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Plastic/Elastomeric Materials for Pharmaceutical Packaging & Production

25/26 September 2019, Barcelona, Spain

Revised USP General Chapters for Plastic Materials and for Elastomeric Closures have been published for Comment!

SPEAKERS

Dr Lars Albermann, Merck, Germany
Senior Regulatory Affairs Manager – Pharma and Food Materials

Dr Bettine Boltres, West, Germany
Principal Scientific Affairs, Member of USP Packaging Expert Committee

Dr Renaud Janssen, Datwyler, Belgium
Head of Regulatory Affairs and Chemical Compliance, Member of USP Packaging Expert Committee

Torsten Kneuss, Bayer, Germany
Quality Manager Combination Products

Horst Koller, HK Packaging, Switzerland
Consultant, Member of Ph. Eur. Packaging Expert Groups at the EDQM

Dr Frank De Smedt, Nelson Labs, Belgium
Director Lab Operations

Dr Ingo Thorwest, Boehringer Ingelheim, Germany
HP Supply

Dr Claudia Vincenzi, EMA, London/Amsterdam
Scientific Specialist -Quality- at European Medicine Agency

HIGHLIGHTS:

- Manufacturing of Plastic/Elastomeric Materials
- U.S., E.U. and Chinese Regulatory Requirements
- Risk-based Supplier Qualification
- Additives
- Extractables & Leachables
- Plastic/Elastomeric Materials used in Manufacturing
- Quality Control (Sampling plans, AQLs and DELs)
- Child-Resistant Packaging

Free PDF-Download - exclusive for Participants
Defect Evaluation List for Rubber Parts, New Edition 2019! Checklists and instructions for use in the testing of packaging material

This conference is recognised for the ECA GMP Certification Programme „Certified Packaging Manager". Please find details at www.gmp-certification.eu

Objectives

This conference deals with the development, manufacture, use and control of plastic/ elastomeric materials for medicinal products, medical devices & combination products and for use in manufacturing. The conference gives you an update on the U.S., E.U. and Chinese regulatory requirements and shows you how these requirements can be put into practice. One of the focus topics is the use of additives as well as their testing and assessment by means of extractables/leachables studies. You also get the latest information on child-resistant packaging. And the conference subjects are rounded off from a GMP compliance point of view with the topics testing of plastic/elastomeric materials and handling of plastic/elastomeric materials during manufacturing.

Background

European Requirements on the development, testing and registration of plastic materials can among others be found in the EMA „Guideline on Plastic Immediate Packaging Materials". **U.S. requirements** are laid down in the FDA Guidance for Industry „Container Closure Systems for Packaging Human Drugs and Biologics". In Addition, since reforms of the existing **Chinese regulations** started as from mid 2016 on, it has become a really hot topic for pharma industry.

The **EMA guideline** covers the specific requirements (data to be submitted) for plastic packaging materials intended to be in direct contact with the medicinal product or the API. The guideline has to be applied in new registration applications or in variation applications. However, the guideline does not cover requirements for elastomeric components. In Addition, the EU regulation 10/2011 on plastic materials and articles intended to come into contact with food also deals with plastic materials but not with elastomeric materials.

According to the **FDA guideline**, each application should contain enough information to show that each proposed container closure system and its components are suitable for its intended use. This includes:

- Protection (light exposure, oxygen, moisture permeation, leakage)
- Compatibility
- Safety (extraction/toxicological evaluation studies)
- Performance (container closure system functionality, drug delivery)

Today, new requirements are coming up, since there are currently many medical devices and combination products (e.g. pre-filled syringes) on the market. These devices sometimes contain materials currently not monographed by the pharmacopoeias (for example **COC and COP**). And: Are there any requirement for plastic materials (e.g. tubes) **used in the manufacture** of pharmaceutical drug products and biopharmaceuticals? This conference presents updates on the regulatory requirements on these materials. There are currently a lot of pharmacopoeial changes/developments going on, e.g. recent drafts for **USP** General Chapters:

- *<381> Elastomeric Closures for Injections (proposed new title: ELASTOMERIC COMPONENTS IN INJECTABLE PHARMACEUTICAL PRODUCT PACKAGING/DELIVERY SYSTEMS),*
- *<382> Elastomeric Component Functional Suitability in Parenteral Products Packaging /Delivery Systems,*
- *<1381> Assessment of Elastomeric Components Used in Injectable Pharmaceutical Product Packaging/Delivery Systems,*
- *<1382> Assessment of Elastomeric Component Functional Suitability in Parenteral Products Packaging /Delivery Systems.*

These 4 chapters were published in Pharmacopeial Forum (PF) 43(3) [May–Jun. 2017]. Revised drafts have recently been pre-published on the USP website. According to the USP, the proposed revisions will be published in Pharmacopeial Forum (PF) 45(4) [Jul.–Aug. 2019]. The objective of this pre-posting is to give stakeholders sufficient time to review the proposals and comment by September 30, 2019. In the absence of any adverse comments the chapters are anticipated to be published in USP 43-NF 38, Second Supplement (the targeted official date is December 1, 2020).

