

2012 Pharma Congress

Production & Technology

Düsseldorf, 24-25 April 2012
www.pharma-kongress.com

Speakers

From leading Pharmaceutical Companies - including:

Bayer Pharma
Bayer Technology Services
Baxter Healthcare
Boehringer Ingelheim
Catalent
Cilag
CSL Behring
F.Hoffmann-La Roche
Fresenius Kabi
Helvoet Pharma
Holopack Verpackungstechnik
Janssen Pharmaceutica
Lilly France
Lonza
Merck
Merial
Merz
Novartis
Nycomed
Pierre FABRE
Pfizer
Rottendorf Pharma
Sandoz
Toxikon Europe
Vet Pharma Friesoythe
Vetter Pharma-Fertigung
Wacker Biotech

From Authorities:

FDA
Regierungspräsidium Tübingen

and many others

Conferences 24 April 2012

- ECA Conference
Current Aseptic Technologies
- ECA Barrier Systems Conference
- ECA Conference
Glass - Glass Breakage - (Micro-)Cracks
- ECA Conference Prefilled Syringes

Conferences 25 April 2012

- ECA Conference
Current Aseptic Technologies
- ECA Barrier Systems Conference
- ECA Conference
Glass - Glass Breakage - (Micro-)Cracks
- ECA Conference
Manufacture of Oral Solid Dosage Forms



**CONCEPT
HEIDELBERG**

Pharmaceutical Quality
Training. Conferences. Services.

Greeting



On 24/25 April the 14th Pharma Congress will be conducted in Düsseldorf, Germany. It has become a tradition that industry professionals get together at this event.

During the Congress many international projects from the areas aseptic technologies, barrier systems, oral solid dosage form production and glass technologies will be discussed. Through practice oriented innovative projects and developments – for today and the future – users will demonstrate for users the current state of the art in PRODUCTION and TECHNOLOGY.

An exhibition with more than 80 exhibitors will accompany the Congress, offering the unique opportunity to further discuss issues intensively. At the same time this event will be the ideal platform for exchanging information and experience, allowing you to find solutions for the challenges in this dynamic global market.

The globalisation as well as the fast changing legal framework makes us all dependent on building and maintaining “good and productive” networks, and in times of Internet and globalisation face to face meetings are especially important.

I look forward to welcoming you at the Pharma Congress – it will most certainly be an interesting event in 2012 again.

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

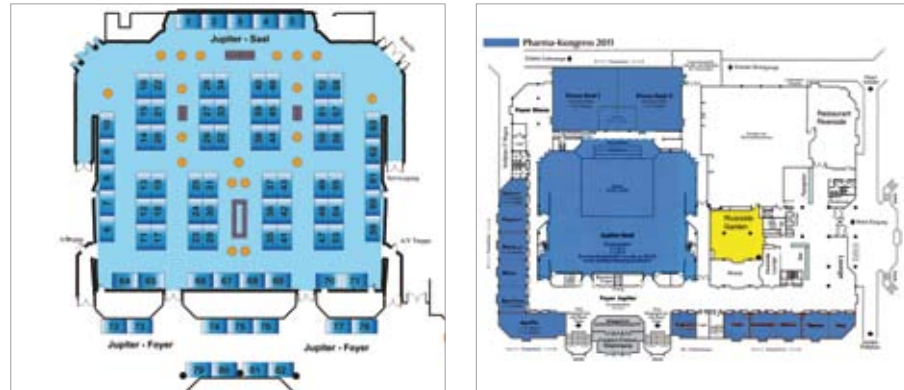
The Pharma Congress Overview

Pharma Congress Overview			
Conference	<u>One Day Ticket 490,- EUR</u>	24 April 8:30am – 6:00pm*	25 April 8:30am – 5:30pm*
ECA Conference Current Aseptic Technologies		✓	✓
ECA Barrier Systems Conference		✓	✓
ECA Conference Glass – Glass Breakage – (Micro-)Cracks		✓	✓
ECA Conference Prefilled Syringes		✓	
ECA Conference Manufacture of Oral Solid Dosage Forms			✓
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.

The Exhibition

Parallel to the Pharma Congress from 24-25 April 2012 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 see below or 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. For registering please use the form on the back of this programme.



Exhibitors (as of March)



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.

