ECA
ACADEMY

Pharma Packaging 2013

Speaker from Authority:

DR KLAUS MENGES
BfArM, Federal Institute for Drugs and Medical Devices, Germany

Industry Speakers:

DR FRANK DE SMEDT
Toxikon Europe, Belgium

DR JOCHEN HEINZ
Transcoject, Germany

TORSTEN KNEUSS
Bayer Pharma, Germany

RICHARD KRUITHOF
MSD, The Netherlands

PATRIK MERCKELL
Novartis Pharma, Switzerland

GABY RECKZÜGEL
Boehringer Ingelheim, Germany

CHRISTIAN RIEDIGER
Bayer Pharma, Germany

JIM RITTENBURG
Authentix, USA

MAJA RYBKA
Novartis Pharma, Switzerland

DR INGO THORWEST
Boehringer Ingelheim, Germany

ULRICH WIDMANN
Teva-ratiopharm, ratiopharm-group, Germany

25 – 26 November 2013, Budapest, Hungary

Printed Packaging Materials

How to Stay Compliant

26 – 27 November 2013, Budapest, Hungary

Plastic Packaging Materials

Development, Manufacture, Use and Control

Book both conferences and save up to € 400,-!

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

Part 1: Printed Packaging Materials

How to Stay Compliant

25-26 November 2013, Budapest, Hungary

Objectives

During this conference, representatives from authorities as well as specialists from the pharmaceutical industry share their expert knowledge about important aspects of secondary packaging components. Hear about best practices from release to handling and control of cartons, leaflets and labels and learn how to stay competitive and compliant in the process of developing printed packaging materials.

Background

The process of developing and releasing printed packaging materials is highly complex. Many contacts (externally and internally) are involved in this process, and therefore it is a big challenge to design these procedures to be effective and efficient.

At the same time, new regulatory requirements are added time and again. Recently, this was in particular the requirement to apply Braille for blind and partially sighted people. And currently the debate about the **readability of printed packaging materials** has also been revived again, since there are new recommendations on the contents and layout of a good modern package leaflet. And the latest new requirements are due to the **FDA Draft Guidance for Industry** (April 2013) about Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors.

Printed packaging materials also play a pivotal role in the fight against counterfeit medicines. These have a large number of open and closed characteristics with which one can mark medicinal products in order to protect them against being counterfeited or at least to identify counterfeits more easily. In this context **the EU Falsified Medicines Directive and EFPIA's European Stakeholder Model (ESM)** are also of great importance. The European Medicines Verification System (EMVS) will enable complete tracing of a medicinal product from the pharmaceutical manufacturer to the distributing pharmacy by means of using the 2 D Data Matrix Code. To illustrate this, a project that has already been established successfully is presented. In addition the **developing product protection regulations in the US** will also be addressed.

Further important topics of the conference are the text control of printed packaging materials and the electronic data transfer between print shop, agency and pharmaceutical company.

Target Group

This conference is designed for all specialists, engineers, managers and executives from Artwork, Packaging Technologies, Purchasing, Quality Control, Quality Assurance, Production and Regulatory Affairs within the pharmaceutical industry but also for Regulatory Authorities and suppliers of cartons, leaflets and labels.

PROGRAMME

Readability of Printed Packaging Materials

- Impact of the Readability Guideline for Packaging Material
- Impact of the Pharmacovigilance Legislation – not only the 'black triangle'
- How to create a good package leaflet
- How to perform target patient group consultation
- Considerations on labelling of cartons and blister
- Braille Requirements Update
- Braille: Marburg Medium as international standard

DR KLAUS MENGES

Case Study: How to Improve the Comprehensibility and Readability of Leaflets

- Influencing factors
- Technical feasibility - limits
- Reduction of the "white areas"
- Layout optimization
- Examples

ULRICH WIDMANN

New FDA Draft Guidance "Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors"

- Medication errors and the role of labeling
- Goals and Key requirements of the Guidance
- Consequences for the pharmaceutical industry

TORSTEN KNEUSS

Part 1: Printed Packaging Materials

HOW TO STAY COMPLIANT

25-26 November 2013, Budapest, Hungary

Pharmaceutical Packaging Material Suppliers

- Necessity of having global standards
- Supply network for efficient handling of pharmaceutical packaging material suppliers

PATRIK MERCKELL

Case Study: Automated Content Proofreading

- Experience
- Capabilities / Benefits
- Limitations / Constraints
- Where to deploy in the artwork chain
- What to look for in technology selection
- Benefits, limitations and pitfalls