In a recent issue of Pharmacopeial Forum (PF 45(2) [March–April 2019]) the following general chapter have been re-published for comment

- *<661> Plastic Packaging Systems and Their Materials of Construction,*
- *<661.1> Plastic Materials Of Construction,*
- *<661.2> Plastic Packaging Systems for Pharmaceutical Use,*
- *<1661> Evaluation of Plastic Packaging Systems and Their Materials of Construction With Respect to Their User Safety Impact,*
- *<665> Plastic Materials, Components, and Systems **Used in the Manufacturing** of Pharmaceutical Drug Products and Biopharmaceutical Drug Substances and Products,*
- *<1665> Characterization of Plastic Materials, Components, and Systems **Used in the Manufacturing** of Pharmaceutical Drug Products and Biopharmaceutical Drug Substances and Products.*

According to the new draft for <661.1> "it is being left up to the material user to evaluate the need for extractable elements testing and, if such testing is necessary, to establish and justify the means by which testing is accomplished".

Furthermore Ph. Eur. Draft Chapters on "new" plastic/ elastomeric materials like, for example, COC/ COP (Cyclo-olefin Polymer) and SBC are expected to be published soon:

- 3.1.17 Cyclo-olefin copolymers (COC),
- 3.1.18 Styrene block copolymers (SBC) for containers and closures for parenteral and ophthalmic preparations.

This conference provides an excellent forum to discuss open questions regarding the ongoing developments directly with speakers from industry, regulators and members of the pharmacopoeial expert working groups!

Target Audience

The conference is especially designed for members of staff and executives from the pharmaceutical industry working in the field of research and development, regulatory affairs, quality control, incoming goods control of packaging materials, quality assurance, production and packaging. It is also directed at employees of suppliers and/or manufacturers of plastic/elastomeric (packaging) materials for the pharmaceutical industry.

Programme

Introduction into Plastic and Elastomeric Materials and Manufacturing of Elastomeric Materials
- Scientific Background of plastics and elastomers
- Relevant physical properties and their impact on product quality
- Overview of manufacturing process for elastomers

U.S. Regulatory Requirements for Plastic/ Elastomeric Materials
- General regulatory requirements
- FDA Guidance on Container Closure Systems
- Update of Compendial Standards: relevant USP General Chapter

E.U. Regulatory Requirements for Plastic/ Elastomeric Materials
- General regulatory requirements
- EMA Guideline on plastic immediate packaging materials
- Update of Compendial Standards: relevant Ph. Eur. General Chapter

Chinese Regulatory Requirements for Plastic/ Elastomeric Materials
- Update on Chinese regulations started as from mid 2016 on

Specific Requirements for Plastic/ Elastomeric Materials
- When is a material of pharmacopoeial quality?
- Material selection criteria
- Material properties and design
- Example: Prefilled plastic syringes made of COC and COP

Polymer Additives in Plastic / Elastomeric Materials
- Types of additives
- Their mode of action
- Use
- Function
- Physical Behaviour

USP <665>: Polymeric components and systems used in the manufacturing of pharmaceutical and biopharmaceutical drug products
- Drivers for Innovative Manufacturing
- Risk Assessment for Manufacturing Systems
- USP <665>
- Our Strategy

Supplier Qualification – A Risk based Approach
- Quality agreement
- Supplier review
- Applicable standards
- Risk-based qualification

Extractables / Leachables (E&Ls)
- Regulatory Requirements
- When is Extractable testing necessary?
- Best Practices for E&L testing
- Which components could be potential E&Ls?
- Case Study

Manufacturing of Plastic Materials (and Handling in the Warehouse)
- Storage
- Processing
- IPC and Reconciliation
- Shopfloor requirements
- Blister integrity testing

Quality Control of Plastic/ Elastomeric Materials
- Specifications
- Sampling plans, AQLs (Acceptable Quality Levels) and DELs (Defect Evaluation Lists)
- Common test methods
- Challenges

Child-resistant Packaging
- Definition
- Testing procedures
- Child resistance vs. Senior friendliness
- Examples

Moderator

Dr Bettine Boltres

Speakers

Dr Lars Albermann, Merck, Germany
Senior Regulatory Affairs Manager – Pharma and Food Materials

Lars is responsible for a group of regulatory experts at Merck Life Science. The team works on regulatory topics on a global level relevant for the entire product portfolio of materials used in pharma and food production.