Speakers

- **Xavier Baert**, *Baxter Healthcare Corporation, Lessines, Belgium*
 At Baxter he is currently Finishing Engineering Assistant Manager BioScience.
- **Nigel Bates**, *Pfizer Ltd, Great Abington, Cambridge, UK*
 Head of the Engineering Sciences Group within the Devices Centre of Emphasis, based in Cambridge UK.
- **Edgar Bauer**, *Bausch + Ströbel Maschinenfabrik Ilshofen GmbH + Co. KG, Ilshofen*
 Mr Bauer (Area Sales Manager) has been in charge of the French market in the Sales Department since 2000.
- **Dirk Beer**, *Nycomed GmbH, Singen, Germany*
 Mr Beer is responsible for assessment of suppliers for packaging materials including auditing and handling of complaints.
- **Dr Andrea Behrenswerth**, *Gerresheimer Bünde GmbH, Bünde, Germany*
 Head of Quality Assurance within Gerresheimer Bünde.
- **Gerald Bürkle**, *Vetter Pharma-Fertigung GmbH & Co. KG, Ravensburg, Germany*
 Director Pharmaceutical Production.
- **Philippe Cappuyns**, *Janssen Pharmaceutica*
 Part of Global Technical Services within Janssen Supply Chain responsible for assessment of innovative technologies and the introduction of QbD in development and production.
- **Dr Olivier Chancel**, *Merial, Toulouse, France*
 Currently Head of Pharmaceutical Support in Merial.
- **Piet Christiaens**, *Toxikon Europe NV, Heverlee, Belgium*
 Mr Christiaens holds the position of Scientific Director.
- **Peter Cornelis**, *Toxikon Europe NV, Heverlee, Belgium*
 Mr Cornelis is Supervisor of the Microbiology and In-vitro Toxicology Department.
- **William Dierick**, *TERUMO EUROPE NV, Leuven, Belgium*
 William Dierick is Business Development Manager – Global Pharmaceutical Solutions of TERUMO.
- **Peter Forceville**, *Medpro, Herent, Belgium*
 He is leading the European business development for MedPro Safety Products, Inc. in Lexington, KY, USA.
- **Jens Gemmecker**, *OPTIMA GROUP pharma GmbH, Mornshausen, Germany*
 Sales manager at OPTIMA GROUP pharma, facility Mornshausen.
- **Angela Gessler**, *Skan AG, Allschwil, Switzerland*
 At Skan AG she supervises a laboratory for H2O2 decontamination studies as well as H2O2 low concentration measurements.
- **Leopold Gruber**, *SBM Schoeller Bleckmann Medizintechnik Ges.m.B., Ternitz, Austria*
 Mr Gruber was active from 1974 till the end of 2010 in the area of the design and sales in leading functions.
- **Dr Roland Guinet**
 Consultant Regulatory Compliance Sites and Processes. From 2002-2011 GMP Inspector at AFSSaPS (French Agency for the Safety of Health Products)
- **Manfred Holzer**, *Skan AG, Allschwil, Switzerland*
 In 2008 he launched the Skan E-Beam System as product manager. Today, he heads the business development of the Skan RABS Systems.
- **Dr Henry Huang**, *AstraZeneca*
 Senior Formulation Scientist.
- **Dr Renaud Janssen**, *Helvoet Pharma Belgium, Alken, Belgium*
 He is currently Global Director of Scientific Affairs for Helvoet Pharma worldwide.
- **Dr Heinrich-Andreas Kracke-Helm**, *GEA Diessel GmbH, Hildesheim*
 Active since 1989 as Sales Manager and Engineer for Biotech Plants, since 2011 for GEA Diessel.
- **Dr Timo Krebsbach**, *Labor L+S AG, Bad Bocklet, Germany*
 Dr Krebsbach is head of the sterility testing department and responsible for sterility tests performed in a cleanroom as well as in isolators.
- **Jens Kubischik**, *Pall GmbH, Dreieich, Germany*
 Mr Kubischik is project manager for single-use-disposables in Europe.
- **Sigrid Lieb**, *Vetter Pharma-Fertigung GmbH & Co, KG, Ravensburg*
 Sigrid Lieb is project manager for internal and investment projects.
- **Dr Santiago Llovera**, *Boehringer Ingelheim Espana S.A., Sant Cugat des Vallès, Spain*
 Dr Llovera is Injectable Manufacturing Manager.
- **Dr Jörg Lümekemann**, *F. Hoffmann-La Roche AG, Basel, Switzerland*
 He is in the development of parenterals and in charge of the implementation of new technologies in this area.
- **Jack Lysfjord**, *Jack Lysfjord Consulting LLC, Minnetonka, US*
 Mr Lysfjord is Consultant in the field of Strategic Aseptic Processing.

