GLASS meets PHARMA

USP - Ph. Eur. - ECA Joint Conference

USP General Chapter <660>:
major revisions coming in 2018!

6-7 June 2018, Berlin, Germany

HIGHLIGHTS:

- Regulatory Requirements:
  - EU
  - USA
- Update of USP General Chapters <660>, <1660>, including proposed revisions
- Update of Ph. Eur. Chapter 3.2.1
- Glass Delamination
- Glass Particles (Particle Contamination in Parenterals)
- Specific Aspects for moulded and tubular glass
- Extractables & Leachables testing for Glass?
- Glass formulations with enhanced chemical stability
- New technologies in filling lines

Speakers from the <660> Expert Panel at United States Pharmacopeia (USP)

DR BETTINE BOLTRES
Westpharma, Member USP General Chapters – Packaging and Distribution Expert Committee, Co-Chair <660> Expert Panel

DR MICHAEL EAKINS
Co-Chair of <660> Expert Panel and Member of USP General Chapters – Packaging and Distribution Expert Committee

DR HOLGER RÖHL
Roche, Member of <660> Expert Panel

Speakers from Industry

FRANK BAMBERG
Roche

ALFRED BREUNIG
Nipro

DR CLAUDIA HEINL
Schott

HORST KOLLER
HK Packaging

VINCENT LANGLADE
SGD

DR OLIVER VALET
Rap.ID

DR JÖRG ZÜRCHER
Bayer, Chair of EDQM Working Party Glass

Speakers from Authorities

DR KATRIN BUSS
Regulatory Expert, Bonn

DR ELLEN PEL
COUNCIL OF EUROPE - EDQM & Healthcare, Ph. Eur.

DR CHARUDHARSHINI SRINIVASAN
Food and Drug Administration (FDA)

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Objectives & Background

Glass materials used in packaging systems must be shown to be suitable for their intended applications. To address these issues, USP is currently revising its general chapters <660> *Glass Containers Used in Pharmaceutical Packaging/Delivery Systems and <1660> Glass Containers Used in Pharmaceutical Packaging/Delivery Systems: Manufacture and Evaluation of the Inner Surface Durability.*

Glass is not fully inert. Therefore, in addition to the glass surface tests, Extractables & Leachables have to be taken into account. Furthermore, in the last number of years, delamination (resulting in "Glass flakes") and visible foreign particulate matter (i.e. glass particles), became the number one reason for recalls in the pharmaceutical industry. Therefore the attention and demands of the authorities has increased, with a special focus on root cause investigation of the particle contamination. Compendial chapters have been changed and specified accordingly. FDA inspectors like to see the staged investigation cycle approach.

Packaging materials also have to be described in the registration process of a drug product according to the particular requirements. The development of pharmaceutical packaging systems is an increasingly complex topic, which is reflected in the most recent requirements for combination products and biologics. To cover all relevant aspects a thorough target product profile needs to be set up.

Furthermore, the pharmaceutical manufacturer has to guarantee that only such packaging materials are used that are correctly printed, in conformity with the specifications and in compliance with the regulatory requirements. In order to determine the scope of the tests for the quality control of pharmaceutical packaging materials, the "Defect Evaluation Lists" have proved efficient. The responsibility for the tests lies now more and more with the suppliers of packaging materials, while the pharmaceutical industry tries to reduce testing at the same time.

This two-day conference will address the following:

- Key issues surrounding USP's and Ph.Eur.´s requirements for glass materials of construction for pharmaceutical packaging systems.
- Regulatory expectations regarding the suitability of glass components and systems used for pharmaceutical drug products.
- USP's proposed revision to General Chapter <660>.
- Future developments and challenges.

Why Attend?

- Learn about USP proposals surrounding testing, chemical characterization, and risk-based testing strategies.
- Help shape the future revision of <660> Containers–Glass.
- Hear the rationale behind the proposed chapters <660> and <1660>.
- Get deep insights in physical and chemical aspects of tubular and moulded glass.
- Use the opportunity to discuss with speakers from industry, authorities and colleagues from other companies and suppliers.

Conference presentations, case studies and open discussions will help participants learn more about the glass packaging materials and analytical procedures and provide a forum for discussing USP's revised general chapters related to this topic. Participants will thus have the opportunity to give feedback and ask questions directly to USP's Expert Panel Members.

The meeting will also address topics such as:

- Delamination
- Control of glass particles and new approaches in packaging pressure monitoring
- Extractables & Leachables
- Regulatory expectations
- Glass formulations with enhanced chemical stability

Target Audience

The USP, the EDQM and the ECA Academy wish to actively involve analytical chemists, QC analysts, quality assurance associates & managers, R&D scientists, as well as manufacturing scientists and managers, regulatory affairs specialists and contract laboratories / research organizations and suppliers.

