ECA Academy
Your GMP/GDP Information Source

Speakers

Dr Bettine Boltres
West Pharmaceutical Services, Germany

Dr Michael Eakins
Eakins & Associates, USA

Dr Matthew Hall
Corning, USA

Torsten Kneuss
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Kevin McLean
SGD, USA

Glass Packaging Systems

Current & Upcoming Requirements, Challenges and Solutions

Live Online Training on 1 February 2024

Highlights

- Fundamentals of Glass Production
- Implications of the New EU GMP Annex 1
- Compendial Update – What May Change
- Extractables & Leachables
- Delamination
- Glass Containers used in Combination Products

Free PDF-Download - exclusive for Participants:
- Defect Evaluation List for Containers made of Molded Glass
- Defect Evaluation List for Containers made of Tubular Glass

Objective

In this live online course, you will learn which requirements apply to primary glass packaging materials. You will get to know all aspects of the GMP manufacture of glass products (e.g., vials, bottles, syringes) that influence the quality of the final product. In addition, practice-oriented presentations and case studies will guide you through the relevant requirements for manufacture, controls and release of glass containers, including impact of the new EU GMP Annex 1 (e.g., for ready-to-use, ready-to-sterilize material).

Background

Glass materials used in pharmaceutical packaging systems must be suitable for the intended use. To address these issues, the pharmacopoeias (e.g., USP / Ph. Eur.) contain dedicated glass chapters providing specifications and quality requirements.
Following a recent FDA request to update the **Type I definition** from one that is composition-based to one that is performance-based (e.g. hydrolytic resistance), the USP is currently revising its general chapter <660> *Containers – Glass*. The request highlighted the FDA's concern about global issues regarding glass production and resulting drug shortages.

Glass is not fully inert. Therefore, in addition to the glass surface tests, Extractables & Leachables have to be considered.
Furthermore, in the last number of years, delamination 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.

In addition, new GMP requirements for the sterile packaging material apply with the revised **EU GMP Annex 1 entitled "Manufacture of Sterile Medicinal Products"**, which provides guidance on the approaches to sterilization of products, equipment and **packaging components**.

> Annex 1, Scope
> The manufacture of sterile products covers a wide range of sterile product types (active substance, excipient, **primary packaging material** and finished dosage form).

This event will therefore deal with the current discussions and trends regarding pharmaceutical glass packaging materials.

Target Audience

This online event is designed for employees working in the pharmaceutical industry (including drug device combination products), for suppliers of packaging materials & devices and to all who have to deal with the manufacture, control and release of primary glass packaging materials.

Programme

Fundamentals of Tubing and Container Production

- Basics of how tubular glass containers are produced
- Fundamental knowledge
- Challenges occurring with tubular glass containers

Fundamentals of Molded Glass Production

- Basics of how molded glass containers are produced
- Fundamental knowledge
- Challenges occurring with molded glass containers

Sterile Glass Containers & EU GMP Annex I Requirements

- Annex I and Sterile primary packaging components
- Packaging suppliers are expected to follow the basic Annex I requirements
- How sterile glass container manufacturers are addressing the respective applicable topics to help customers becoming or staying compliant with EU GMP Annex I

Q&A Session 1

USP Update – What May Change

- USP General Chapter <660> *Containers - Glass*
- USP General Information Chapter <1660> *Evaluation of the Inner Surface Durability of Glass Containers*
- Upcoming major revision to the 2 glass chapters to allow the addition of both modern analytical technologies and additional glass formulations now being used to produce pharmaceutical glass containers
- Discussion of the progress made in updating the analytical methods that are used to ensure the quality of glass containers, and how new glass formulations could be added to the USP's glass chapters

Extractables & Leachables / Delamination

- Brief review of mechanisms by which drug products interact with glass containers
- Implications of extractables & leachables for the safety and efficacy of parenteral drug products
- Brief review of glass delamination and a discussion of factors that can impact the propensity for delamination

Requirements for Glass Containers used in Combination Products

- Introduction to Combination Products
- Regulatory Requirements for Combination Products
- Applicable Standards and Regulations for Glass Containers (e.g. syringes)
- Requirements related to manufacturers of Glass Containers

Q&A Session 2

Speakers

Dr Bettine Boltres
West Pharmaceutical Services, Germany

As Director Scientific Affairs & Technical Solutions, Glass Systems, Bettine is supporting the scientific exchange between West and the pharmaceutical industry. This is complementing her work as Product Manager for Schott Pharmaceutical Tubing, where she provided scientific consulting for glass primary packaging. Bettine is member of the USP PDEC as well as the Ph. Eur. Group of Experts 16 and the Glass Working Party and convenor of the ISO TC76/WG 4 and member of WG 2.

Dr Michael Eakins
Eakins & Associates, USA

Michael is President and Principal Consultant at Eakins & Associates having held senior positions at Bracco S.p.A. and Bristol Myers Squibb. Eakins & Associates is a consulting company specializing in pharmaceutical primary packaging, especially glass defects, extractables & leachables from packaging components and single use systems. He has been a member of the USP Packaging and Distribution Expert Committee since 2005 with 15 years as Vice-Chair including for the 2020 – 2025 cycle.

Dr Matthew Hall
Corning, USA

Matthew is Technical Affairs Director for Corning Pharmaceutical Technologies (CPT), a supplier of pharmaceutical glass tubing and containers for parenteral packaging. Prior to joining CPT in 2019, Matthew was a faculty member in the glass and biomaterials programs of the Kazuo Inamori School of Engineering at Alfred University for 14 years.

Torsten Kneuss
Bayer, Germany

Torsten has been working since 1999 with pharmaceutical packaging materials, medical devices and combination products, including several years within the field of quality control, development, operations, and pharmacovigilance. Since October 2020 he is, as a Quality Product Steward Medical Devices and Head of Project Office Medical Devices, responsible for devices and combination products within Bayer.

Kevin McLean
SGD, USA

Kevin is Quality & Technical Manager at SGD Pharma. His experience and expertise is in Glass Pharma Packaging & High Performance Polymers. Kevin's current responsibilities are to provide technical and regulatory support during early phase development, and extend through post-approval technical and product quality support.

Your Benefits

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...". This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

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Reservation Form (Please complete in full)

Live Online Training: Glass Packaging Systems, 1 February 2024

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

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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)! (As of July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.

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Date of Live Online Training

Thursday, 1 February 2024,
9.00 h – 17.00 h CET

Technical Requirements

We use Webex for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 1,090
APIC Members € 1,140
Non-ECA Members € 1,190
EU GMP Inspectorates € 595

The conference fee is payable in advance after receipt of invoice.

Registration

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

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

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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