**Speakers
(cont.)**

- **Dr Jean-Denis Mallet**, *SNC Lavalin, Ivry-sur-Seine, France*
Director Pharma Europe, formerly Head of the French Pharmaceutical Inspection Department (AFSSAPS).
- **Gert Moelgaard**, *NNE Pharmaplan, Søborg, Denmark*
Gert Moelgaard is Vice President for Innovation & Business Development in NNE Pharmaplan.
- **Alessandro Morandotti**, *Nuova OMPI, Piombino Dese, Padova, Italy*
Alessandro Morandotti is leading the development of new sterile product within the R&D organisation.
- **Alicia Mozzachio**, *FDA, USA*
Director Regulatory, Office of Manufacturing and Product Quality (OMPQ).
- **Dr Daniel Müller**, *Regierungspräsidium Tübingen, Germany*
Dr Müller is GMP-Inspector with focus on biotechnological active ingredients and sterile drug products.
- **Dr Wenzel Novak**, *groninger & co. gmbH, Crailsheim, Germany*
Dr Novak is responsible for pharmaceutical research and development.
- **Franck Pavan**, *Pierre FABRE Medicament Production, Idron, France*
Business Development Manager focused on Strategy and Development of contract manufacturing.
- **Matthias Poslovski**, *OPTIMA GROUP pharma GmbH, Schwäbisch Hall, Germany*
Director Technical Sales, responsible for US and South American markets.
- **Dr Ingo Presser**, *Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach, Germany*
Dr Presser is in charge of the clinical trial supply and process transfer unit with the Process Science Department.
- **Dr Heino Prinz**, *Wilco AG, Wohlen, Switzerland*
Dr Prinz is in charge of research and development.
- **Oliver Pütz**, *A. Nattermann & Cie. GmbH*
Head of Maintenance, also managing the production and maintenance of strategic TPM projects.
- **Dr Johannes Rauschnabel**, *Robert Bosch GmbH, Crailsheim, Germany*
He is now Director Process Engineering at Robert Bosch GmbH, Packaging Technology Pharma.
- **Dr Bernd Renger**, *Bernd Renger Pharma Consulting GmbH, Radolfzell, Germany*
He is running his own consultancy business and was prior Director of QC at Vetter Pharma-Fertigung.
- **Harald Römer**, *Notter GmbH*
Mr Römer is consultant and also working for Notter in the field of application technology.
- **Dr Uwe Rothhaar**, *SCHOTT AG, Mainz, Germany*
He primarily focuses on the chemical resistance and mechanical stability of pharmaceutical primary packing.
- **Hartmut Schaz**, *NNE Pharmaplan GmbH, Bad Homburg, Germany*
He is Senior Expert for Small Volume Parenteral Products and Director of the Board of NNE Pharmaplan India.
- **Dr Hans-Georg Schindler**, *Seidenader Vision GmbH, Markt Schwaben, Germany*
Since 2006 responsible for development and integration of innovative inspection methods.
- **Bernhard Sippel**, *Robert Bosch GmbH, Crailsheim, Germany*
He currently leads a qualification team for aseptic packaging machines.
- **Dr Harald Stahl**, *GEA Pharma Systems*
Harald Stahl presently is Senior Pharmaceutical Technologist. He has published more than 20 papers on various aspects of pharmaceutical production.
- **Dr Alexander Sterchi**, *F. Hoffmann-La Roche AG, Basel*
Since 2008 he is heading Logistics, Services & Infrastructure.
- **Paul Stone**, *Stäubli (UK) Ltd.*
General Manager of Stäubli (UK) based in Telford. With over 25 years experience in the application of robotics within the Pharmaceutical industry.
- **Klaus Ullherr**, *Robert Bosch GmbH, Crailsheim, Germany*
Mr Ullherr is Product Manager for the business fields syringes and cartridges.
- **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.
- **Norm Weichbrodt**, *Catalent Pharma Solutions, Woodstock, IL, USA*
R&D Strategic Account Manager with >30 years pharmaceutical experience in sterile injectables, lyophilization, and blow, fill, seal technology platforms.
- **Dr Jürgen Werani**, *Schuh & Co. Komplexitätsmanagement AG, St. Gallen, Switzerland*
Formerly Executive Director of Pfizer Deutschland, today member of the executive board of Schuh & Co. Komplexitätsmanagement.
- **Jörg Zimmermann**, *Vetter Pharma-Fertigung GmbH & Co. KG, Ravensburg, Germany*
Mr Zimmermann is Director Process Development and Implementation.

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



Image: groninger & co.

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 companies as well as from Inspectorates deal with pivotal developments in the field of sterile manufacture.

Target Audience

The event is directed at specialists from the pharmaceutical industry, at engineers and planners who have to deal with current aseptic technologies in clean areas in their daily practice.

It particularly aims at the departments:

- Production
- Quality assurance
- Engineering / technology

Moderator

- **Hartmut Schaz**, *NNE Pharmaplan (Day 1)*
- **Gert Moelgaard**, *NNE Pharmaplan (Day 2)*

Programme

Case study on Container closure integrity; from design to stabilities

☞ **Dr Olivier Chancel**, *Meriel*

- Design: microbial ingress testing to validate both the stopper / bottle association and the crimping parameters
- In process parameters and stability studies; experience of a vacuum test to confirm container and closure system integrity as a part of an IPC program on stability protocol

Mediafill Readout by Tunable Diode Laser Spectroscopy

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

- Detection of bacterial grow in Mediafill units
- Automated and fast detection method differing from visual control of Mediafill units
- Detection of oxygen consumption of microbial species
- Workload reduction and detection safety enhancement for Mediafill control

Case Study: Turn Key Cytotoxic Line

☞ **Matthias Poslovski, Jens Gemmecker**,
– *OPTIMA GROUP pharma*

- Washing
- Sterilizing
- Filling / Stoppering
- Lyophilization with automatic loading
- Capping
- Isolator / Decontamination



Image: groninger & co.

