Quality Control and Quality Assurance of Pharmaceutical Packaging Materials

6 – 7 May 2009, Vienna, Austria

SPEAKERS:

Dr Helmut Gaus
Rentschler Biotechnologie, Germany

Dr Gerald Kindermann
F. Hoffmann-La Roche, Switzerland

Dr Mayk Kresse
Bayer Schering Pharma, Germany

Dr Jörg Zürcher
Bayer Schering Pharma, Germany

LEARNING GOALS:

- Regulatory Requirements on Pharmaceutical Packaging Materials: EU and US
- Instrument Calibration and Qualification in the QC Packaging Laboratory
- Defect Evaluation Lists
  - Random Sampling Tables
  - Acceptable Quality Levels (AQL)
- Control of Dimensions / Control of Printed Packaging Materials
- IR for Packaging Materials: Benefits and Limits
- cGMP-Compliant Documentation of Packaging Control Activities
- Sampling and Testing of Packaging Materials - Practical Examples:
  - Bottles/Caps
  - Films/Foils
  - Glass/Rubber Stoppers
- Testing of Extractables/Leachables

- New EU GMP Guide Annex 19: Impact on Reference Samples of Packaging Materials
- Participate in 2 Workshops
  - Examples of Defect Packaging Materials
  - Strategies for Reduced Testing
Learning Goals

The focus of this GMP Education Course is on the presentation of concrete tests for packaging materials, as carried out in every incoming-goods laboratory of the pharmaceutical quality control. Among these are sampling and determining the necessary random sampling sizes, the use of infrared spectroscopy, the control of dimensions and the control of printed packaging materials, including the GMP-compliant documentation of these packaging control activities. The impact of the new requirements of EU Annex 19 on packaging material reference samples will also be discussed.

Background

There is a great number of regulatory requirements on pharmaceutical packaging materials, in the pharmacopeias, the GMP regulations, in the FDA guidances, etc. 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, in some countries the „Defect Evaluation Lists“ have proved efficient. The responsibility for the tests lies now more and more with the manufacturers of packaging materials. However, as a precondition for this, additional QA measures, like vendor qualification, supplier audit and technical agreements, have to be taken.

It is the objective of this seminar to describe the GMP requirements on packaging materials, the sampling of packaging materials and the control of incoming packaging materials comprehensively and to illustrate them with the help of examples.

Target Group

This GMP Education Course on the testing of pharmaceutical packaging materials is directed at employees in pharmaceutical quality control departments who are responsible for sampling, testing, approval and control of primary and secondary packaging materials.

The Course is also intended for quality assurance personnel as well as for staff of manufacturers and suppliers of packaging materials.

Moderator

Dr Jörg Zürcher, Bayer Schering Pharma AG, Germany

Programme

Regulatory Requirements on Pharmaceutical Packaging Materials
- Regulatory framework
- US Guidance for Industry: Container Closure Systems
- EC Guidance: Plastic Immediate Packaging Materials
- US Drug Master Files
- EC legislation, Eudralex, foodstuff regulations
Dr Mayk Kresse, Bayer Schering Pharma AG, Germany

Equipment Calibration and Qualification in Pharmaceutical Packaging Control
- Principles of instrument qualification, calibration and analytical method validation in the QC laboratory
- DQ, IQ, OQ, PQ
- Examples of instrument qualification in the QC packaging laboratory
Dr Helmut Gaus, Rentschler Biotechnologie GmbH, Germany

Defect Evaluation Lists
- General principles and specific Defect Evaluation Lists (DEL)
- Random Sampling Tables for qualitative and for time-consuming, destructive and quantitative tests
- Acceptable Quality Level
- “Applied DEL” – LIMS-supported routine release testing
- Sample defects and their classification
Dr Mayk Kresse, Bayer Schering Pharma AG, Germany