Chairs

Dr Bettine Boltres
Dr Michael Eakins

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Programme

Introduction to the ECA Foundation, the Ph. Eur. and the USP

- ECA introduction (DR ANDREA KÜHN)
- EDQM introduction (DR ELLEN PEL)
- USP introduction (DR MICHAEL EAKINS)

Overview of Key Issues for the Revision of USP Chapters <660> and <1660>

- ▶ DR MICHAEL EAKINS
- Update from the <660> Expert Panel: Review of the revision process for USP General Chapters <660> and <1660>

Specific Aspects for Glass Containers made of Tubular Glass

- ▶ ALFRED BREUNIG
- Overview of production processes for tubular glass containers
- Overview of ISO Modifications in relation to tubular glass containers
- Specific Defect Evaluation Lists
- Change Control

Biologics in Molded Glass

- ▶ VINCENT LANGLADE
- Overview of production processes for molded glass
- Overview of DIN ISO Modifications in relation to molded glass
- Specific Defect Evaluation Lists
- Modern Applications and Case Studies

Glass Delamination

- ▶ HORST KOLLER
- What is delamination
- What is the route cause
- Contribution to delamination
- How to avoid
- How to control

Extractables from Glass

- ▶ DR CLAUDIA HEINL
- Glass types: Differences in composition
- Chemical and physical properties
- Potential Extractables & Leachables from glass
- Elemental Impurities acc. to ICH-Q3D

Risk Evaluation of Elemental Impurities from Glass

- ▶ DR JÖRG ZÜRCHER
- Risk evaluation of glass extractables
- Concepts to avoid extractables from glass

Glass Materials and Their Use in Packaging Systems: U.S. Regulatory Expectations

- ▶ DR CHARUDHARSHINI SRINIVASAN (TO BE CONFIRMED)
- Legal Basis
- Quality requirements for glass
- Demonstration of suitability

Glass Materials and Their Use in Packaging Systems: EU Regulatory Expectations

- ▶ DR KATRIN BUSS
- Legal Basis
- Quality requirements for glass
- Demonstration of suitability

Proposed Revisions to specific Tests in USP Chapter <660>

- ▶ DR HOLGER RÖHL
- The presentation exhibits an overview of the current status of the tests described in chapter USP<660> and the intended changes for the revised edition

Overview and developments in glass-related texts in the Ph. Eur.

- ▶ DR ELLEN PEL
- Update on Ph. Eur. activities related to Glass Containers for Pharmaceutical use
- Revision of General Chapter 3.2.1. Glass Containers for Pharmaceutical use

Different Glass Compositions for Pharmaceutical Primary Packaging – Latest developments

- ▶ DR BETTINE BOLTRES
- Chemical Challenges for Glass Formulations
- Examples of Enhanced Chemical Stability
- Challenges in the Regulatory Field

Real Time Packaging Pressure Monitoring

- ▶ DR HOLGER RÖHL
- Introduction to a system for measuring line pressure
- Understand the effect operational parameters have on line performance, improving efficiency, reducing wastage and minimizing downtime

Special Aspects in Development of Syringes made of Glass

- ▶ FRANK BAMBERG
- Drug-Contact
- Device-Functionality
- Container Closure Integrity
- Suitability for Processing

Control of Glass Particles: Examples of Testing and Thorough Root-Cause investigations

- ▶ DR OLIVER VALET
- Visible and Sub-visible particles root cause investigations
- Raman and LIBS investigations
- FPM glass suspect in a vial
- Pre-filled syringe washing optimization study

USP Summary: Next Steps

- ▶ DR BETTINE BOLTRES / DR MICHAEL EAKINS

Q & A panel session & Conference Concludes

Speakers

▶ FRANK BAMBERG

Roche, Basel, Switzerland

Frank is a Plastic Engineer by training and conducted his study at the University of Darmstadt in Germany. He holds a MBA in business sciences from the University Bern in Switzerland. Frank joined Roche in Oct 2011 and leads the Engineering Group Pre-Fillable Syringe. Prior to his time at Roche, Frank was 10 years with SCHOTT Switzerland as Head of Business Development and Customer Service Syringe.