Current regulatory requirements: interpretation, main differences and technological implementation

☞ **Dr. Roland Guinet**, *Consultant*

- General comments on the PIC/S document
- Aseptic process validation interpretation
- Requalification frequencies
- Alternatives for Grade A capping
- Issues related to RTU components
- Some deviations observed in inspections

Possible evolutions of the annex 1: what's next ?

☞ **Dr Jean-Denis Mallet**, *SNC-Lavalin*

- Introduction: history of the successive versions of annex 1
- Parallel evolution of EU annex 1 and US-FDA guidance
- Some missing points in the current version
- Possible additional points to come

Robotics provides high efficiency and reliability in aseptic production areas

➔ Paul Stone, *Stäubli (UK)*

- Robot system safety in aseptic drug manufacturing
- Robotics ensures patient and personnel safety
- Increase of product quality
- Sterile drug manufacturing
- Stäubli TX robot series Stericlean
- Cleanroom and sterile environment

Application possibilities of continuous aseptic processing in liquid pharma

➔ Dr Heinrich-Andreas Kracke-Helm, *GEA Diessel*

- Advantages of continuous processes compared to batch and fed batch processes
- Examples for possible fields of applications
- Process parameters for continuous processes compared to batch processes
- Design criteria and requirements for components in continuous sterile processes
- Concepts / examples for continuous processes based on current continuous applications in non pharma

Advanced Aseptic Processing using Blow, Fill, Seal Technology

➔ Norm Weichbrodt, *Catalent Pharma Solutions*

- Overview of blow, fill, seal process (BFS)
- Current applications of BFS
- Engineering controls of automated aseptic process vs. traditional filling process administrative controls
- Flexibility of BFS forms
- BFS Benefits vs. glass
- Case Study – Microbial performance of BFS



Image: OPTIMA GROUP pharma

Aseptic Pharmaceutical Manufacturing – where are we going?

➔ Gert Moelgaard, *NNE Pharmaplan*

- Trends and challenges in aseptic processing
- Manufacturing opportunities in a business perspective
- Regulatory issues today and tomorrow
- Operating efficiency in aseptic processing

Ready – To – Use aluminium / plastic caps in view of new capping requirements

➔ Dr Renaud Janssen, *Helvoet Pharma*

- What are 'EU GMP Annex 1' capping requirements about?
- Learn on how Ready-To-Use aluminium/plastic caps are defined
- Get a detailed insight into the validation package for RTU caps:
 - Product Validation
 - Process Validation
 - Packaging Validation

Implementation of Single-Use Downstream Technologies for GMP Processing

➔ Jens Kubischik, *Pall*

- Single-Use-Systems (SUS) for Fluid Management
- Single-Use Key Technologies for Downstream Processing (Single-Use TFF, Single-Use Mixing etc.)
- Sterile processing with SUS
- Validation approach for process specific SUS



Single use technology in pharmaceutical manufacturing - an inspector's point of view

➔ Dr Daniel Müller, *Regierungspräsidium Tübingen*

- Guidelines & regulatory framework
- Pharmaceutical applications for disposable systems
- Single-use - versus multi-use systems
- Importance of supplier management
- Future prospects

The Closed Vial technology reduces risk of contamination

➔ Benoit Verjans, *Aseptic Technologies*

- Presence of living particle is possible in Grade A environment
- Risk of contamination is proportional to exposed surface and exposed time
- 5 different technologies have been assessed: open glass vials, PFS, open ampoules, BFS and closed vials
- The results show a difference factor for the risk of contamination over than 2 logs between closed vials and BFS versus open vials

Capacity extension through a high performance line for pre-sterilized syringes

➔ Gerald Bürkle, *Vetter Pharma-Fertigung*

- Current facts regarding the youngest Vetter production site RVS
- Presentation of the high performance filling line for pre-sterilized syringes RVS3
- Spray Tunnel regarding tub disinfection
- Waste logistics out of the Cleanroom
- Process video

Sterilisation of pre-filled Syringes

➔ Leopold Gruber, *SBM Schoeller Bleckmann Medizintechnik*

- Suitable packaging
- Arrangement
- Process-oriented parameters
- Sterilisation method in the test bench

Objectives

- Case studies from various pharmaceutical companies deal with the implementation and qualification of barrier systems
- You get to know the current state of the art as well as future technological developments in the field of barrier systems
- 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



Image: Bosch

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 focuses on topical questions on barrier systems in detail from the perspective of pharmaceutical operators, planners and engineers.

