

Speakers



Jean-Francois Decoster
UCB Pharma, Belgium



Sandra Hafner
AbbVie Deutschland, Germany



Dr Gerald Kindermann
formerly F. Hoffmann-La Roche,
Switzerland



Torsten Kneuss
Bayer, Germany



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



Dr Jörg Zürcher
Chair of EDQM WP Glass
Bayer, Germany

Pharmaceutical Packaging Systems

Development & Quality Control

Part 1: Pharmaceutical Packaging Systems - Development

18/19 February 2020 | Budapest, Hungary

Part 2: Pharmaceutical Packaging Systems - Quality Control

19/20 February 2020 | Budapest, Hungary



Highlights

- Regulatory Requirements & Update of Compendial Standards:
 - EU
 - USA
- Glass Delamination
- Container Closure Integrity (CCI)
- Packaging and the Common Technical Document (CTD)
- Development of Specifications for Container Closure Systems
- Combination Products & Update on Medical Devices
- How to Define the Shelf-life for Packaging Components?
- Extractables/Leachables
- Application of AQL & Defect Evaluation Lists
- Risk-based QC System for Packaging Materials
- Control of Packaging Material
 - Primary
 - Secondary
- Supplier Management
- Dimensional Checks

Objective

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 is 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. To cover all relevant aspects a thorough target product profile needs to be set up. Not only regulatory requirements drive container closure system development, also current hot topics such as container closure integrity and glass delamination need to be considered as well.

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, the "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 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.

Programme

Part 1: Pharmaceutical Packaging Systems - Development

Regulatory Requirements applicable to Pharmaceutical Packaging Materials

- Code of Federal Regulations (CFR)
- US Guidance for Industry: Container Closure Systems
- EC Guidance: Plastic Immediate Packaging Materials

Glass Delamination

- What is delamination
- What is the root cause
- Contribution to delamination
- How to avoid
- How to control

Container Closure Integrity (CCI)

- Definition (Leakage)
- Test methods
- USP <1207>

Update of Compendial Standards

- USP E&L <1663>, <1664>
- Glass delamination – USP, Ph.Eur.
- Rubber section JP, Elastomers USP <381>
- Ph.Eur. plastic materials, USP <661>, <665>

Packaging Related Topics of the Common Technical Document (CTD)

- CTD structure (packaging related)
- Translation of CTD requirements to Technical Regulatory Documents (TRD)
- Best practice (blister and infusion bottle)

Development of Specifications for Container Closure Systems

- Transforming a wish-list into a target profile
- Conversion of a target profile into a specification
- Critical parameters / acceptance criteria

Combination Products

- Definitions and regulations
- Development process
- Documentation

Update on Medical Devices and Drug-Device Combination Products/Medical Devices

- New EU regulation on Medical Devices and how to be prepared
- Other upcoming regulations and guidances for combination products

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

Extractables/Leachables

- Regulatory background
- Principles of extractable and leachable testing
- Potential extractables of different container materials
- PQRI initiative on parenteral & ophthalmics
- ICH genotoxic impurities vs. leachables values

End of Course 1 / Registration for Course 2

Part 2: Pharmaceutical Packaging Systems - Quality Control

Defect Evaluation Lists

- Manufacturing of moulded and tubular glass containers
- Application of AQL (Acceptable Quality Level) Concept
- Concept of Defect Evaluation List
- Special Defect Evaluation Lists: Containers made of moulded and tubular glass

Control of Printed Packaging Materials

- Legal requirements
- Level of certification
- Sample size & test procedures
- Reference samples vs. retention samples (Annex 19)



WORKSHOP I

Examples of Defective Glass Packaging Materials

The aim of this workshop is to discuss in small discussion groups the evaluation of some defective packaging materials that are presented. Are the defects of these packaging materials critical or non-critical? Has the lot to be rejected or can it still be used?

Participants will learn how to apply the general recommendations of accepted and published Defect Evaluation Lists for specific and individual packaging materials.

