Pharmaceutical Packaging Systems

Part 1: Pharmaceutical Packaging Systems - ***Development***
16 - 17 June 2015, Vienna, Austria

Part 2: Pharmaceutical Packaging Systems - ***Quality Control***
17 - 18 June 2015, Vienna, Austria

SPEAKERS:

Jean-Francois Decoster
UCB Pharma, Belgium

Sandra Hafner
AbbVie Deutschland,Germany

Dr Gerald Kindermann
F. Hoffmann-La Roche, Switzerland

Torsten Kneuss
Bayer Pharma, Germany

Dr Karl Siemoneit
Sanofi, Germany

Dr Jörg Zürcher
Bayer Pharma, Germany

ECA ACADEMY

LEARNING GOALS:

- Regulatory Requirements:
  - EU
  - US
- Glass Delamination
- Container Closure Integrity
- Update of Compendial Standards
- Packaging and the Common Technical Document (CTD)
- Combination Products
- How to Define the Shelf-life for Packaging Components?
- Testing of Extractables/Leachables
- Application of AQL (Acceptable Quality Level) Concept
  - How to Use Defect Evaluation Lists?
- Risk-based QC System for Packaging Materials
- Control Packaging Material
  - Primary
  - Secondary
- Supplier Management
- Dimensional Checks

This education course is recognised for the ECA GMP Certification Programme „Certified Quality Control Manager". Please find details at www.gmp-certification.eu

Pharmaceutical Packaging Systems: Development & Quality Control

16 - 18 June 2015, Vienna, Austria

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 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, 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 of directed at employees of suppliers of primary and secondary packaging materials for the pharmaceutical industry.

Programme Course 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

Jean-Francois Decoster, UCB Pharma

Glass Delamination

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

Dr Karl Siemoneit, Sanofi

Container Closure Integrity

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

Dr Jörg Zürcher, Bayer Pharma

Update of Compendial Standards

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

Jean-Francois Decoster, UCB Pharma

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)

Dr Jörg Zürcher, Bayer Pharma

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

Dr Jörg Zürcher, Bayer Pharma

Combination Products
- Definitions and regulations
- Development process
- Documentation

Dr Jörg Zürcher, Bayer Pharma

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

Torsten Kneuss, Bayer Pharma

Testing of 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

Dr Jörg Zürcher, Bayer Pharma

Calibration/Qualification/Validation
- Definitions
- Regulatory requirements
- Equipment lifecycle qualification for the control of packaging materials
- Process validation

Dr Gerald Kindermann, F. Hoffmann-La Roche

End of Course 1 / Registration for Course 2

Programme Course 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

Torsten Kneuss, Bayer Pharma

Control of Printed Packaging Materials (60 min)
- Legal requirements
- Level of certification
- Sample size & test procedures
- Reference samples vs. retention samples (Annex 19)

Dr Gerald Kindermann, F. Hoffmann-La Roche

WORKSHOP I
Examples of Defective 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

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

Sandra Hafner, AbbVie Deutschland

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

Dr Gerald Kindermann, F. Hoffmann - La Roche

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

Torsten Kneuss, Bayer Pharma

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

Torsten Kneuss, Bayer Pharma

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 is the Head of Primary Packaging Development for UCB.

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 & Co. KG in 2012 as Qualified Person Trainee in R&D Quality Assurance. Since 2014 Sandra Hafner is responsible as Qualified Person in R&D Quality Assurance, AbbVie Deutschland GmbH & Co. KG.

Dr Gerald Kindermann,
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, currently working as Head Network Support, focusing on project- and knowledge management.

Torsten Kneuss,
Bayer Pharma AG, Berlin, Germany
Since 1999 Torsten Kneuß has been working with pharmaceutical packaging materials, including several years within the fields of packaging quality control and packaging development. Since November 2010 he is as an Operations Manager responsible for pre-filled syringes and medical devices.

Dr Karl Siemoneit,
Sanofi, Frankfurt, Germany
Dr Karl Siemoneit works as head of quality supplier management at Sanofi in Frankfurt, Germany. During his 20 years in the diagnostic / pharmaceutical industry he held several positions in technical support, manufacturing and quality. Dr Siemoneit received his Dr hum biol. at the University of Ulm.

Dr Jörg Zürcher,
Bayer Pharma AG, Berlin, Germany
Dr Zürcher joined Schering (since 2007: Bayer Pharma) 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.

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

Dates

Course 1:
Pharmaceutical Packaging Systems - Development
Tuesday, 16 June 2015, 10.00 h - 18.00 h
(Registration and coffee 09.30 h - 10.00 h)
Wednesday, 17 June 2015, 08.30 h - 12.30 h

Course 2:
Pharmaceutical Packaging Systems - Quality Control
Wednesday, 17 June 2015, 14.00 h - 18.30 h
(Registration and coffee 13.30 h - 14.00 h)
Thursday, 18 June 2015, 08.30 h – 16.00 h

Venue

Austria Trend Hotel
Park Royal Palace Vienna
Schlossallee 8
1140 Vienna, Austria
Phone +43/1/89110 9 200
Fax +43/1/891 109 050

Fees (per delegate plus VAT)

Course 1: Pharmaceutical Packaging Systems - Development
Non-ECA Members € 1,490
ECA Members € 1,290
APIC Members € 1,390
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.

Course 2: Pharmaceutical Packaging Systems - Quality Control
Non-ECA Members € 1,490
ECA Members € 1,290
APIC Members € 1,390
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 "Course 1: Pharmaceutical Packaging Systems - Development" AND "Course 2: Pharmaceutical Packaging Systems - Quality Control" simultaneously, the fee for each course reduces as follows:
Non-ECA Members € 1,290
ECA Members € 1,090
APIC Members € 1,190
EU GMP Inspectorates € 645
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 when you have registered for the event. Please use this form for your room reservation to receive the specially negotiated rate for the duration of your stay. 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

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg
Germany
Phone +49 (0) 62 21/84 44-0
Fax +49 (0) 62 21/84 44 34
E-mail: info@concept-heidelberg.de
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For questions regarding content:
Dr Günter Brendelberger (Operations Director)
at phone +49-62 21 / 84 44 40, or by e-mail at
brendelberger@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Ms Jessica Stürmer (Organisation Manager)
at phone +49-62 21 / 84 44 43, or by e-mail at
stuermer@concept-heidelberg.de.

Social Event

On the evening of 16 June 2015 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)

+ 49 6221 84 44 34

☐ **Pharmaceutical Packaging Systems - Development & Quality Control (Part 1 AND Part 2)**
16 – 18 June 2015, Vienna, Austria
☐ **Pharmaceutical Packaging Systems - Development (Part 1 only)**
16 – 17 June 2015, Vienna, Austria
☐ **Pharmaceutical Packaging Systems - Quality Control (Part 2 only)**
17 – 18 June 2015, Vienna, Austria

☐ Mr ☐ Ms

Title, first name, surname

Company | Department

Important: Please indicate your company's VAT ID Number | **P.O. Number, if applicable**

Street/P.O. Box

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 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

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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)

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