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 barrier systems.

Moderator

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

Programme

Current Aseptic Processing Trends with the use of Isolators and RABS

☞ **Jack Lysfjord**, *Lysfjord Consulting*

- Review of concepts for separation of operators from the critical zone
- Review global data from 2010 Isolator survey
- Review global data from 2011 RABS survey
- Review trends and observations

CVFS – A new concept in advanced barrier systems

☞ **Benoit Verjans**, *Aseptic Technologies*

- Introduce a new barrier concept: the CVFS containment
- This CVFS has been approved for Synflorix (a vaccine of GSK) in grade C clean room despite that the bottom is open
- The CVFS introduce multiple concepts which make it clearly different from RABS (no door opening, for closed containers, RTP or airlock use for all material entry,...)

How to run a RABS clean room successfully

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

- Aseptic Process Design
- Types of RABS and implications
- Mock-up studies
- Daily operations of a RABS
- Glove integrity testing
- Media fills
- Case studies from real life
- Conclusions

Design, Construction and Qualification of a Room Decontamination System for Aseptic Filling Room with RABS

☞ **Dr Alexander Sterchi**, *F. Hoffmann-La Roche*

- Design
- Distribution of hydrogen peroxide
- Decontamination of a room in overpressure
- RABS



Image: groninger & co.

Aseptic small scale filling in isolator technology

☞ **Dr Ingo Presser**, *Boehringer Ingelheim*

- Implementation of a customized small scale filling isolator
- Set up and operator of filling machine
- Process flow, Packaging materials – advantages and restrictions
- Usability and operating expense

Handling non water material in Aseptic Manufacturing under Isolator

☞ Franck Pavan, *Pierre Fabre*

- Isolators applied for new molecules
- Handling of VHP sanitization system
- Production under isolators of ATEX regulated molecules
- Choice of suppliers Leak test and OEL Key points for switching to isolator manufacturing

Rapid Sterility Test by Solid Phase cytometry in Isolator: Technology & Validation

☞ Peter Cornelis, *Toxikon Europe NV*

- Description of technology
- Set-up in Isolator
- Advantages of a rapid sterility test for IPC & Batch release
- Guidance for FDA & EMA approval
- Guidance for validation (EP & USP)
- Validation of a Sterility test: A case study
- Feasibility for different types of product

Comparison Isolator vs. Cleanroom (Sterility Testing)

☞ Dr Timo Krebsbach, *Labor L+S*

- Regulatory requirements
- Qualification / Validation of Isolators
- Isolators for Production vs. Testing
- Movie: Sterility Testing in Isolators
- Decision for Isolator / Cleanroom: Monitoring, Costs, Handling, Reliability



Image: Skan

Microbiology in Filling and Sterility Test Isolators

☞ Dr Christian Vogt, *Novartis Pharma*

- Bringing an isolator under microbiological control
- How to achieve a state of “practically free of microorganisms”
- Control of an isolator with physical and microbiological monitoring
- Maintenance aspects and integrity checks of isolator systems
- Validation of an filling isolator with media fills
- Microbiological problems in isolators

Improvements in the use of Isolators: practical experience

☞ Dr Santiago Llovera, *Boehringer Ingelheim*

- Learnings from design to start-up
- Improving operations in the isolator
- Campaigning products
- Aseptic transfer of components and waste
- Environmental monitoring critical controls
- Cleaning and optimization of sterilization / sanitization cycles

Relevance of Physical Glove Integrity Testing to Microbiological Contamination of Isolators

☞ Angela Gessler, *Skan*

- Regulatory Background to Glove Integrity Tests
- Physical methods for glove integrity tests and their boundaries
- Risk of Microbiological Contamination with leaky gloves
- Routine program for glove integrity testing

H₂O₂ decontamination – From Cycle development to robust production cycles

☞ Dr Johannes Rauschnabel, *Robert Bosch*

- Meanings and interpretations of different testing, cross-influence of the different parameters
 - D-Value in the isolator (assuming a perfect isolator and a perfect BI)
 - Thermal mapping
 - Chemical indicators mapping
 - Air flow pattern mapping
- What is recommended, feasible, reasonable, not recommended?

