Development activities down to the manufactured Drug Substance
- Results how comparable they are regarding
  - Titers
  - Molecule quality
- Results how different they are regarding
  - Organization
  - Financial aspects

Case Study Merck Millipore:

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

- Practical experiences of implementing a single use final filtration assembly
- Process design considerations
- Unforeseen problems with the implementation of the assembly and the operational steps involved to pre-use, post-sterilisation integrity test the assembly
- Understand the implementation process from the design stage to the operation of a disposable final filtration assembly

Case Study Vetter Pharma-Fertigung:

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

- Disposable bags as alternative for stainless steel vessels in compounding of bulk solutions
- Advantages and limitations of disposables
- Innovative solution for handling of heavy bags
- How to minimize risk of damage/leakage
- Example of a multistep compounding process with disposable bags
- Supply chain challenges

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**

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

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

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


Image: Finesse


Image: Bosch


Image: Merck Millipore


Image: Pall

ECA Academy Conference

Manufacture of Oral Solid Dosage Forms

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: Global Sourcing of Machinery & Equipment in a Pharma MNC (Takeda)
Dr. Barthold Piening, Takeda

- Equipment sourcing strategy and key processes
- Supplier structure , segmentation by regions
- Selected project and site references

Indian Perspective
Dr Sanjit Singh Lamba, Eisai, India

- Factors Influencing Equipment Procurement
  - URS compliance / market need
  - Level of automatic control
  - Productivity and Operational excellence
  - Quality by design features
  - GAMP / Part 11 compliance
  - Continuous quality verification
  - Remote diagnostics
  - Cost of manufacturing
- Importance of these factors for the different markets

Image: Bosch

Tableting

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

- Comparison of the FDA Process Validation Guidance and the EU approach to process validation
- Implementation of process validation in the product life cycle
- Concept of a state-of-the-art process validation for tableting processes
  - QbD
  - Selection of critical process parameters
- Approach for existing products / transition phase
- Practical experience

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

- Root Causes for the occurrence of tableting problems
- Sticking, lamination, weight variation
- Variances in the tableting process
- Optimisation of preceding processes

Continuous Manufacturing

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

- Validation
- Cleaning
- Technological aspects and the use of QbD & PAT
- Deviation handling
- Release procedures

Case Study:

Implementing Continuous Manufacturing for Rapid Development in the Pharmaceutical Industry
Dr Hayden Thomas, Vertex

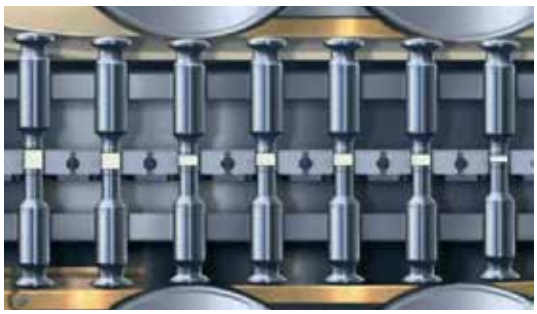
- Benefits of Continuous Manufacturing
- Comparison Batch vs Continuous processing equipment
- Realizing the true potential of QbD paradigm
- Real-time release testing
- Regulatory implications

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

- Focus on avoiding cross contamination
- Dedicated vs. multipurpose: how to calculate
- New aspects for cleaning and cleaning validation
- Pros & Cons of the proposed legislation

Image: GEA Pharma Systems



ECA Academy Conference

Particles in Parenterals

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. Apart from technical aspects and quality assurance also the practical operation of inspection systems will be examined, and you will receive guidance on putting them into operation.

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. Recent publications have emphasised the need to measure these small particles as well, and the FDA wants to further understand possible threats to the health of patients by these particles. New requirements are expected. 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

- Current requirements for visible particles
- Current requirements for subvisible particles
- Trends and upcoming changes
- FDA proposals & industry response
- Harmonisation and differences in EU and Japan
- Particle Identification
  - the nature of particles and their sources
  - current trends for compendial guidance

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

- FDA regulations relating to particulate matter in injectable drug products
- FDA drug application requirements and trends,
- Recent recall events due to particulate matter contamination
- Clinical concerns regarding particulate matter contamination
- The <10 µm particle issue

Image: Seidenader

Particles – origin and root cause analysis

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

- External sources
  - containers & closures
  - filters, tubing etc.
  - gowning
  - abrasion form equipment
- Internal sources (product inherent particles, ..)
- Risks associated with particles

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

- Root cause investigation
  - Processes and methods
  - Equipment and components
  - Visual inspection
- Examples
- Release considerations
- Documentation

Particle Detection and Inspection Systems

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

- Defect classes
- Warning limits
- OOS- and Deviation-Matrix
- Training of the personnel
- AQL-testing, release decision
- Test kits und test samples

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

- Qualification program
- Validation program
- Sample sets for qualification purposes
- Generation and Classification of defects and defect libraries
- Performance comparison with the manual inspection
- Ejection of defects & re-inspection
- Routine inspection and system capability

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**

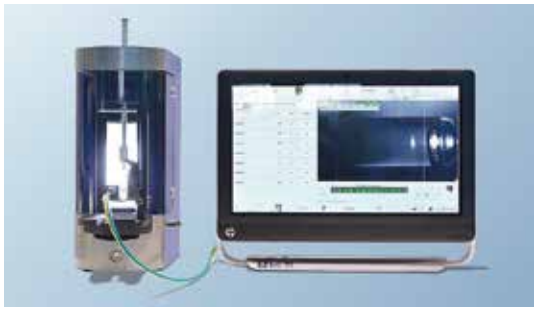


Image: Bosch

Easy Registration

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(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.)

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 2014.

☐ **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

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- 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.

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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 %.

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