

# 20 Pharma Congress

Production & Technology  
12 Düsseldorf, 24-25 April 2012  
[www.pharma-kongress.com](http://www.pharma-kongress.com)



## Agenda

for all Congress Conferences

### 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



**With speakers from leading pharmaceutical companies and authorities - including** Bayer Pharma, Bayer Technology Services, Boehringer Ingelheim, Catalent, Cilag, CSL Behring, F.Hoffmann-La Roche, Fresenius Kabi, Glycotope Biotechnology, 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, FDA, Regierungspräsidium Tübingen... and many more.

CONCEPT  
HEIDELBERG

Uhrzeit Time	ECA Current Aseptic Technologies	ECA Barrier Systems Conference	ECA Conference Glass – Glass Breakage – (Micro-)Cracks	ECA Conference Prefilled Syringes
8.30 Uhr				
8.45 Uhr	Welcome / Introduction	Welcome / Introduction	Welcome / Introduction	
9.00 Uhr				
9.15 Uhr	Aseptic Pharmaceutical Manufacturing – where are we going? <i>Gert Moelgaard, NNE Pharmaplan</i>	Current Aseptic Processing Trends with the use of Isolators and RABS <i>Jack Lysfjord, Lysfjord Consulting</i>	“Zero Glass Breakage; illusion or an achievable goal?” <i>Dr Bernd Renger, Bernd Renger Consulting</i>	
9.30 Uhr				Welcome / Introduction
9.45 Uhr				
10.00 Uhr	Mediafill Readout by Tunable Diode Laser Spectroscopy <i>Dr Jörg Lümke, F.Hoffmann-La Roche</i>	CVFS – A new concept in advanced barrier systems <i>Benoit Verjans, Aseptic Technologies</i>	Glass breakage – Microcracks – inspector’s point of view <i>Dr Daniel Müller, Regierungspräsidium Tübingen</i>	Enhance the PFS glass containers quality through an optimized control process designed for sensitive and biodrugs <i>Alessandro Morandotti, Nuova OMPI</i>
10.15 Uhr				
10.30 Uhr				
10.45 Uhr	Coffee Break	Coffee Break	Coffee Break	Coffee Break
11.00 Uhr				
11.15 Uhr	Case Study: Turn Key Cytotoxic Line <i>Matthias Poslovski / Jens Gemmecker / Christoph von Stenglin, OPTIMA GROUP pharma</i>	How to run a RABS clean room successfully <i>Jörg Zimmermann, Vetter Pharma-Fertigung</i>	Glass Container Breakage: Reasons – Characterization – Prediction <i>Dr Uwe Rothhaar, SCHOTT</i>	How to design extractables / leachables studies for prefilled syringe applications <i>Piet Christiaens, Toxikon Europe</i>
11.30 Uhr				
11.45 Uhr				
12.00 Uhr	Current regulatory requirements: interpretation, main differences and technological implementation <i>Dr Roland Guinet, Consultant</i>	Design, Construction and Qualification of a Room Decontamination System for Aseptic Filling Room with RABS <i>Dr Alexander Sterchi, F. Hoffmann-La Roche</i>	Crack prevention and process controls in pre-fillable syringe manufacturing <i>Dr Andrea Behrenswerth, Gerresheimer Bünde</i>	Specific challenges of nested syringe filling - in small batch production and industrial scale <i>Klaus Ullherr, Robert Bosch</i>
12.15 Uhr				
12.30 Uhr				
12.45 Uhr				
13.00 Uhr				
13.15 Uhr	Lunch Break	Lunch Break	Lunch Break	Lunch Break
13.30 Uhr				
13.45 Uhr				
14.00 Uhr				
14.15 Uhr	Possible evolutions of the annex 1: what’s next ? <i>Dr Jean-Denis Mallet, SNC-Lavalin</i>	Aseptic small scale filling in isolator technology <i>Dr Ingo Presser, Boehringer Ingelheim</i>	Glass Strength Considerations for Injector Design <i>Nigel Bates, Pfizer</i>	Polymer based prefilled syringes-update from Japanese experience <i>William Dierick, TERUMO Europe</i>
14.30 Uhr				
14.45 Uhr				
15.00 Uhr	Robotics provides high efficiency and reliability in aseptic production areas <i>Sylvie Algarra, Stäubli Favergé</i>	Handling non water material in Aseptic Manufacturing under Isolator <i>Franck Pavan, Pierre Fabre</i>	„Moulded glass – how to avoid breakage with glass containers type I” <i>Dirk Beer, Nycomed</i>	Prefilled Syringe and Autoinjector: a complex relationship <i>Jörg Zimmermann, Vetter Pharma-Fertigung</i>
15.15 Uhr				
15.30 Uhr				
15.45 Uhr	Coffee Break	Coffee Break	Coffee Break	Coffee Break
16.00 Uhr				
16.15 Uhr	Application possibilities of continuous aseptic processing in liquid pharma <i>Dr Heinrich-Andreas Kracke-Helm, GEA Diessel</i>	Rapid Sterility Test by Solid Phase cytometry in Isolator: Technology & Validation <i>Peter Cornelis, Toxikon Europe</i>	CSI Supplier Quality Management <i>Dr Thomas Scholzen, F.Hoffmann-La Roche</i>	Qualifying a new technology: A case study about outside decontamination of tubs by Plasma technology <i>Dr Wenzel Novak, groninger &amp; co</i>
16.30 Uhr				
16.45 Uhr				
17.00 Uhr	Advanced Aseptic Processing using Blow, Fill, Seal Technology <i>Norm Weichbrodt, Catalent Pharma Solutions</i>	Comparison Isolator vs. Cleanroom (Sterility Testing) <i>Dr Timo Krebsbach, Labor L+S</i>	TBN	Basics of E-Beam Systems for Prefilled Syringes <i>Manfred Holzer, Skan</i>
17.15 Uhr				
17.30 Uhr				
17.45 Uhr	Final Discussion	Final Discussion	Final Discussion	Final Discussion
18.00 Uhr				
18.30 Uhr	Social Event for Congress Delegates, Speakers and Exhibitors			