VHP Cycle Development and Validation activities at vendor and customer site: A Case Stud

☞ Bernhard Sippel, *Robert Bosch*

- General Biodecontamination Cycle Development approach, both for activities at vendor site and at customer site
- Importance of Biological Indicator incoming inspection
- Scheduling and utilisation of resources and related challenges
- Transfer of results obtained from Cycle development at vendor site to customer site
- Onsite cycle validation activities and results
- Lessons learned and conclusions

Barrier Systems for the Production of High Potent Aseptic Products

☞ Hartmut Schaz, *NNE Pharmaplan*

- Basics
 - Introduction / Scope of this presentation
 - Terms / Definitions
 - Risk potential / Protection measures
 - Risk analysis
- Requirements for the process equipment
 - Sampling / Weighing / Compounding
 - Filing / Lyophilisation
 - Outside decontamination / Inspection / Secondary Packaging
 - Equipment decontamination
- Conclusion / Recommendation

Case study: Optimization of a filling line isolator

☞ Xavier Baert, *Baxter Healthcare*

- Optimization of a filling line isolator to achieve project and later production efficiency
- Optimization from design to qualification approaches
- Ergonomic aspects: Handling, Fast airlock for flexibility
- Decontamination time to reduce the production standby between 2 batches.

Objectives

Why you should attend this conference:

- What are the causes of glass defects? You will learn what process steps in the production chain jeopardise the containers
- The conference will cover the problems in daily practice and will demonstrate solution approaches making processes safer
- You can discuss questions and problems with inspectors, glass manufacturers, equipment suppliers and pharmaceutical users

Background



Ensuring the integrity of pharmaceutical glass containers for parenterals is currently among the most discussed issues. Various incidents in the recent past led to an increased focus on the topic in authority and customer audits.

That's why in practice "0" defects are either requested or defined as goal. For that purpose the entire process chain from production of the glass tubes to the final packaging has to be carefully checked.

In many process steps there is a lot potential for improvement regarding the reduction and detection of glass defects. This requires an intensive cooperation and exchange of experience of packaging materials manufacturers and pharmaceutical companies.

Target Audience

This conference targets staff from glass manufacturers, equipment suppliers and pharmaceutical users who deal with glass as packaging material every day (development, quality assurance and quality control, production).

Moderator

- **Dr Bernd Renger**, *Bernd Renger Pharma Consulting*

Programme

"Zero Glass Breakage; illusion or an achievable goal?"

☉ **Dr Bernd Renger**, *Bernd Renger Pharma Consulting*

- Regulatory expectations
- Pharmaceutical Industry's response
- Incoming inspection – AQL versus ppm
- Wishful thinking and reality

Glass breakage – Microcracks – inspector's point of view

☉ **Dr Daniel Müller**, *Regierungspräsidium Tübingen*

- Typical genesis of a quality related recall
- Glass breakage & micro cracks - a risk for drug products
- Decision criteria for introducing a recall
- Expectations of a GMP inspector
 - On handling recalls and associated investigations & measures
 - And on detection & mitigation of glass breakage during production process
- Examples of quality issues & recalls based on glass defects

Glass Container Breakage: Reasons - Characterization – Prediction

☉ **Dr Uwe Rothhaar**, *SCHOTT*

- Introduction to glass as a material for drug containers
- Glass faults
- Interaction between strength/breakability and surface properties
- Characterization of glass breakage by fractography
- Fracture statistics and prediction of failure probabilities



Crack prevention and process controls in pre-fillable syringe manufacturing

☉ **Dr Andrea Behrenswerth**, *Gerresheimer Bünde*

- Definition of cracks
- Analysis of syringes with cracks
- Development of cracks
- Prevention of cracks
- Technical solutions

Glass Strength Considerations for Injector Design

☞ Nigel Bates, *Pfizer*

- Break force measurement of glass syringes including method development, analysis and interpretation of strength data
- Impact of glass handling processes on glass strength
- Theoretical and practical evaluation of forces within injector devices
- Design considerations for injector devices in relation to glass syringes

„Moulded glass – how to avoid breakage with glass containers type I“

☞ Dirk Beer, *NYCOMED*

- Forming of containers made of moulded glass type I
- Glass quality and treatments
- Quality control of glass containers
- Challenge on pharmaceutical manufacturer



Current issues with prefilled glass syringes: how to solve them without compromising on functionality and safety

☞ Peter Forceville, *Medpro*

- Tungsten and use of adhesives with staked on needles
- Sprayed-on silicone and sv particle count
- Glass breakage (entire syringe / luer lock)
- Dimensional tolerances of glass production and high speed filling lines
- How to take device complexity out of the sterile filling zone
- Selection of primary container material (glass, COC/COP) independent from preferred device

Discussion of critical issues

☞ Dr Bernd Renger, *Bernd Renger Pharma Consulting*

- Was our previous monitoring and control of primary packaging material suppliers inadequate?
- Did we apply the appropriate level of quality risk management to primary packaging material components?
- Did and do we apply the appropriate level of quality risk management to primary packaging material component failures and complaints?
- Do we have reliable estimates or data concerning serious incidents caused by glass failures or breakage?
- Are there reliable data and/or experimental evidence of a sterility failure caused by glass breakage (“hairline cracks”) see suspected cause at Uniklinik Mainz
- Did we assess the risk associated with glass breakage in the market appropriately or did we underestimate it?
- Are we overreacting today?
- Is there a noticeable difference in the scrutiny and concern between different competent authorities?

