ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Packaging Manager

Speakers

Dr Katrin Buss (invited)
Quality Assessor, Germany

Jean-François Decoster
UCB Pharma, Belgium

Peter Huonker
FRÜH, Switzerland

Dr Deolinda Izumida Martins
West Pharmaceutical Services, Germany

Dr Gerald Kindermann
Capgemini Engineering, Switzerland

Torsten Kneuss
Bayer, Germany

Horst Koller
HK Packaging, Switzerland

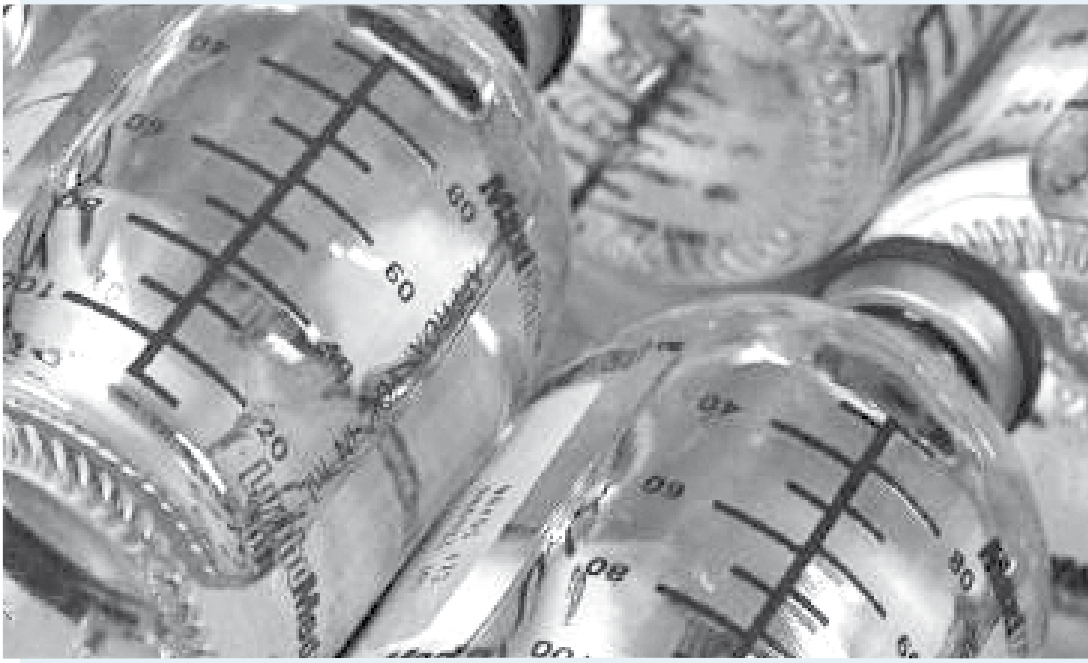
Dieter Mößner
Packaging Expert, Germany

Pharmaceutical Packaging Systems

Development & Quality Control

Part 1: Pharmaceutical Packaging Systems - **Development**
29/30 November 2022 | Live Online Training

Part 2: Pharmaceutical Packaging Systems - **Quality Control**
30 November - 1 December 2022 | Live Online Training



Highlights

- Regulatory Requirements & Compendial Standards:
  - EU
  - USA
- Sterile Packaging Material
- Container Closure Integrity (CCI)
- Packaging and the Common Technical Document (CTD)
- Specifications for Container Closure Systems
- Combination Products & Medical Devices
- Extractables & Leachables
- Application of AQLs & Defect Evaluation Lists
- Control of Packaging Material
  - Primary
  - Secondary
- Supplier Management
- Reduced Testing / Reduced Sampling

With Case Study on Reduced Testing / Reduced Sampling!

Programme

Objectives

The focus of these 2 GMP Education Courses is on the development and routine control of pharmaceutical packaging systems.

In Course 1 participants will learn how to develop pharmaceutical packaging materials systematically, and how to translate the requirements of the Common Technical Document (CTD) to regulatory documents for packaging materials. Topics to be addressed include compendial standards, container closure integrity, and combination products.

Course 2 will focus on the testing of a variety of different packaging materials, as carried out in every incoming-goods laboratory in quality control. This includes the setting of sound and scientific specifications and Acceptable Quality Levels (AQLs), the control of dimensions, and the control of primary and secondary packaging materials.