RICHARD KRUITHOF

Case Study: Automated Artwork Management

- Workflow
- Composition
- Quality Assurance
- Inspection and proofreading technology
- Experience, benefits and constraints

RICHARD KRUITHOF

Case Study: Quality Control of Printed Packaging Materials

- Quality Requirements for Printed Packaging Materials
- Specifications, Sampling plans, AQLs (Acceptable Quality Levels) and DEL (Defect Evaluation Lists)
- Specific test methods
- Risk-based approach for determination of scope and extent of quality testing

TORSTEN KNEUSS

Case Study: Management of Dates and Deadlines for the Use of Printed Packaging Materials

- Various ways of monitoring terms and deadlines
- Different approaches for an implementation
- The way from a printout to an electronic system
- Practical example
- Experience and findings

ULRICH WIDMANN

The Role of Packaging in the War Against Counterfeits

- Packaging as a Medium for Counterfeit Protection and Detection
- Product Protection Regulations (focus on the US regulatory landscape)
- Overt or Covert Technology?
- Counterfeit Prevention or Package Authentication?
- Tamper Evident Technologies
- Technology Layering and Insertion into Packaging
- Strategies for Minimizing Impact on Manufacturing Process
- Implementation and Management of Product Protection Programs

DR JIM RITTENBURG

EPFIA – The European Stakeholder Model (ESM)

- EU Falsified Medicines Directive: New legal framework
- The European Medicines Verification System: The joint stakeholder proposal
- The Memorandum of Understanding: Different partners working together
- Next steps: Perspectives for EU roll-out

CHRISTIAN RIEDIGER

Case Study: Implementing Track and Trace Solutions to Combat Counterfeit Medicines

- Background from Bayer perspective
- Legal Requirements in other countries
- Setup of a Team to define a Bayer HealthCare Standard Solution
- System Selection and Implementation
- Quality Aspects
- Project Challenges

CHRISTIAN RIEDIGER

Part 2: Plastic Packaging Materials

Development, Manufacture, Use and Control

26-27 November 2013, Budapest, Hungary

Objectives

This conference deals with the development, manufacture, use and control of plastic packaging materials for medicinal products, medical devices and combination products. The conference gives you an update on the regulatory requirements and shows you how these requirements can be put into practice. One of the focus topics is the use of additives as well as their testing and assessment by means of extractables/leachables studies. You also get the latest information on child-resistant packaging. And the conference subjects are rounded off from a GMP compliance point of view with the topics testing of plastic packaging materials and handling of plastic packaging materials during packaging.

Background

Requirements on the development, testing and registration of plastic packaging materials can among others be found in the EMA „Guideline on Plastic Immediate Packaging Materials" of 2005 and the FDA Guidance for Industry „Container Closure Systems for Packaging Human Drugs and Biologics".

The EMA guideline covers the specific requirements (data to be submitted) for plastic packaging materials intended to be in direct contact with the medicinal product. The guideline has to be applied in new registration applications or in variation applications.

According to the FDA guideline, each application should contain enough information to show that each proposed container closure system and its components are suitable for its intended use. This includes:

- Protection (light exposure, oxygen, moisture permeation, leakage)
- Compatibility
- Safety (extraction/toxicological evaluation studies)
- Performance (container closure system functionality, drug delivery)

Today, new requirements are added, since there are currently many medical devices and combination products on the market. Therefore, this conference also presents the regulatory requirements on medical devices and combination products (CP) in Europe and the USA.

Target Group

The conference 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 plastic primary packaging materials for the pharmaceutical industry.

PROGRAMME

Plastic for Medical Packaging: Manufacturing of Materials and Devices

- Overview of materials, additives and plastic auxiliaries
- Overview of manufacturing processes for polymers and devices
- Material and supplier selection criteria and contracting
- GMP requirements and compliance including documentation and testing of materials and processes
- ISO 15378 - Particular requirements for primary packaging materials
- Recycling
- The big issue: Material changes

DR JOCHEN HEINZ

Regulatory Requirements for Plastic Packaging Materials

- FDA Guidance on container closure systems
- EMA Guideline on plastic immediate packaging materials
- Pharmacopoeial regulations
- Miscellaneous requirements: BSE/TSE, Packaging Waste Directive, legislation on individual substances, etc.