Moderator: Torsten Kneuss

Calibration/Qualification/Validation

- Definitions
- Regulatory requirements
- Equipment lifecycle qualification for the control of packaging materials
- Process validation

Quality Control of Primary Packaging Material

- What is a suitable QC system for Primary Packaging Materials
- Definition of critical parameters
- Best practice in testing
- AQL-testing, skip lot
- Must to have QA systems (i.e. OOS, complaints)
- Sample management incl. reference samples

Supplier Management

- Supplier qualification and audits
- Supply agreements and supplier qualification
- Quality standards for suppliers
- Cascade of Quality Control, reduced testing
- Sampling plans



WORKSHOP II

Risk Management (Focus: FMEA)

The aim of this workshop is to define in small discussion groups the critical/major parameters to build up a suitable quality control system for your packaging materials. Focus will be on the practical application in a FMEA. The groups will evaluate

- What, why, and where to test
- Value of FMEA in the Quality Control concept for packaging materials
- Strategies for reduced testing

Moderator: Dr Gerald Kindermann

Dimensional Checks in Packaging Development and Quality Control

- Measurement equipment: overview
- Application ranges
- Practical examples

Technical Specifications

- Scope & content
- Concept (proposal)
- Template and practical example

Speakers

Jean-Francois Decoster
UCB Pharma SA, Belgium

Jean-Francois Decoster holds a Master Degree in Chemical Engineering from the Brussels Industrial Superior School. After 5 years of experience with Eli Lilly & Co in Packaging Development, he joined UCB in 2005 where he took increasing responsibilities in Primary Packaging Development. Since 2010, he has been the Head of Primary Packaging Development for UCB. Currently he is Director & Head of Packaging Development & Industrialization.

Sandra Hafner
AbbVie Deutschland GmbH & Co. KG, Ludwigshafen, Germany

Sandra Hafner studied pharmacy at the Johannes-Gutenberg-University in Mainz and joined AbbVie Deutschland GmbH in 2012 as Qualified Person (QP) Trainee in R&D Quality Assurance. From 2014 to 2018 Sandra was responsible as QP in R&D QA. Since 2018 she is Head of Production for IMP Packaging/Labelling.

Dr Gerald Kindermann
formerly F. Hoffmann-La Roche AG, Basel, Switzerland

Dr Kindermann joined Roche in 1996. From 2001 to 2003 he led the group for the control of incoming packaging materials where he was responsible for release analysis of packaging materials 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 at AGIDENS AG in Switzerland.

Torsten Kneuss
Bayer AG, Berlin, Germany

Torsten Kneuss 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
Member of Ph. Eur. Packaging Expert Groups at the EDQM | 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.

Dr Jörg Zürcher
Chair of EDQM Working Party Glass | Bayer AG, Berlin, Germany

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.

Dates

Part 1:

Pharmaceutical Packaging Systems - Development

Tuesday, 18 February 2020, 10.00 h - 18.00 h

(Registration and coffee 09.30 h - 10.00 h)

Wednesday, 19 February 2020, 08.30 h - 12.30 h

Part 2:

Pharmaceutical Packaging Systems - Quality Control

Wednesday, 19 February 2020, 14.00 h - 18.30 h

(Registration and coffee 13.30 h - 14.00 h)

Thursday, 20 February 2020, 08.30 h - 16.00 h

Venue

Hilton Budapest City

Váci út 1-3.

1062 Budapest, Hungary

Phone +36 1 288 5500

Email Info.budapest-city@hilton.com

Fees (per delegate, plus VAT)

Part 1:

Pharmaceutical Packaging Systems - Development

ECA Members € 1,290

APIC Members € 1,390

Non-ECA Members € 1,490

EU GMP Inspectorates € 745

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.

Part 2:

Pharmaceutical Packaging Systems - Quality Control

ECA Members € 1,290

APIC Members € 1,390

Non-ECA Members € 1,490

EU GMP Inspectorates € 745

The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch on the second day and all refreshments. VAT is reclaimable.

Would you like to save money?



If you book both courses "Part 1: Pharmaceutical Packaging Systems - Development" AND "Part 2: Pharmaceutical Packaging Systems - Quality Control" simultaneously, the fee for each part reduces as follows:

ECA Members € 1,090

APIC Members € 1,190

Non-ECA Members € 1,290

The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch on all 3 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 conference. 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 www.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

69007 Heidelberg, Germany

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For questions regarding content please contact:

Dr Andrea Kühn-Hebecker (Operations Director) at +49(0)62 21/84 44 35, or at kuehn@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc. please contact:

Mr Rouwen Schopka (Organisation Manager) at +49(0)62 21/84 44 13, or at schopka@concept-heidelberg.de.

Social Event

In the evening of 18 February, 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.



If the bill-to-address deviates from the specifications on the right, please fill out here:

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

- Pharmaceutical Packaging Systems - Development & Quality Control (Part 1 AND Part 2), 18-20 February 2020, Budapest, Hungary
- Pharmaceutical Packaging Systems - Development (Part 1 only), 18/19 February 2020, Budapest, Hungary
- Pharmaceutical Packaging Systems - Quality Control (Part 2 only) , 19/20 February 2020, Budapest, Hungary

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 week 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 HEIDELBERG will 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 can-

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.