Background

There are a great number of regulatory requirements on pharmaceutical packaging materials, in the pharmacopoeias, the GMP regulations, in the FDA guidances, etc. Packaging materials also have to be described in the registration process of a drug product according to the requirements of the CTD.

The development of pharmaceutical packaging systems is an increasingly complex topic, which is reflected in the most recent requirements for combination products and sterile packaging materials (Annex 1 of the EU GMP Guide). To cover all relevant aspects a thorough target product profile needs to be set up. Not only regulatory requirements drive container closure system development, but also current challenges such as package integrity, glass delamination and particles on ready-to-sterilize (RTS) and ready-to-use (RTU) components.

Furthermore, the pharmaceutical manufacturer has to guarantee that only such packaging materials are used that are correctly printed on, 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, **Defect Evaluation Lists** have proved efficient. The responsibility for the tests lies now more and more with the manufacturers of packaging materials, while the pharmaceutical industry tries to reduce testing & sampling at the same time. However, as a precondition for this, additional QA measures, like supplier qualification, audits and supply agreements, have to be taken.

Target Audience

These GMP Education Courses are designed for employees working in pharmaceutical research and development, regulatory affairs, quality control, incoming goods control of packaging materials, and quality assurance departments. They are also directed at employees of suppliers of primary and secondary packaging materials for the pharmaceutical industry.

Course 1: Pharmaceutical Packaging Systems - Development

Day 1

Regulatory Framework applicable to Pharmaceutical Packaging Materials

- Code of Federal Regulations (CFR)
- US Guidance for Industry: Container Closure Systems
- EU Guidance on Plastic Immediate Packaging Materials
- Compendial Standards (USP, Ph. Eur., JP)

Packaging Related Topics of the Common Technical Document (CTD)

- CTD structure (packaging related)
- Quality of components and materials
- Declaration of compliance
- Information to be provided in the dossier

Specific Aspects for Glass Materials

- Ph. Eur. / USP
- Extractable Elements
- Sterilization
- Critical parameters

Q&A Session 1

Specific Aspects for Plastic Materials

- Ph. Eur. / USP
- Extractable Elements
- Sterilization
- Critical parameters

Specific Aspects for Elastomeric Materials

- Material background
- Compendial compliance
- Formulations and extractable elements
- Sterilization
- Critical parameters

Extractables & Leachables

- Regulatory background
- Principles of extractable and leachable testing
- Potential extractables & leachables
- Case Studies

Q&A Session 2

Day 2

Regulatory Expectations on Drug / Device Combinations

- Medicinal products vs. medical devices
- Legal requirements and scientific guidelines
- Medicinal products with medical device part

Development of Drug/Device Combination Products

- Regulatory Background
- Design Control
- Usability
- Risk management

Container Closure Integrity (CCI)

- Definition (Leakage)
- Test methods
- USP <1207>
- Challenges & Solutions

Q&A Session 3

Course 2: Pharmaceutical Packaging Systems - Quality Control

Day 1

Defect Evaluation Lists

- Principles for the Defect Evaluation Lists (DELs)
- Application of AQLs (Acceptable Quality Levels)
- Examples for Containers made of moulded and tubular glass

Control of Printed Packaging Materials

- Defect Evaluation Lists for Secondary Packaging Materials
- Printing, Coding & Artwork
- Serialization & Tamper Evidence
- Defect classes and (100%) test procedures (Examples)

Technical Specifications

- Scope & content
- Concept (proposal)
- Defect classes and selected test procedures (Example)

Shelf-life of Packaging Components

- Why is a defined shelf-life required?
- How to define the shelf-life for packaging components?
- Re-Testing of packaging components

Q&A Session 1

Day 2

Qualification of Analytical Instruments used for Packaging Control

- Important points for qualification (IQ/OQ/PQ)
- Software validation
- Examples (e.g. tensile testing)

Control of Primary Packaging Materials - Examples for Pouches and Blisters

- Overview of the development / production of pouches / blisters
- Control of process parameters / products during production (IPC)
- Control of final products

Supplier Management

- Applicable GMP standards for packaging suppliers
- Selection of suppliers
- Technical agreements, supplier qualification and audits
- Continuous supplier evaluation

Q&A Session 2

Risk Based Inspections of Packaging Materials

- How to set up a control system for packaging materials
- Practical application of FMEA
- What, why, and how to test
- Strategies for reduced testing

Case Study on Reduced Testing / Reduced Sampling:

- Inspection Procedures for Primary and Secondary Packaging Materials

Q&A Session 3

Speakers

Dr Katrin Buss, Quality Assessor, Bonn, Germany (invited)
Katrin Buss is a pharmacist and worked from 2001-2004 as Scientific Project Manager at Memorec/ Miltenyi Biotec. Since 2005 she is quality assessor in the department "Pharmaceutical Biotechnology" at the BfArM. She is member of the ICH Q3E EWG on Assessment and Control of Extractables and Leachables.