Uhrzeit Time	ECA Conference Current Aseptic Technologies	ECA Barrier Systems Conference	ECA Conference Glass – Glass Breakage – (Micro-)Cracks	ECA Conference Manufacture of Oral Solid Dosage Forms
8.30 Uhr				
8:45 Uhr				
9.00 Uhr				
9:15 Uhr	Case study on Container closure integrity; from design to stabilities <i>Dr Olivier Chancel, Merial</i>	Microbiology in Filling and Sterility Test Isolators <i>Dr Christian Vogt, Novartis Pharma</i>	Inline detection of cracks in pharmaceutical glass containers <i>Dr Hans-Georg Schindler, Seidenader Vision</i>	Regulatory Update on Continuous Processing <i>Alicia Mozzachio, FDA</i>
9:30 Uhr				
9:45 Uhr	Ready – To – Use aluminium / plastic caps in view of new capping requirements <i>Dr Renaud Janssen, Helvoet Pharma</i>	Improvements in the use of Isolators: practical experience <i>Dr Santiago Llovera, Boehringer Ingelheim</i>	Foreign particle detection of glass in vials, ampoules and syringes by 100% inline within lyophilisates and suspensions <i>Dr Heino Prinz, Wilco</i>	Coffee Break
10.00 Uhr				
10:15 Uhr				
10.30 Uhr	Coffee Break	Coffee Break	Coffee Break	Case Story Continuous Processing: Janssen Pharmaceutica <i>Philippe Cappuyns, Janssen Pharmaceutica</i>
10:45 Uhr				
11.00 Uhr	Implementation of Single-Use Downstream Technologies for GMP Processing <i>Jens Kubischik, Pall</i>	Relevance of Physical Glove Integrity Testing to Microbiological Contamination of Isolators <i>Angela Gessler, Skan</i>	Case Study: Safe glass handling – possibilities for risk mitigation <i>Dr Ingo Presser, Boehringer Ingelheim</i>	
11:15 Uhr				
11:30 Uhr				
11:45 Uhr	Single use technology in pharmaceutical manufacturing - an inspector's point of view <i>Dr Daniel Müller, Regierungspräsidium Tübingen</i>	H <sub>2</sub> O <sub>2</sub> decontamination – From Cycle development to robust production cycles <i>Christian Doriath, Lilly France</i>	Baseline Study: Glass Monitoring of aseptic Pre-Filled Syringes, Carpules and Vials <i>Sigrid Lieb, Vetter Pharma-Fertigung</i>	Case Story Continuous Processing: AstraZeneca <i>Henry Huang, AstraZeneca</i>
12.00 Uhr				
12:15 Uhr				
12.30 Uhr	Lunch Break	Lunch Break	Lunch Break	Lunch Break
12:45 Uhr				
13.00 Uhr				
13:15 Uhr				
13:30 Uhr				
13:45 Uhr				
14.00 Uhr	The Closed Vial technology reduces risk of contamination <i>Benoit Verjans, Aseptic Technologies</i>	The BI as a tool to predict a cycle efficiency? <i>Christian Doriath, Lilly France</i>	Cosmetic and critical Impacts of fill- and finish lines to glass containers (incl. a case study) <i>Dr Wenzel Novak, groninger &amp; co</i>	Increasing the efficiency of tableting processes <i>Harald Römer, Notter GmbH</i>
14:15 Uhr				
14:30 Uhr				
14:45 Uhr	Coffee Break	Coffee Break	Coffee Break	
15.00 Uhr				
15:15 Uhr	Capacity extension through a high performance line for pre-sterilized syringes <i>Gerald Bürkle, Vetter Pharma-Fertigung</i>	Barrier Systems for the Production of High Potent Aseptic Products <i>Hartmut Schaz, NNE Pharmaplan</i>	Avoiding surface damage and glass breakage on filling and packaging lines <i>Edgar Bauer, Bausch + Ströbel Maschinen-fabrik</i>	Coffee Break
15:30 Uhr				
15:45 Uhr				Tools for increasing manufacturing efficiency <i>Dr Jürgen Werani, Schuh &amp; Co.</i>
16.00 Uhr				
16:15 Uhr	Sterilisation of pre-filled Syringes <i>Leopold Gruber, SBM Scholler Bleckmann Medizintechnik</i>	Case study: Optimization of a filling line isolator <i>NN</i>	Impact of filling lines to glass container <i>Klaus Ullherr, Robert Bosch</i>	
16:30 Uhr				
16:45 Uhr	Final Discussion	Final Discussion	Final Discussion	Total Productivity Management (TPM) & Change Management <i>Oliver Pütz, A. Nattermann &amp; Cie. GmbH</i>
17.00 Uhr				
17:15 Uhr				
17:30 Uhr				
17:45 Uhr				
18:00 Uhr				