GABY RECKZÜGEL

Part 2: Plastic Packaging Materials

Development, Manufacture, Use and Control

26-27 November 2013, Budapest, Hungary

Regulatory Requirements for Medical Devices and Drug Device Combination Products

- Definitions Medical Device (MD)/ Combination Product (CP) in EU and US
- MD/CP regulations for EU and US
- MD/CP quality system requirements
- Implementation in the pharmaceutical sector
- Transfer of the device regulatory requirements (e.g. Design Control) into the pharmaceutical development process

MAJA RYBKA

Pharmaceutical Development: Requirements for Plastic Packaging Materials

- General material and regulatory requirements for primary and secondary packaging and devices
- Material selection criteria
- Material properties and design
- Example: Pre-filled plastic syringes

DR JOCHEN HEINZ

Polymer Additives in Plastic Packaging Materials

- Types of additives
- Their mode of action
- Use
- Function
- Physical behaviour

FRANK DE SMEDT

Extractables / Leachables: Testing and Assessment

- Regulatory requirements
- In which cases is extractables testing necessary?
- Best practices for extractables and leachables testing
- Safety qualification process

GABY RECKZÜGEL

Child-Resistant Packaging

- Definition
- Testing procedures
- Child resistance vs. senior friendliness
- Examples

DR INGO THORWEST

Quality Control of Plastic Packaging Materials

- Definition of Specifications
- Sampling plans, AQLs (Acceptable Quality Levels) and DEL (Defect Evaluation Lists)
- Common test methods
- Challenges

TORSTEN KNEUSS

Handling of Plastic Packaging Materials in Warehouse and Manufacturing

- Storage
- Processing
- IPC and reconciliation
- Shopfloor requirements
- Blister integrity testing

DR INGO THORWEST

Dr Frank De Smedt, Toxikon Europe N.V., Heverlee, Belgium
Frank De Smedt has a PhD in chemistry from the Katholieke Universiteit Leuven. He is the department supervisor of the Extractables and Leachables laboratory of Toxikon Europe nv. He is also responsible for Method Developments and Validations for all analytical methods implemented in the laboratory.

Dr Jochen Heinz, Transcoject GmbH & Co. KG, Neumünster, Germany
Jochen Heinz has a Master of Engineering in Material-Science and Technology. Since 2001 he is working for Transcoject, a manufacturer of medical products. In the board of directors he is in charge for 'New Products'. Prior to that he was responsible at Schott Glas for the product development of the business unit 'Pharmaceutical Packaging'.

Torsten Kneuss, Bayer Pharma AG, Berlin, Germany
Torsten Kneuss studied Business Administration and Engineering. He joined Schering AG / Bayer Pharma AG in 1996. Since 1999 he has been working with pharmaceutical 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. In this position he was responsible for several development projects, mainly pre-filled syringes made of glass and plastic. 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.

Richard Kruithof, MSD B .V., Haarlem, The Netherlands
Richard Kruithof started his career with MSD B.V. in 1990. As Director Business & Decision Support in the EMEA Quality Operations organisation he is involved in a number of regional and global projects including Artwork Management Quality and Compliance. In a previous role he was Director of Client Services with global responsibility for IT services to the Quality and Compliance function of the Manufacturing Division. Prior to his current position, Richard has held positions in Quality (Project Manager for the European Artwork Management System), New Products Planning, Vaccine Business Support and Plant Engineering.

Dr Klaus Menges, Director and Professor in Staff Position for Strategy and Planning, Federal Institute for Drugs and Medical Devices (BfArM), Bonn, Germany
Klaus Menges is currently responsible in a project called PharmNet. Bund, which will offer several services for applicants, the general public and other agencies in regard to medicinal products. Additionally, he is German representative in the Telematic Implementation Group for e-submission (TIGes) and their subgroups for harmonisation of the e-submission guidelines, the ICH Working Group M8 on electronic submission implementation as well and the RPS Working Group at HL7.

Patrik Merckell, Global Program Manager Packaging Technology Strategy, Novatis Pharma AG, Basel, Switzerland
Patrik Merckell has worked for Novartis Pharma AG for eleven years in the areas of Packaging Technology, Product Security (Tamper Evident Packaging, Verification Features) and Artworks. He has a degree from the esig+ in Lausanne, the Swiss School for Engineers of the Graphical Industry.

Gaby Reckzügel, Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim, Germany
Gaby Reckzügel is head of a laboratory for chemical characterization of device components and packaging materials within the Respiratory Drug Delivery Department. Coming with analytical experience in the food industry as a food chemist she started in Research & Development at Boehringer Ingelheim, Germany in 2000. Here she is involved in the selection of materials for packaging and device components and is responsible for chemical analytical aspects during development.

Speakers (cont'd)

Christian Riediger, Bayer Pharma AG, Berlin, Germany
Christian Riediger is an engineer in electro-technics. He was project manager at KVP Pharma & Veterinary Products, responsible for the implementation of the Datamatrix encoding according the IFAH directive. He is now working in the supply chain management of Bayer Pharma and head of the BayerHealthCare 2D Matrix Code Core Team for mass serialization.