Inline detection of cracks in pharmaceutical glass containers

☞ Dr Hans-Georg Schindler, *Seidenader Vision*

- Presentation of two solutions for the inspection of container integrity at the latest possible steps of the packaging process:
 - Inspection of liquid filled vials using high voltage (HV) technology - “HV inspection technology” and “blue dye testing” will be elaborated
 - Inspection of lyophilisates using Head Space Analysis (HSA) a new technique to exclude environmental effects on HSA will be discussed

Foreign particle detection of glass in vials, ampoules and syringes by 100% inline within lyophilisates and suspensions

☞ Dr Heino Prinz, *Wilco*

- Soft X-ray technology
- 100% detection in production speed
- Detection inside the product
- Minimal false rejects due to bubble transparency
- Validation

Case Study: Safe glass handling - possibilities for risk mitigation

☞ Dr Ingo Presser, *Boehringer Ingelheim Pharma*

- Failure types and causes during the aseptic filling process
- Risk assessment
- Handling of rare events
- Specifications, tolerances and machines

Baseline Study: Glass Monitoring of aseptic Pre-Filled Syringes, Carpules and Vials

☞ Sigrid Lieb, *Vetter Pharma-Fertigung*

- Glass breakage requirements
- Identification of critical process steps / approach
- From incoming inspection of packaging materials to secondary packaging of pre-filled application systems
- Evaluation of glass breakage events and actions
- Trending Perspektive

Cosmetic and critical Impacts of fill- and finish lines to glass containers (incl. a case study)

☞ Dr Wenzel Novak, *groninger & co.*

- Handling of primary packaging containers made from glass during the fill process
- Causes to create damage during filling
- Options to avoid damage (new design vs. existing equipment)
- Options to avoid any glass-glass-contact

Avoiding surface damage and glass breakage on filling and packaging lines

☞ Edgar Bauer, *Bausch + Ströbel*

- Types of surface damage
- Cause of surface damage
- Case study
 - Standard processing line
 - „Stress-free“ processing line for primary and secondary packaging requirements

Impact of filling lines to glass container

☞ Klaus Ullherr, *Robert Bosch*

- “Zero defects” from the suppliers point of view
- Critical parts of the machine
- Solutions to avoid damage

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 the involved parties

Background



Image: groningen & co.

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.

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

- Klaus Ullherr, *Robert Bosch*
- Dr Wenzel Novak, *groninger & co*

Programme

Enhance the PFS glass containers quality through an optimized control process designed for sensitive and biodrugs

➤ Alessandro Morandotti, *Nuova OMPI*

- Glass forming knowledge
- Integrated dimensional and inspection control
- Production fully in a controlled environment

How to design extractables / leachables studies for prefilled syringe applications

➤ Piet Christiaens, *Toxikon Europe*

- Container / closure guidelines for the pharmaceutical Industry in US and Europe
- How basic knowledge of materials can help to understand the leaching mechanism
- How to design an extractable study for prefilled syringes
- How to design a leachable study for prefilled syringes
- Case study

Specific challenges of nested syringe filling - in small batch production and industrial scale

➤ Klaus Ullherr, *Robert Bosch*

- Filling of high potent drugs; impact on the machine solutions
- Small batch production for development under cRABS
- Production line under isolator
- IPC (In Process Checkweigh)
- Sampling and reject solutions
- Combination filling stations

Polymer based prefilled syringes- update from Japanese experience

➤ William Dierick, *TERUMO Europe*

- Plastic prefilled syringes for use in biopharmaceuticals as well as for specific applications
- Conditions of use
- Examples of successful implementation
- Latest update on developments for COP based pre-filled syringes

Prefilled Syringe and Autoinjector: a complex relationship

➤ Jörg Zimmermann, *Vetter Pharma-Fertigung*

- Introduction to the product
 - Patient advantages
 - Optimization project
 - Project objectives
 - Project organisation
- Key factors addressed
 - Functionality of syringe & pen
 - Bulk processing of syringes
 - Siliconization
 - Review of syringe filling
 - Review of pen assembly
- Summary & Conclusion

Qualifying a new technology: A case study about outside decontamination of tubs by Plasma technology

➤ Dr Wenzel Novak, *groninger & co.*

- Challenges using a new decontamination method
- What's important?
- Regulatory aspects
- Experiences from Validation and Qualification

Basics of E-Beam Systems for Prefilled Syringes

➤ Manfred Holzer, *Skan*

- Sterilization principle
- System components
- Case studies
- Frequently asked questions

Objectives

This conference aims at informing about recent technologies in the manufacture of oral solid dosage forms and how the efficiency in the manufacturing plant can be increased or costs can be reduced.