Jean-François Decoster, UCB, Belgium
After 5 years of experience with Eli Lilly & Co in Packaging Development, Jean-François joined UCB in 2005 where he took increasing responsibilities in Primary Packaging Development. He was Head of Primary Packaging Development and Director & Head of Devices & Delivery Systems Science. Currently he is Agile Quality Lead at UCB.

Peter Huonker, FRÜH, Switzerland
Peter was a Microbiology Lab Supervisor at Zimmer GmbH, responsible for sterilization processes, among other things. Since the beginning of 2018, he has been Head of Quality Management at Früh Verpackungstechnik AG. Among other things, he is responsible for deviations, complaints, CAPA, Change Control, Environmental Monitoring, internal and external audits for medical products and packaging processes.

Dr Deolinda Izumida Martins, West Pharmaceutical Services, Germany
Deolinda has been working as Technical Account Manager at West since 2014. She graduated in Pharmacy, has a Master of Sciences in Toxicology and a Ph.D. in Public Health. Deolinda is experienced in technical consulting services with a demonstrated history of working in the pharmaceuticals industry and a scientific background in pharma primary packaging, analytical chemistry and toxicology.

Dr Gerald Kindermann, Capgemini Engineering, Switzerland
From 2001 to 2003 Gerald led the group for the control of incoming packaging materials where he was responsible for release analysis of packaging materials at Roche and the technical control of all packaging materials. After that he was responsible for packaging materials as Quality Manager. In 2008 he joined the Global Quality group at Roche. Since 2019 he is working as Senior Pharma Consultant.

Torsten Kneuss, Bayer AG, Berlin, Germany
Torsten Kneuss 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.

Horst Koller, HK Packaging, Switzerland
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 focusing 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.

Dieter Mößner, Packaging Expert, Essingen, Germany
Dieter is working as a Global Key Account Manager at a leading German manufacturer of packaging machines. Before that he was working as Project Engineer Pharma and Key Account Manager at a leading manufacturer of folding boxes and package leaflets for the pharmaceutical and cosmetics industries. Dieter had led projects in Braille application, serialization, tamper evidence and anti-counterfeiting of pharma and consumer goods packaging.

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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Live Online Training Courses

☐ Part 1: Pharmaceutical Packaging Systems - Development (29/30 November 2022)
☐ Part 2: Pharmaceutical Packaging Systems - Quality Control (30 November - 1 December 2022)

Title, first name, surname

Department | Company

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

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

General terms and conditions
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 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.
If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERGwill not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.
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.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date of the Live Online Training Courses

Part 1: Pharmaceutical Packaging Systems - Development
Tuesday, 29 November 2022, 09.00 h - 17.00 h CET
Wednesday, 30 November 2022, 09.00 h - 12.30 h CET

Part 2: Pharmaceutical Packaging Systems - Quality Control
Wednesday, 30 November 2022, 13.30 h - 17. 30 h CET
Thursday, 1 December 2022, 09.00 h – 15.30 h CET

Technical Requirements

We use Webex Events for our live online training courses and webinars. At https://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)

Part 1: Pharmaceutical Packaging Systems - Development
ECA Members € 1,290 Non-ECA Members € 1,490
APIC Members € 1,390 EU GMP Inspectorates € 745
The conference fee is payable in advance after receipt of invoice.

Part 2: Pharmaceutical Packaging Systems - Development
ECA Members € 1,290 Non-ECA Members € 1,490
APIC Members € 1,390 EU GMP Inspectorates € 745
The conference fee is payable in advance after receipt of invoice.

Save money and book both online courses:

ECA Members € 2,180 Non-ECA Members € 2,580
APIC Members € 2,380 EU GMP Inspectorates € 1,290
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.

Ordering Recordings

Independent from the Live Online Training Courses, you can also order recordings of selected Live Online Training Courses at the same conditions – at www.gmp-compliance.org/recordings. These recordings will be provided on our media server. All you need to watch it is an Internet browser – no additional software.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this Live Online Training:
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