Dr Bettine Boltres, West, Germany
Principal Scientific Affairs, Packaging & Delivery Systems, Member of USP Packaging Expert Committee, Member of EP CGE 16

Bettine is supporting the scientific exchange between West and the pharmaceutical industry. This is complementing her 7 years' work as Product Manager for Schott Pharmaceutical Tubing, where she provided scientific consulting for glass primary packaging. Since 2015 Bettine is an active member of the USP Packaging and Distribution Expert Committee as well as the ISO TC76/WG 4 on elastomers. Additionally, in 2018, she joined the European Pharmacopoeia Commission Group of Experts 16 (elastomers and plastics) and the GLS Working Party (glass). Since January 2019 she is also a member of the PDA Board of Directors.

Dr Renaud Janssen, Datwyler, Belgium
Head of Regulatory Affairs and Chemical Compliance, Member of USP Packaging Expert Committee, Member of EP CGE 16

For over 30 years Renaud has been holding R&D, Technical Support and Quality functions at Datwyler Pharma Packaging where he currently acts as Head of Regulatory Affairs and Chemical Compliance. Renaud is a member of various standardization committees and task forces in the field of pharmaceutical rubber. Currently he is member of the USP <381> revision Expert Panel and of the USP Packaging & Distribution Committee for the 2015-2020 cycle.

Torsten Kneuss, Bayer, Germany

Quality Manager Combination Products

Torsten studied Business Administration and Engineering. Since 1999 he has been working with pharmaceutical packaging materials, medical devices and combination products, including several years within the field of quality control, development, operations, and pharmacovigilance. Since November 2017 he is, as a Quality Manager Combination Products, responsible for devices and combination products within Bayer AG.

Horst Koller, HK Packaging, Switzerland

Consultant, Member of EP CGE 16

Prior to becoming a consultant, Horst 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.

Dr Frank De Smedt, Nelson Labs, Belgium

Director Lab Operations

Frank has a PhD in chemistry from the Katholieke Universiteit Leuven. He is the department supervisor of the physicochemistry department of Toxikon Europe nv (a.o. Extractables and Leachables Testing). He is also responsible for Method Developments and Validations for all analytical methods implemented in the analytical laboratory.

Dr Ingo Thorwest, Boehringer Ingelheim, Germany

HP Supply

Ingo has a Process Engineering background and is with Boehringer Ingelheim Corporation since 1992. He had managing positions at various sites in Project Engineering, Packaging Process Engineering and Pharmaceutical Production and is currently head of Global Maintenance for Human Pharma business units in Ingelheim.

Dr Claudia Vincenzi, EMA, London/Amsterdam

Scientific Specialist -Quality- at European Medicine Agency

Claudia is an experienced Regulatory CMC Quality Specialist with a demonstrated history of working in Regulatory Agencies (MHRA and EMA) and industry (Mylan). She is skilled in the preparation and critical review of the Module 3 (CTD), including its components, and quality overall summary for all stages of the lifecycle of a pharmaceutical product. In addition, she works on scientific advice procedures, guidelines and supports the formulation working group.

Social Event

In the evening of the first conference day, 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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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.

We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

*Please note: You may have to enable pop-ups on the Mobility Partner Program website – other-wise the booking platform window will not open.

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:
www.gmp-compliance.org

Date
Wednesday, 25 September 2019, 9.00 to approx. 17.30 h
(Registration and coffee 8.30 to 9.00 h)
Thursday, 26 September 2019, 8.30 to approx. 13.30 h

Venue
Barcelo Sants Hotel
Pl. Països Catalans, s/n
08014 Barcelona, Spain
Phone +34 93 503 53 00
Email sants@barcelo.com

Fees (per delegate plus VAT)
ECA Members € 1.690
APIC Members € 1.790
Non-ECA Members € 1.890
EU GMP Inspectorates € 945
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, 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/POG when you have registered for the event. Reservations should be made directly with the hotel. Early reservation is recommended.

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
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For questions regarding content please contact:
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. please contact:
Ms Julia Grimmer (Organisation Manager) at +49(0)62 21/84 44 44 or per e-mail at grimmer@concept-heidelberg.de.

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Reservation Form (Please complete in full)

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Plastic/Elastomeric Materials for Pharmaceutical Packaging & Production
25/26 September 2019, Barcelona, Spain

☐ Mr ☐ Ms

Title, first name, surname

Company

Department

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

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City Zip Code

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1. We are happy to welcome a substitute colleague at any time.
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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 January 2012). German law shall apply. Court of jurisdiction is Heidelberg.

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