

SPEAKERS

NIGEL BATES

Pfizer

EDGAR BAUER

Bausch + Ströbel

DIRK BEER

Nycomed

DR ANDREA BEHRENSWERTH

Gerresheimer Bünde

SIGRID LIEB

Vetter Pharma Fertigung

DR DANIEL MÜLLER

Regierungspräsidium Tübingen

DR WENZEL NOVAK

groninger

DR INGO PRESSER

Boehringer Ingelheim

DR HEINO PRINZ

Wilco

DR BERND RENGER

Bernd Renger Consulting

DR UWE ROTHHAAR

Schott

DR HANS-GEORG

SCHINDLER

Seidenader Vision

DR THOMAS SCHOLZEN

F. Hoffmann-La Roche

KLAUS ULLHERR

Bosch

**This conference is part of the
Pharma Congress 2012**

Glass – Glass Breakage – (Micro-)Cracks

Düsseldorf/Neuss, Germany, 24-25 April 2012

HIGHLIGHTS:

- Types of glass container faults
- Inline detection of cracks and glass particles
- Supplier Quality Management
- Crack prevention - case studies from
 - Pharmaceutical companies
 - Glass manufacturers
 - Equipment suppliers
- Regulatory expectations

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 manufacturers and pharmaceutical operators

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 manufacturers and pharmaceutical companies.

Target Audience

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

Moderator

Dr Bernd Renger, *Bernd Renger Consulting*

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.

Special offer from Lufthansa – discounted travel for Pharma Congress attendees

Lufthansa is the mobility partner for all ECA events. This means, that, as an ECA course or conference attendee, you will receive up to 20% discounted travel fares (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.



And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

Programme 24 April

“Zero Glass Breakage; illusion or an achievable goal?”

- Regulatory expectations
 - Pharmaceutical Industry's response
 - Incoming inspection – AQL versus ppm
 - Wishful thinking and reality
- DR BERND RENGER**, *Bernd Renger Pharma Consulting*

Glass breakage – Micro-cracks – inspector's point of view

- 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
- DR DANIEL MÜLLER**, *Regierungspräsidium Tübingen*

Glass Container Breakage: Reasons - Characterization – Prediction

- 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
- DR UWE ROTHHAAR**, *SCHOTT*

Crack prevention and process controls in pre-fillable syringe manufacturing

- Definition of cracks
 - Analysis of syringes with cracks
 - Development of cracks
 - Prevention of cracks
 - Technical solutions
- DR ANDREA BEHRENSWERTH**, *Gerresheimer Bünde*

Glass Strength Considerations for Injector Design

- 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
- NIGEL BATES**, *Pfizer*

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

- Forming of containers made of moulded glass type I
 - Glass quality and treatments
 - Quality control of glass containers
 - Challenge on pharmaceutical manufacturer
- DIRK BEER**, *Nycomed*

CSI Supplier Quality Management: Glass defects in primary packaging materials - challenges for the global Supplier Quality Management at the interface between production, supplier and QA

- Role Supplier Quality Management
 - Glass quality: experiences from deviation management and glass quality-related projects
- DR THOMAS SCHOLZEN**, *F. Hoffmann-La Roche*

