How to apply scientific understanding of critical parameters to achieve appropriate pharmaceutical packaging systems

Image: Bayer Pharma AG

Protective Packaging Solutions for Pharmaceutical Product Stability

Barrier Packaging: Basic Principles – Measuring Methods - Systems

28 - 29 January 2014, Berlin, Germany

SPEAKERS:

Torsten Kneuß
Bayer Pharma AG, Germany

Dr Mayk Kresse
Bayer Pharma AG, Germany

Horst Koller
Schott Schweiz AG, Switzerland

Dr Jörg Zürcher
Bayer Pharma AG, Germany

Prof Dr Ursula Probst
Stuttgart Media University, Packaging Technology, Germany

PROGRAMME:

- The Science behind Migration and Permeation
- Permeation Measurement: Systems and Methods
- Practical Case Studies:
  - Blisters
  - Flexible Packaging Systems
  - Bottle Systems for Oral Products
  - Vials and Syringes
- The Value of Desiccants and Drying Systems
- Container Closure Integrity Testing
- Tightness and Integrity During Shipment?
- New Quality Paradigm by ICH Q8/ Q9/Q10:
  - Quality by Design
  - Design of Experiments
  - Design Space

ECA ACADEMY

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

Protective Packaging Solutions for Pharmaceutical Product Stability

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Objectives

The aim of this Conference is to provide up-to-date knowledge about protective packaging solutions for the stability of pharmaceutical drug products (Barrier Packaging). Which physical fundamentals are relevant? Which measuring procedures and methods do exist? Which drying agent systems are used? By means of specific packaging types and dosage forms (blister, oral, parenteral), all these questions will be answered and practical case studies will be presented.

Background

Moisture permeation/barrier packaging and container closure system integrity is a constant challenge and a regular work stream for expert groups like the Product Quality Research Institute (PQRI) or the Parenteral Drug Association (PDA).

Moisture permeation is a common challenge that can impact the quality of the drug product, so having a more accurate and reproducible method to determine how effective the packaging is at keeping moisture out will be a benefit to industry. Accordingly, also USP is currently revising the packaging and moisture permeation chapters (USP General Chapter <671> Containers—Performance Testing) to include a new method for determining moisture permeation for high and low barrier pharmaceutical packaging. USP is also considering changing the USP classification system for packaging, which is limited so far to "well-closed" and "tight" containers.

Today, the appropriate packaging system is commonly chosen on a „trial & error" approach (orientating stability investigations under stress conditions). However, this "procedure" shows its limits when no appropriate packaging has been identified within this „trial & error" approach. Hence, only precise knowledge of the physical processes of permeation in conjunction with the material features of the packaging and the protection requirements of the dosage form will finally provide a scientific rational for the selection of the best packaging system with optimal product protection.

Moreover, regarding new regulatory options (ICH Q8), scientific understanding of critical parameters is required - for example to be able to identify critical quality attributes and to define a Design Space.

Target Group

This course is especially designed for members of staff and executives from the pharmaceutical industry working in the field of research and development, regulatory affairs, quality control, incoming goods control of packaging materials, quality assurance, production and packaging. It is also directed at employees of suppliers manufacturing packaging materials for the pharmaceutical industry.

Programme

Introduction: The Importance of Barrier Packaging

- Factors, which endanger the stability of pharmaceuticals
- Introduction to stability and stability testing
- Climate parameters (Mean kinetic temperature)
- Climate zone concepts (ICH, ASEAN)
- Options to improve stability

Torsten Kneuß, *Bayer Pharma AG*

Important Fundamentals: Relevant Physical Aspects of Migration and Permeation

- Definition of terms
- Migration models
- Permeation models
- Practical applications in packaging technology

Prof Dr Ursula Probst, *Stuttgart Media University*

Measuring Systems and Methods

- Different types of methodologies
- Common measuring systems for leakage and permeability testing
- Standard for measuring systems and methods (e.g. ISO, ASTM)

Torsten Kneuß, *Bayer Pharma AG*

Blisters

- Polymers for thermoformed blisters: COC, PCTFE, PAN, PP, PVC, PET, etc.
- Critical parameters for barrier properties
- Barrier of flat film and the formed film
- Simulation of permeation through mono- and multilayer structures

