

Quality of Pharmaceutical Packaging Systems

From Development to Routine Control

21 - 22 May 2014, Berlin, Germany

SPEAKERS:

Dr Helmut Gaus Rentschler Biotechnologie

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Dr Jörg Zürcher Bayer 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
- Dimensional Checks: Measurement Equipment and Application Ranges
- Testing of Extractables / Leachables



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

Dr Helmut Gaus, Rentschler Biotechnologie GmbH

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 Pharma AG

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 AG

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 AG

WORKSHOP I Examples of Defective Packaging Materials

The aim of this workshop is to discuss in small discus-

sion 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

Dr Helmut Gaus, Rentschler Biotechnologie GmbH

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

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

Torsten Kneuss, Bayer Pharma AG

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

Technical Specifications

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

Torsten Kneuss, Bayer Pharma AG

Testing of Extractables/Leachables

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

Dr. Jörg Zürcher, Bayer Pharma AG

Moderator

Dr Jörg Zürcher, Bayer 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.



Torsten Kneuss

Bayer Pharma AG, Berlin, Germany
Torsten Kneuss studied Business Administration and Engineering. He joined Schering AG
/ Bayer Schering Pharma AG in 1996. Since
1999 he has been working with pharmaceuti-

cal packaging materials, including several years within the field of packaging quality control. Since 2007 he has been employed in packaging development, lately as an Application System Development expert. Since November 2010 he has been working as project coordinator within Contract Manufacturing Biotech, and as Operations Manager he is responsible for pre-filled syringes and medical devices.



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.

Social Event

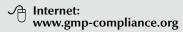
On the evening of the first course day you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.



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