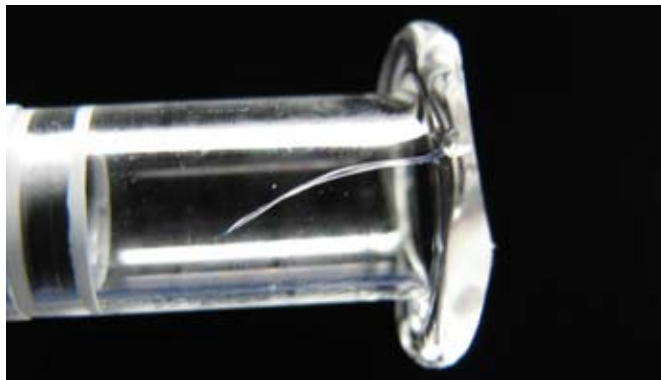


Programme 25 April

Inline detection of cracks in pharmaceutical glass containers

- 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

DR HANS GEORG SCHINDLER, *Seidenader Maschinenbau*



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

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

DR HEINO PRINZ, *Wilco*

Case Study: Safe glass handling - possibilities for risk mitigation

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

DR INGO PRESSER, *Boehringer Ingelheim Pharma*

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

- 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 Perspective

SIGRID LIEB, *Vetter Pharma-Fertigung*

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

- 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

DR WENZEL NOVAK, *groninger & co.*

Avoiding surface damage and glass breakage on filling and packaging lines

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

EDGAR BAUER, *Bausch + Ströbel*

Impact of filling lines to glass container

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

KLAUS ULLHERR, *Bosch*

Speakers

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*

Edgar Bauer (Area Sales Manager France) started working for Bausch+Ströbel in 1989. Since 2000 he has been in charge of the French market in the Sales Department.

DIRK BEER, *Nycomed GmbH, Singen, Germany*

Since 2009 he 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

SIGRID LIEB, *Vetter Pharma-Fertigung GmbH & Co, KG, Ravensburg*

Sigrid Lieb is project manager for internal and investment projects at Vetter Pharma-Fertigung

DR DANIEL MÜLLER, *Regierungspräsidium Tübingen, Germany*

In 2001 he joined a German inspectorate and has been working as a GMP-Inspector with focus on biotechnological active ingredients and sterile drug products since that time

DR WENZEL NOVAK, *groninger & co. gmbH, Crailsheim, Germany*

Since 2006, he has been responsible for pharmaceutical research and development at Groninger.

DR INGO PRESSER, *Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach, Germany*

Since May 2011 he took over the responsibility of the clinical trial supply and process transfer unit with the Process Science Department of Boehringer Ingelheim.

DR HEINO PRINZ, *Wilco AG, Wohlen, Switzerland*

In August 2010 he joined Wilco AG in charge for research and development.

DR BERND RENGER, *Bernd Renger Pharma Consulting GmbH, Radolfzell, Germany*

Since 2011, is running his own consultancy business. Before that he was Director of Quality Control at Vetter Pharma-Fertigung.

DR UWE ROTHHAAR, *SCHOTT AG, Mainz, Germany*

Since 2000 he is working for SCHOTT, in the last years primarily focused on the chemical resistance and mechanical stability of pharmaceutical primary packing.

DR HANS-GEORG SCHINDLER, *Seidenader Maschinenbau GmbH, Markt Schwaben, Germany*

Since 2006 he is responsible for development and integration of innovative inspection methods at Seidenader Vision.

DR THOMAS SCHOLZEN, *F. Hoffmann-La Roche AG, Basel, Switzerland*

Quality Management of primary packaging materials. Moved to Roche Global Supplier Quality Management in 2010 (Non-formulation Materials).


KLAUS ULLHERR, *Robert Bosch GmbH, Crailsheim, Germany*

Klaus Ullherr joined Bosch in 2000. Since 2002 he is working as a Product Manager for the business fields syringes and cartridges.

Easy Registration

 **Reservation Form:**
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

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 **e-mail:**
info@concept-heidelberg.de

 **Internet:**
www.pharma-kongress.com

Date

Tuesday, 24 April 2012, 08.45-18.00 h
(Registration Monday, 23 April 19.00 – 20.30 h and
Tuesday, 24 April, 08.00 – 08.45 h)
Wednesday, 25 April 2012, 09.00-17.00 h

Venue

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

Fees

EUR 980.- per delegate plus VAT

The conference fee is payable in advance after receipt of invoice and includes lunch on that day as well as beverages during the event and during breaks. It also includes the Social Event on the evening of the first congress day (24 April 2012) VAT is reclaimable.

Your registration also entitles you to participate in all other Pharma Congress conferences during the two days. For further information please visit www.pharma-kongress.com.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.pharma-kongress.com

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.

Please further note that 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.

Organisation & Contact

CONCEPT HEIDELBERG
P.O. Box 10 17 64
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Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:


Dr Andreas Mangel (Operations Director) at +49-6221/84 44 41, or per e-mail at mangel@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:

Mr Detlef Benesch (Organisation Manager) at +49-6221/84 44 45, or per e-mail at benesch@concept-heidelberg.de.

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Glass – Glass Breakage – (Micro-)Cracks

Part of the Pharma Congress Production & Technology 2012
Düsseldorf/Neuss, Germany, 24-25 April 2012

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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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