▶ DR BETTINE BOLTRES

WestPharma, Eschweiler, Germany
Member of the General Chapters-Packaging and Distribution Expert Committee at USP, Co-Chair <660> Expert Panel

Bettine Boltres is a frequent speaker at industry conferences and has chaired, moderated, organized and held numerous technical training events, conferences and workshops. A number of articles for several global magazines have also been penned by her, as well as the book "When Glass Meets Pharma". She is actively working in the USP Expert Committee "Packaging and Distribution" as well as in the ISO committee TC76/WG4 on elastomeric parts. With her former work as Product Manager for SCHOTT Pharmaceutical Tubing and her current position as Technical Account Manager at West Pharmaceutical Systems she covers the broad spectrum of both glass and elastomeric parts of primary packaging materials. By profession she is a chemist with a PhD in biochemistry.

▶ ALFRED BREUNIG

NiproGlass, Münnerstadt, Germany

Alfred Breunig is the Director Technical Customer Support & Regulatory Affairs at Nipro Pharma Packaging Germany GmbH (NPG). NPG (former "MGlas AG") is a manufacturer of primary packaging materials made of tubular glass for the pharmaceutical industry. After heading the chemical-physical and microbiological laboratories from 1982 to 1990, he became the Quality Director. In 2004, he took over the newly created position of the Director Technical Customer Support & Regulatory Affairs.
He is Chairman of the Working Group "Quality Assurance for Primary Packaging Materials Made of Tubular Glass" in the BV Glas (association of the German glass industry). Furthermore, he is Chairman of the standardization committee NA 063-02-11 ("QM Systems for Primary Packaging Materials") at the German Institute for Standardization (DIN, Berlin) and member/expert of the standardization committees (DIN) NA 063-02-01 "Injection Systems", NA 063-02-03 "Infusion and Injection Containers Made of Tubular Glass" and NA 063-01-11 "Small Bore Connectors".

▶ DR KATRIN BUSS

Regulatory Expert, Bonn, Germany

Katrin Buss is a pharmacist and received her Ph. D. in Pharmaceutical Biology in 2000. She worked as a Scientific Project Manager at Memorec/ Miltenyi Biotech from 2001-2004. Since 2005 she is a Quality Assessor in the Biotech Unit at BfArM (Federal Institute for Drugs and Medical Devices, Germany).

▶ DR MICHAEL EAKINS

Co-Chair of <660> Expert Panel and Member of USP General Chapters – Packaging and Distribution Expert Committee, New Jersey, USA

Michael was Senior Director of Product Internationalization for Bracco S.p.A. responsible for the strategic development of new packaging within R&D and then Senior Director of the International Packaging Center for Corporate Worldwide Sales and Marketing. He was Co-Chair of the Parenteral Drug Association's (PDA) Glass Task Force on the Classification of Nonconformities in Molded and Tubular Glass Containers - published as PDA Technical Report 43 (2013). Michael has extensive experience in the packaging of drug products in glass vials and in glass and plastic prefilled syringes, the development of extractable and leachable (E&L) protocols including compliance with European and US regulations and pharmacopeias. In addition, Michael provides assistance in the investigation of glass defects and glass delamination. He is currently a member of the USP Packaging and Distribution Expert Committee for the 2015-2020 cycle, having been Vice-Chair of the USP Packaging, Storage and Distribution Expert Committee for the 2005-2010 and 2010-2015 cycles.

▶ DR CLAUDIA HEINL

Schott, Mitterteich, Germany

Claudia Heinl, Product Manager Pharmaceutical Tubing, SCHOTT AG, is a chemist by training and has obtained her PhD in Inorganic/Organometallic Chemistry at the University of Regensburg, Germany. In December 2015, she joined the Scientific Services and Product Management team of SCHOTT AG Tubing for providing global scientific support about glass. This primarily includes glass trainings for converters and pharmaceutical companies, fault analyses of defect samples as well as advice on specific regulations.

▶ HORST KOLLER

HK Packaging Consulting, Uznach, Switzerland

Prior to becoming a consultant, Horst Koller worked for Abbott Diagnostic and SCHOTT Pharmaceutical Packaging with a total of more than 20 years industry experience. His consulting company is focussing on Technical, Regulatory and QM Support around Primary and Secondary Packaging Systems including Medical Devices. He is an active member within the technical ISO Committees TC76 and TC84 as well as an active speaker on international conferences.

▶ VINCENT LANGLADE

SGD, France

Vincent Langlade is currently Marketing Director at SGD Pharma, a manufacturer of molded and tubular glass primary packaging. From 2002 to 2004, he was R&D Director at Rexam Pharma, from 1991 to 2002, he held several positions including Product Development, Quality Assurance and Regulatory Affairs at Aptar Stelmi, a supplier of primary packaging for parenteral products. He received his Chemical Engineering degree from Lyon University (France) in 1989 and his Master of Sciences in Polymers Science and Biotechnology from the Polytechnic School of Montreal (Canada) in 1991. He is a contributor to ISO TC76 committee and delivered numerous papers at PDA, Pharmapack, ISPE, A3P, PMP and AFI conferences. He acquired expertise of the global pharmaceutical market for sterile injectable drug products and, more

globally, for drug delivery systems (injectable forms, inhaled products, nasal, ophthalmic, solid forms). He experienced a FDA inspection (no 483) as well as an ANSM (French Drug Agency).

