ECA Academy
Your GMP/GDP Information Source

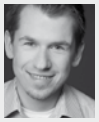
Protective Packaging Systems

Basic Principles – Barrier Systems – Performance Testing

Images: Gerresheimer & Schott & Linhardt

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

SPEAKERS:



Torsten Kneuß
Bayer Pharma AG, Germany

Dr Mayk Kresse
Bayer Pharma AG, Germany

Horst Koller
HK Packaging Consulting, Switzerland

Dr Eva Maria Moser
Incoat GmbH, Switzerland

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

Dr Jörg Zürcher
Bayer Pharma AG, Germany

14-15 September 2016, Prague, Czech Republic

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 for Injections
  - Tubes for Topical Products
- The Value of Desiccants and Drying Systems
- Container Closure Integrity Testing
- Tightness and Integrity during Shipment?
- Examples of Container/ Drug Interactions

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

Protective Packaging Systems

14-15 September 2016, Prague, Czech Republic

Objectives

The aim of this conference is to provide up-to-date knowledge about protective packaging solutions for the stability of pharmaceutical and cosmetic products, and foodstuff (Barrier Packaging). Which physical fundamentals are relevant? Which measuring procedures and methods do exist? Which drying agent systems are used? Which options in terms of protective packaging (blisters, bottles, tubes, vials, and syringes) in relation to the dosage form (solids, liquids, semi-solids) and the route of administration (oral, parenteral, and topical) exist, all these questions will be answered and practical case studies will be presented.

Background

Pharmaceutical and cosmetic products and foodstuff have to be packaged in container-closure systems that protect them from factors that can endanger the stability of the product. 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 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, USP recently revised 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", "tight", and "hermetic" 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, the scientific understanding of the most important parameters helps to identify critical quality attributes and to define a "design space" which is in line with increasing demands of Quality by Design (QbD).

Target Audience

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 or cosmetic and foodstuff industry.

Programme

Introduction: The Importance of Protective 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

Important Fundamentals: Relevant Physical Aspects of Migration and Permeation

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

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)

Blisters

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

„Tight" and "hermetic" Containers

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

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

Packaging Systems (Tubes) for Topical Products

- Highly efficient and sustainable diffusion barrier layer
- Corrosion protection for metallic supports
- Complete emptying of content
- Protecting content from undesired interactions by packaging
- Protecting content from external contamination

Permeation in Parenteral Dosage Forms: Vials and Syringes

- Methods for measurements of barrier properties
- Barrier coatings
- Barrier improvement factor (BIF)
- QbD: Burden or benefit
- Case study: Polymer vs. glass

Desiccants and Drying Systems

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

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

Container Closure Integrity Testing

- Physical test methods
- Microbiological test methods
- USP 1207
- Method comparison and recommendations

Tightness during Shipment

- Why to test
- What to test
- How to test
- Practical experience from development projects

Migration through Containers

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

Container/ Drug Interactions

- Examples of recent observations and recalls
- Possible root causes
- Alternative packaging systems

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 and medical devices. His duties there have included several years within the fields of packaging quality control and packaging development. Currently he holds the position of a Device Safety Leader in Global Pharmacovigilance. For the past five years he has been employed as Operations Manager, responsible for pre-filled syringes and medical devices within Product Supply Biotech.

Dr Mayk Kresse
Bayer Pharma AG, Berlin, Germany
Dr Mayk Kresse started his carrier at Schering (since 2007: Bayer Pharma) more than 25 years ago. Over the years he has gained in depth experience in Packaging Quality Control, Quality Assurance and Packaging Development. Currently he holds the position of a Principal Scientist in the R&D function <Special Technologies and Application Systems>. Main areas of work are protective packaging, smart packages, devices and combination products.

Horst Koller
HK Packaging Consulting, Uznach, Switzerland
Prior to becoming a consultant, Horst Koller worked for Abbott Diagnostic and SCHOTT Pharmaceutical Packaging with a total of more than 20 years industry experience. His consulting company is focussing on Technical, Regulatory and QM Support around Primary and Secondary Packaging Systems including Medical Devices. He is an active member within the technical ISO Committees TC76 and TC84 as well as an active speaker on international conferences.

Dr Eva Maria Moser
Incoat GmbH, Neuhausen am Rheinfall, Switzerland
Eva Maria Moser is Founder & CEO of incoat GmbH. Her company holds several patents on plasma deposited thin films exhibiting outstanding properties. From 2001 to 2015, Eva Maria Moser has been teaching nano technology and plasma enhanced chemical vapour deposition methods at the University of Applied Sciences of Geneva. She has been head of the research group regarding the development of novel nanostructured surfaces. Prior to that, she was responsible for the establishment of the research domain “plasma polymerised thin films” and leader of the research group “functional Films” at the Swiss Federal Institute of Material Testing and Research (EMPA).

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.

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

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.

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Protective Packaging Systems: Basic Principles – Barrier Systems – Performance Testing
14-15 September 2016, Prague, Czech Republic

☐ 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)

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

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- until 2 weeks prior to the conference 10 %,
- until 1 week prior to the conference 50 %
- within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012)

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date

Wednesday, 14 September 2016, 09.00 h - 17.30 h
(Registration and Coffee 8.30 h - 9.00 h)
Thursday, 15 September 2016, 08.30 h - 16.00 h

Venue

Corinthia Hotel Prague
Kongresova 1
14069 Prague, Czech Republic
Phone + 420 261 191 111
Fax + 420 261 225 011

Fees (per delegate plus VAT)

ECA Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845
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

ECA has entrusted Concept Heidelberg with the organisation of this event.

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-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. Andrea Kühn-Hebecker (Operations Director) at +49-62 21/84 44 35, or per e-mail at kuehn@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:
Ms Marion Grimm (Organisation Manager) at +49 (0) 62 21 / 84 44 18, or per e-mail at grimm@concept-heidelberg.de.