

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



KEVIN MCLEAN
SGD, Member of <660> Expert Panel



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

Speakers from Industry



FRANK BAMBERG
Roche



ALFRED BREUNIG
Nipro



DR CLAUDIA HEINTZ
Schott



HORST KOLLER
HK Packaging



DR OLIVER VALET
Rap.ID



DANIELE ZUCCATO
ICG, Ompi



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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USP - Ph. Eur. - ECA Joint Conference

USP General Chapter <660> and <1660>:
new draft chapter proposals coming in 2019!



Free PDF-Download - exclusive for Participants:

- Defect Evaluation List for Containers made of Moulded Glass
 - Defect Evaluation List for Containers made of Tubular Glass
- Checklists and instructions for use in the testing of packaging material

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
- How to prevent breakage in filling lines using an innovative technology

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 glass related 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 breakage via new technologies in filling lines
- 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

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

Specific Aspects for Glass Containers made of Molded Glass

- ▶ KEVIN MCLEAN
- Overview of process and products for molded glass
- Overview of ISO Modifications in relation to molded glass
- Specific Defect Evaluation Lists
- Type II Glass: the other parenteral container

Glass Delamination

- ▶ HORST KOLLER
- What is delamination
- What is the root 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

Risk Evaluation of Elemental Impurities (EIs) from Glass

- ▶ DR JÖRG ZÜRCHER
- Elemental Impurities acc. to ICH-Q3D
- Risk evaluation
- Concepts to avoid extraction of EIs

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

- ▶ DR CHARUDHARSHINI SRINIVASAN
- 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

Control of breakage in filling lines by using an innovative pressure monitoring technology

- ▶ 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

ICG-TC12 advices for a proper autoclaving cycle to measure the hydrolytic resistance

- ▶ DANIELE ZUCCATO
- Hydrolytic resistance testing according to the Ph. Eur. and USP prescription: Differences in results due to the autoclaving cycle
- How to improve the reliability of compendial autoclaving testing
- Target: Produce a common document to be shared with Pharmacopoeia Authorities (E.U. and U.S.)

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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". In Addition, she is a member of the EDQM Working Party Glass. 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, Műnnerstadt, 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 pre-filled 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.

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► KEVIN MCLEAN

Member of <660> Expert Panel at USP, SGD Pharma Packaging, Inc., New York, USA



Kevin is Quality & Technical Manager, Americas, at SGD Pharma Packaging, Inc., a manufacturer of molded and tubular glass primary packaging. His responsibilities involve all five of SGD's plants located in France (2), Germany, China and India, and all of SGD's clients in North, Central and South America. He is a member of SGD's global Quality Management team and works in close support to the central office regulatory affairs department in France. Furthermore, Kevin is the primary FDA contact for SGD's DMF's. Kevin is a PDA member and was on the Task Force for Technical Report 43 (Glass Container Defects). Currently he is a member of the PDA Task Force on Visible Particles (Glass Containers Sub-Team). Other professional associations include the ISPE (International Society for Pharmaceutical Engineering), ASQ (American Society for Quality) and American Association of Pharmaceutical Scientists (AAPS).

► 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. Charudharshini Srinivasan is currently at the US-FDA, as a Research Scientist and a Reviewer in the Office of Testing and Research (OTR), Center for Drug Evaluation and Research (CDER). Her work focuses on regulatory research on parenteral formulations and packaging; use of PAT in lyophilization process understanding; evaluation of drug product quality and regu-

latory review. She currently serves as the government liaison to the USP Expert Committee -Glass Expert Panel. She is also the OTR representative for emerging technology program (ETT) at the agency for new packaging design for parenteral products.

► 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 investigation. 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.

► DANIELE ZUCCATO

ICG, Nuova Ompi, Piombino Dese, Padova, Italy



Daniele Zuccato achieved his Master Degree in Industrial Chemistry at Venice Cà' Foscari University in the framework of a collaboration project with the National Research Council Institute on the speciation of heavy metals in foodstuffs with HPLC-ICP-MS hyphenated techniques. In 2009, he joined the R&D Glass Division of the Stevanato Group as project leader of the investigation studies on the migration of trace elements from the glass surface, following and coordinating from the very beginning the startup of the SGLab and assuming the position of Core Team Leader, in charge of the physicochemical improvement of pharmaceutical glass primary packaging. Dr Zuccato is member of ISO TC76/WG2 and secretary/ member of TC 12 "Glasses for Pharma" of the International Commission on Glass (ICG).

► 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.

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 **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
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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.
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Conference language

The official conference language will be English.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event

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For questions regarding reservation, hotel, organisation etc.:
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or per e-mail at weidemeier@concept-heidelberg.de.

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