Background



Image: GEA Pharma Systems

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.

This conference focuses on two hot topics: **Continuous Processing** and **Increase of Efficiency**. Both topics are of importance for the question, where future production will take place. Moreover, 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. The second block of the conference will further deal with how the efficiency of a production plant for oral solid dosage forms can be increased and how production costs can be reduced. These are important points for the discussion about future manufacturing locations and site to site competition.

Target Audience

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

Moderator

- **Dr Harald Stahl**, *GEA Pharma Systems*

Programme

Block: Continuous Processing

Regulatory Update on Continuous Processing

- ☉ **Alicia Mozzachio**, *FDA, Office of Manufacturing and Product Quality*
- Validation of continuous processes
- Handling deviations
- Release procedure

Case Story: Janssen Pharmaceutica Continuous Processing – The Ultimate in Lean Manufacturing

- ☉ **Philippe Cappuyens**, *Janssen Pharmaceutica, subsidiary of Johnson & Johnson*
- Comparison Batch vs Continuous
- Benefits & Pitfalls of Continuous
- Business Case for Continuous
- Continuous & Quality-by-Design
- Continuous Processing Equipment

Case Story: AstraZeneca

- ☉ **Dr Henry Huang**, *AstraZeneca*

Block: Increasing Efficiency

Increasing the efficiency of tableting processes

- ☉ **Harald Römer**, *Notter*
- Technical approaches
 - Multi-tip tools
 - Increased number of punches of the torrents
 - process technology
- Quality aspects
- Examples from the field

Tools for increasing manufacturing efficiency

- ☉ **Dr Jürgen Werani**, *Schuh & Co. Komplexitätsmanagement*
- OPEX Scan: Analyze the Status Quo – Structure the Future
- Outcome of Operational Excellence programmes: experiences from the pharmaceutical industry
- How to save costs and expenses

Total Productivity Management (TPM) & Change Management

- ☉ **Oliver Pütz**, *A. Nattermann & Cie.*
- Optimization of staffing levels
- Reducing storage space
- Reducing of processing time
- Increase of productivity

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

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 24 April 2012). 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 24 April 2012, 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 Conference Solid Dosage Forms:
Dr. Robert Eicher (Fachbereichsleiter), Tel. 06221/84 44 12,
E-Mail: eicher@concept-heidelberg.de.

ECA Conferences Barrier Systems / Prefilled Syringes / Current Aseptic Technologies / Glass – Glass Breakage – (Micro-)Cracks:
Dr. Andreas Mangel (Fachbereichsleiter), Tel. 06221/84 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

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





„I was pleasantly surprised about the density of information in the lectures and the high quality speakers – and this in a perfect combination with an exhibition. In total a very compact, very well organised and high-class event.“

Dr Hanns-Cord Walter, General Manager Klosterfrau



„I believe it was a very well attended event. As usual there were plenty of opportunities for networking with colleagues from industry and from suppliers and service providers.“

Dr Friedrich Haefele, Vice President Biopharma Operations, Boehringer Ingelheim



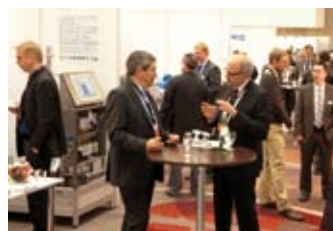
„We were very satisfied with this year's congress. We already noticed the last time that the congress is quite popular with our customers, especially for those in the German speaking area. However, we also noticed that we had more foreign visitors due to the international orientation of the presentations.“

Willem Berends, groningen & co. gmbh (Exhibitor)



„The participation was already quite good in the last year. And this year the positive trend continued. We had many good contacts with users as well as with technology representatives.“

Jens Kubischik, Pall GmbH (Exhibitor)



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 (24 April 2012)

Day 2 (25 April 2012)

(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. You will receive a confirmation/invoice for your registration for the exhibition per mail.)

Attending Conferences – One Day Tickets for € 490,-

(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 1. congress day (One Day Ticket for 24 April 2012). 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 (24 April 2012)** and I'm primarily interested in the conference:

- ECA Conference Current Aseptic Technologies
- ECA Barrier Systems Conference
- ECA Conference Glass – Glass Breakage – (Micro-)Cracks
- ECA Conference Prefilled Syringes

I would also like to take part in the Social Event on the evening of 24 April 2012.

I would like to attend on day **2 (25 April 2012)** and I'm primarily interested in the conference:

- ECA Conference Current Aseptic Technologies
- ECA Conference Barrier Systems Conference
- ECA Conference Glass – Glass Breakage – (Micro-)Cracks
- ECA Conference Manufacture of Oral Solid Dosage Forms

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

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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 %

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)!