▶ DR ELLEN PEL
Ph. Eur., EDQM, Strasbourg, France

Ellen Pel is scientific officer to groups of experts in charge of the elaboration of European Pharmacopoeia texts related to containers for pharmaceutical use, antibiotics, radiopharmaceuticals, pesticides, medicinal gases and a number of general methods. Before joining the EDQM in 1996, she held an expert and a post-doctoral position at the Institute for Reference Materials and Measurements (IRMM), European Commission Joint Research Centre in Geel, Belgium. She obtained her degree in food chemistry from the Technical University of Karlsruhe, Germany and her PhD in the field of radiochemistry from the same university.

▶ DR HOLGER RÖHL
Roche, Basel, Switzerland
Member of <660> Expert Panel at USP

Holger Roehl, Ph.D. is Head of Primary Packaging Development at Roche. He holds a doctorate in Physical Chemistry, with a focus on surface analysis, from University of Siegen (Germany). He has worked at the Materials' Laboratory of IBM in Mainz, where he focused on surface analysis of hard disks by Mass Spectrometry (MS) during his doctorate. After successful completion of his studies, he went on to work for the German biotech company QIAGEN, where he specialized in the field of protein / peptide analysis by MS. In 2007, Holger joined SCHOTT Pharma Services as a scientific advisor, where he was responsible for performing studies on delamination, surface contamination, Extractables & Leachables, glass breakage and drug container interaction. Since 2012, he works at Roche where he manages a team responsible for all aspects related to the parenteral primary packaging components including vials, cartridges, ampoules, stoppers, and caps.

▶ DR CHARUDHARSHINI SRINIVASAN
Food and Drug Administration (FDA), USA

▶ DR OLIVER K. VALET
rap.ID Particle Systems GmbH, Berlin, Germany

Oliver Valet is one of the co-founders and Managing Directors of rap.ID Particle Systems GmbH, which develops, manufactures and sells rapid particle identification systems. In Europe, rap.ID operates as contract testing laboratory for FPM ID in parenteral drug products. rap.ID Inc. based in New Jersey, USA, has years of invaluable experience and knowledge, in regards to customized application development and analysis services. rap.ID's technology has combined particle isolation, imaging analysis and spectroscopic technologies, creating investigative tools for particle identification and characterization. Dr. Valet has extensive experience in foreign particulate matter testing and Root Cause investiga tion. He has also worked on the development of accurate and reproducible technologies for characterizing silicone oil layer thicknesses, and its distribution in parenteral packaging materials.

He has published his work continuously and presented on various conferences all throughout Europe and the USA.

▶ DR JÖRG ZÜRCHER
Bayer AG, Berlin, Germany
Chair of EDQM Working Party Glass

Dr Zürcher joined Schering (since 2007: Bayer AG) in 1990. Starting with systems for solid and semi-solid formulations his focus is now on the development of state-of-the-art container closure and application systems for liquid dosage forms, sterile products, inhalatives and ophthalmics.

Social Event

On 6 June 2018, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Easy Registration

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

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
http://glassmeetspharma.gmp-compliance.org/

Date

Wednesday, 6 June 2018, 9.00 h – 17.30 h
(Registration and coffee 8.00 h – 9.00 h)
Thursday, 7 June 2018, 8.30 h – 15:30 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10557 Berlin, Germany
Phone +49 (0) 30 21 27 0
Fax: +49 (0) 30 21 27 117
Email berlin@steigenberger.de

Fees (per delegate plus VAT)

ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
The conference fee is payable in advance after receipt of invoice and includes conference documentation, social event & dinner, lunch on both days, and all refreshments. VAT is reclaimable.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration

Via the attached reservation form, by e-mail or by fax message.
Or you register online at glassmeetspharma.gmp-compliance.org.

Conference language

The official conference language will be English.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0 | Fax +49 (0) 62 21/84 44 34
info@concept-heidelberg.de | www.concept-heidelberg.com

For questions regarding content:
Dr Andrea Kühn-Hebecker (Operations Director)
at +49-62 21/84 44 35, or per e-mail at kuehn@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Marion Weidemeier (Organisation Manager)
at +49-62 21/84 44 46,
or per e-mail at weidemeier@concept-heidelberg.de.

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You will receive a USB memo stick containing all the presentations when you register in Berlin.
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Reservation Form (Please complete in full)

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