Dr Mayk Kresse, *Bayer Pharma AG*

„Tight Container" versus „Hermetic Container"

A) Flexible Packaging Systems

- Systems overview: Coldform blisters, bags, sachets, etc.
- Definitions
- Pinholes and cross diffusion
- Simulation of moisture permeation across pinholes and sealing area

B) Bottle Systems for Oral Products

- Plastic and glass systems
- Closure construction and induction seals
- Moisture barrier and leakage tightness
- Transfer of barrier properties from blisters to bottles and vice versa

Dr Mayk Kresse, *Bayer Pharma AG*

Permeation in Parenteral Dosage Forms: Vials and Syringes

- Methods for measurements of barrier properties
- Barrier Coatings
- Barrier Improvement factor (BIF)
- Case Study: Polymer vs. Glass

Horst Koller, *Schott Schweiz AG*

Desiccants and Drying Systems
- Desiccant types and packaging systems
- Desiccant selectivity
- Adsorption capacity and adsorption rate
- Residual moisture
- Modified atmosphere packaging (MAP)

Dr Mayk Kresse, *Bayer Pharma AG*

Case Study: Calculation/Simulation
- How to compare own measurements with literature data: Pitfalls related to unit conversion
- Prediction of barrier for numerous T/RH conditions
- How to use the Arrhenius expression for shelf-life prediction

Dr Mayk Kresse, *Bayer Pharma AG*

Container Closure Integrity Testing
- Physical test methods
- Microbiological test methods
- USP 1207
- Method comparison and recommendations

Dr Jörg Zürcher, *Bayer Pharma AG*

Tightness during Shipment
- Why to test
- What to test
- How to test
- Practical experience from development projects

Dr Jörg Zürcher, *Bayer Pharma AG*

Migration through Containers
- Migration process
- Test methods for migration testing
- Case study - study design
- Conclusions from the case study

Dr Jörg Zürcher, *Bayer Pharma AG*

Quality by Design
- QbD Principles
- Benefit of QbD
- Life cycle management
- Case Study

Horst Koller, *Schott Schweiz AG*

Introduction to ICH Q8/Q9/Q10 and the new Quality Paradigm
- Guidelines and Training Material
- DoE (Blister) and Design Space

Dr Mayk Kresse, *Bayer Pharma AG*

Social Event

At the end 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.

Speakers

Torsten Kneuß
Bayer Pharma AG, Berlin, Germany
Torsten Kneuß joined Schering AG (since 2007: Bayer Pharma AG) in 1996. Since 1999 he has been working with pharmaceutical packaging materials, including several years within the fields of packaging quality control and packaging development. 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.

Dr Mayk Kresse
Bayer Pharma AG, Berlin, Germany
Dr Mayk Kresse joined the packaging department of Schering (since 2007: Bayer Pharma) in 1998. Fields of work were Quality Control, Quality Assurance Packaging and Packaging Development. Main tasks are the development of state-of-the-art container closure systems and devices for solid dosage forms in compliance with pharmaceutical, legal/regulatory, technical and economical requirements.

Horst Koller
Schott Schweiz AG, St. Gallen, Switzerland
Mr. Koller joined the business segment Pharmaceutical Packaging in the year 2000. He has been a key player in building the manufacturing unit for the Schott TopPac® polymer syringe. In his current position he is responsible for the global Technical and Quality Support syringes for Schott Pharmaceutical Packaging.

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.

Prof Dr Ursula Probst
Stuttgart Media University, Stuttgart, Germany
Ursula Probst received her PhD at the University of Freiburg. She worked in the field of material research for Aerospatiale and at the University of Konstanz. In 2003 she was appointed as Professor for Packaging Technology at the Stuttgart Media University.

Easy Registration

Reservation Form:
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69007 Heidelberg
Germany

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www.gmp-compliance.org

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 **P.O. Number, if applicable**

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Date

Tuesday, 28 January 2014, 09.00 h - 17.30 h
(Registration and Coffee 8.30 h - 9.00 h)
Wednesday, 29 January 2014, 08.30 h - 16.00 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
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Fees

ECA Members € 1,490.- per delegate plus VAT
APIC Members € 1,590.- per delegate plus VAT
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 with all further information when you have registered for the event. 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

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