Workshop 1

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
**Control of Dimensions**
- Control of dimension for packaging materials
  - Overview over systems/equipment
  - Measuring screws, digital measuring slides, dial gauges
  - Measuring microscope
  - Contour-projector
  - Perthometer
- Requirements on measuring devices in daily use at the incoming control for packaging materials:
  - Monitoring and calibration of testing equipment
- Special applications

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

**Documentation of Packaging Control**
- Regulatory background
- Set-up of specifications
- Testing procedures
- Documentation

Dr Jörg Zürcher, Bayer Schering Pharma AG, Germany

**Infrared Spectroscopy for Packaging Materials**
- Principle of the method
- Pharmacopoeial background
- Identity testing by IR
- Quantitative analysis by IR
- Method evaluation (benefits and limits)

Dr Jörg Zürcher, Bayer Schering Pharma AG, Germany

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**WORKSHOP II**  
**Strategies for Reduced Testing**

The aim of this workshop is to evaluate in small discussion groups how the opportunities and requirements of EU Annex 8 and 21 CFR Part 211.84 should be implemented in the everyday practice of pharmaceutical quality control departments for packaging materials.

**Moderator:** Dr Gerald Kindermann

**Testing of Extractables/Leachables**
- Regulatory Background
- Principles of Extractable and Leachable testing
- Potential Extractables of different Container Materials
- Routine Testing of Extractables

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 Gerald Kindermann
*F. Hoffmann-La Roche AG, Basle, Switzerland*

Dr. Kindermann joined Roche in 1996. From 2001 to 2003 he led the group for control of incoming packaging materials at Roche Kaiseraugst (galenical production). His area of responsibility covered release analysis of packaging materials, the technical control of all packaging materials, and change control of specifications and analytical methods. He then became Quality Manager for the Supply Centre Kaiseraugst, and has been responsible for the quality aspects of a SAP project at Roche within Europe. 2008 he joined the Global Quality group at Roche working on quality systems.

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.
Date

Wednesday, 6 May 2009, 09.00 h - 18.30 h  
(Registration and Coffee 8.30 h - 9.00 h)
Thursday, 7 May 2009, 08.30 h - 16.30 h

Venue

Renaissance Wien Hotel  
Linke Wienzeile/Ullmannstr. 71  
1150 Wien  
Phone: +43 1 89 102  
Fax: +43 1 102 300

Fees

Non-ECA Members € 1,690.- per delegate plus VAT  
ECA Members € 1,521.- per delegate plus VAT  
EU GMP Inspectorates € 845.- per delegate plus VAT  
APIC members € 1,605.- per delegate plus VAT (does not include ECA membership)

The course 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 conference. Please use this form for your room reservation or be sure to mention “VA 5951 ECA Event” to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 6 April 2009. 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  
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  
www.concept-heidelberg.de

For questions regarding content:  
Dr Günter Brendelberger (Operations Director) at phone: +49-6221-84 44 40, or per e-mail at brendelberger@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:  
Marion Weidemaier (Organisation Manager) at phone: +49-6221-84 44 46, or per e-mail at weidemaier@concept-heidelberg.de.

About CONCEPT HEIDELBERG

Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Europe. This year more than 240 events will be organised by CONCEPT HEIDELBERG. ECA has entrusted CONCEPT HEIDELBERG with the organisation of its events.

GMP Certification Programme

This seminar is recognised within the GMP Certification Programme. By attending selected seminars, the participant can acquire an additional certificate. We offer the following certification modules:

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- Certified Pharmaceutical Engineering Manager (ECA)
- Certified Computer Validation Manager (ECA)
- Certified Regulatory Affairs Manager (ECA)
- Certified Validation Manager (ECA)

On the internet at www.gmp-compliance.org you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to info@gmp-compliance.org or a fax to +49-6221-84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

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Reservation Form (Please complete in full)

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Mr.  Ms.

Title, first name, surname

Company  Department

Important: Please indicate your company’s VAT ID Number

Street/P.O. Box

City

Zip Code

Country

Phone/Fax

E-Mail (please fill in)

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P.O. Box 101764
Fax +49 (0) 62 21/84 44 34
D-69007 Heidelberg
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