Image: Bayer Pharma AG

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

Barrier Packaging

Basic Principles – Measuring Methods – Systems

26 - 27 February 2013, 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
EUROPEAN COMPLIANCE ACADEMY

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

Barrier Packaging

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Objectives

The aim of this Conference is to provide up-to-date knowledge about 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

The most important requirements for primary packaging systems are the compatibility with the dosage form and the protection of the medicinal product. While compatibility of solid dosage forms for oral administration is rather of minor importance, particular attention must be paid to the protective function for particularly sensitive active substances. Here, the focus is on protection against hydrolyses (water vapour) and oxidation (oxygen) which are the main sources of chemical degradation reactions.

In many cases the stability of the dosage form that is sufficient for a registration is only accomplished through the protection provided by the packaging.

Today, the appropriate packaging system is 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. Only sufficient understanding of the physical processes can help identifying the right element to achieve appropriate packaging. Moreover, regarding new regulatory options (ICH Q8) scientific understanding of critical parameters is required - for example to be able to define a Design Space.

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 is of fundamental importance for the selection of the packaging system with optimal product protection. In this context, the necessary protection measures must be ensured and in addition, unnecessarily expensive exterior packaging should be avoided. Finally, the use of modern regulatory approaches like definition of Design Space should be available.

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

Reservation Form:
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info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

Date

Tuesday, 26 February 2013, 09.00 h - 17.30 h
(Registration and Coffee 8.30 h - 9.00 h)
Wednesday, 27 February 2013, 08.30 h - 16.00 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49 (0)30 2127 - 0
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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 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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Dr Günter Brendelberger (Operations Director) at phone +49-62 21 / 84 44 40, or per e-mail at brendelberger@concept-heidelberg.de.
For questions regarding reservation, hotel, organisation etc.:
Ms Nicole Bach (Organisation Manager) at +49-62 21 / 84 44 22, or per e-mail at bach@concept-heidelberg.de.

Reservation Form (Please complete in full)

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Barrier Packaging,
26-27 February 2013, Berlin, Germany

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