ECA Certified Quality Control Manager Course*

Participate in 2 Workshops:
- Examples of Defect Packaging Materials
- FMEA: Critical Parameters for a Suitable Quality Control System for Packaging Materials

Quality of Pharmaceutical Packaging Systems

From Development to Routine Control

6 - 7 April 2011, Copenhagen, Denmark

SPEAKERS:

Dr Helmut Gaus
Rentschler Biotechnologie

Dr Mayk Kresse
Bayer Schering Pharma

Dr Jörg Zürcher
Bayer Schering Pharma

LEARNING GOALS:

- Regulatory Requirements: EU and US
- Packaging Related Topics of the Common Technical Document (CTD)
- Specifications for Container Closure Systems
- Defect Evaluation Lists
  - Random Sampling Tables
  - Acceptable Quality Levels (AQL)
- Quality Control
  - Receipt, Identification, Sampling, Testing, Approval, and Rejection of Packaging Materials
- Strategies for Reduced Testing
- Control of Printed Packaging Materials
- Reference Samples of Packaging Materials According to EU GMP Guide Annex 19
- Testing of Extractables / Leachables

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

Quality of Pharmaceutical Packaging Systems: From Development to Routine Control

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Objectives

The focus of this GMP Education Course is on the development and routine control of pharmaceutical packaging systems. 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.

The course will also 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 printed packaging materials.

The impact of EU Annex 19 on packaging material samples will also be discussed.

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.

And 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.
The quality control unit is responsible for the control of pharmaceutical packaging materials including the receipt, identification, sampling, testing, and approval or rejection of drug product containers and closures.
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

This GMP Education Course is directed at employees working in pharmaceutical research and development, regulatory affairs, quality control, incoming goods control of packaging materials, and quality assurance departments. The Course is also intended for staff of manufacturers and suppliers of packaging materials.

Programme

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
- European Foodstuff Regulations

Dr Mayk Kresse
Bayer Schering Pharma AG, Germany

Packaging Related Topics of the Common Technical Document (CTD)

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

Dr Jörg Zürcher
Bayer Schering Pharma AG, Germany

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 Schering Pharma AG, Germany

Defect Evaluation Lists

- Manufacturing of moulded and tubular glass containers
- Concept of Defect Evaluation List
- Special Defect Evaluation Lists: Containers made of moulded and tubular glass

Dr Mayk Kresse
Bayer Schering Pharma AG, Germany

WORKSHOP I
Examples of Defect Packaging Materials

The aim of this workshop is to discuss in small discussion groups the evaluation of some defect 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: Dr Mayk Kresse

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, scip lot
- Must to have QA systems (i.e. OOS, complaints)
- Sample management incl. reference samples

Dr Helmut Gaus
Rentschler Biotechnologie GmbH, Germany

Supplier Management

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

Dr Helmut Gaus
Rentschler Biotechnologie GmbH, Germany

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 Helmut Gaus

Dimensional Checks in Packaging Development and Quality Control

- Measurement equipment: overview
- Application ranges
- Practical examples

Dr Mayk Kresse, *Bayer Schering Pharma AG, Germany*

Control of Printed Packaging Materials

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

Dr Helmut Gaus
Rentschler Biotechnologie GmbH, Germany

Technical Specifications

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

Dr Mayk Kresse
Bayer Schering Pharma AG, Germany

Testing of Extractables/Leachables

- Regulatory Background
- Principles of Extractable and Leachable testing
- Potential Extractables of different Container Materials

Dr. Jörg Zürcher
Bayer Schering Pharma AG, Germany

Moderator

Dr. Jörg Zürcher
Bayer Schering Pharma AG, Germany

Speakers

Dr Helmut Gaus
Rentschler Biotechnologie GmbH, Laupheim, Germany
Dr. Gaus started at Merckle/ratiopharm, in 2001 he took over at Novartis-Generics, the position of Qualified Person and Head of Quality Control. From 2003 to 2006 he was Head of Quality Control at Vetter Pharma. Since 2006 he is Qualified Person and Vice President Quality Control at Rentschler Biotechnologie. Within his various positions in the pharmaceutical industry the incoming inspection of packaging components was always part of his responsibility.

Dr Mayk Kresse

Bayer Schering Pharma AG, Berlin, Germany
Dr Kresse joined the packaging department of Schering in 1998. Main fields of work were Quality Control, Quality Assurance Packaging and Packaging Development. Since 2003 he has been heading the packaging development team for solid dosage forms within Pharmaceutical Development. Main task is the development of state-of-the-art packaging solutions in compliance with pharmaceutical, legal/regulatory, technical and economical requirements.

Dr Jörg Zürcher

Bayer Schering Pharma AG, Berlin, Germany
Dr Jörg Zürcher is responsible for the development of containers and packaging materials at Schering since 1990. He started as a scientist with focus on immediate container development for all dosage forms. Since 2002 he is leading the group responsible for development of all packaging components for liquid and parenteral dosage forms.

Social Event

On the evening of the first course 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.

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

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Quality of Pharmaceutical Packaging Systems: From Development to Routine Control
6 - 7 April 2011, Copenhagen, Denmark

☐ 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)

CONCEPT HEIDELBERG
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Date

Wednesday, 6 April 2011, 09.00 h - 18.15 h
(Registration and Coffee 8.30 h - 9.00 h)
Thursday, 7 April 2011, 08.30 h - 16.30 h

Venue

Radisson BLU Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S
Denmark
Phone +45 33 96 5000
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Fees

ECA Members € 1,490.- per delegate plus VAT
APIC Members € 1,590.- per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members € 1,690.- per delegate plus VAT
EU GMP Inspectorates € 845.- per delegate plus VAT
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 when you have registered for the event. Please use this form for your room reservation or be sure to mention "A050411CON" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 5 March 2011. 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

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