Dr James H. Rittenburg, Authentix Inc., USA
Dr Rittenburg joined Authentix in 1994 and is currently Vice President of the company's Healthcare and Life Sciences division. He has over 25 years experience developing diagnostic systems for detecting trace levels of chemicals in samples including pharmaceuticals, foods, beverages, petrochemicals, and agricultural products. He has edited several books, authored numerous journal articles and is an inventor on a number of patents in this field. Dr Rittenburg has worked with many of the leading pharmaceutical manufacturers to design and implement product security systems. Prior to joining Authentix, Dr Rittenburg was Director of Product Development for Quantix Systems.

Maja Rybka, Novartis Pharma AG, Basel, Switzerland
Maja Rybka studied Biomedical Engineering and worked after her studies at the University Rostock in biomaterial research. From 1999 to 2007 she was Project Manager for Medical Devices and Combination Products at Schering AG Berlin. After that she worked as Quality Systems Engineer responsible for quality- and regulatory compliance in the Device Development department at Novartis Pharma AG. Since 2010 she is Senior Quality Auditor for Medical Devices, Packaging and Drug Products. She is the author of the "Defect Evaluation List for Medical Needles" (Edito Cantor Publishing House).

Dr Ingo Thorwest, Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim, Germany
Dr. Ingo Thorwest received his Diploma in Process Engineering from the RWTH University in Aachen/Germany and received his Ph.D. in Process Engineering from the Technical University in Braunschweig/Germany. Since 1992 he has been with Boehringer Ingelheim Corporation at various sites (Technical Dept., Packaging Process Engineering, Production). Currently, he is Head of Global Maintenance at Global Engineering.

Ulrich Widmann, Teva-ratiopharm, Ulm, Germany
Ulrich Widmann studied mathematics and physics. After some years experience in a software developing company he started at Merckle in 1991 in the production dept. of the IT. In 1999 the company decided to start up with a CIP-Process and he was in charge of a team which integrates this process in the whole company. From 2004 until 2010 he was heading the Packaging Material Management of the ratiopharm-group. Since 2010 he is Head of Artwork Management of th EU Supply and Demand Control at Teva Generics System.

Social Event

Participants of Part 1 of the Conference (Printed Packaging Materials) are cordially invited to a guided sight-seeing tour of Budapest and to dinner on Monday evening.

Participants of Part 2 of the conference (Plastic Packaging Materials) are invited for a dinner on Tuesday evening.

These are excellent opportunities to share your own views and experiences with colleagues from other companies in a relaxed and casual 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

Dates
Conference „Printed Packaging Materials“
Monday, 25 November 2013, 09.00 h - 18.00 h
(Registration and coffee 08.30 h - 09.00 h)
Tuesday, 26 November 2013, 08.30 h – 12.30 h

Conference fees
ECA Members € 1,290.-*
APIC Members € 1,390.-*
Non-ECA Members € 1,490.-*
EU GMP Inspectorates € 745.-*
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both day and all refreshments. VAT is reclaimable.

Conference „Plastic Packaging Materials“
Tuesday, 26 November 2013, 14.00 h - 18.15 h
(Registration and coffee 13.30 h – 14.00 h)
Wednesday, 27 November 2013, 8.30 h – 16.00 h

Conference fees
ECA Members € 1,290.- *
APIC Members € 1,390.-*
Non-ECA Members € 1,490.-*
EU GMP Inspectorates € 745.-*
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on second day and all refreshments.
VAT is reclaimable.

*per delegate plus VAT

Would you like to save money?
If you book the conference „Printed Packaging Materials“ TOGETHER WITH the conference „Plastic Packaging Materials“, the fee for each conference reduces as follows:
ECA Members € 1,090.-*
APIC Members € 1,190.-*
Non-ECA Members € 1,290.-*
EU GMP Inspectorates € 645.-*
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first and second day, lunch on all day and all refreshments. VAT is reclaimable.

Venue
of both conferences
Hilton Budapest WestEnd
Váci út 1-3.
1062 Budapest, Hungary
Phone +36 1 288 5500
Fax +36 1 288 5500

Accommodation
CONCEPT 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 to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration
Via attached reservation form, by 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
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:
Dr Günter Brendelberger (Operations Director)
phone +49(0) 62 21/84 44 40,
e-mail: brendelberger@concept-heidelberg.de

For questions regarding reservation, hotel, organisation, etc:
Ms Marion Weidemaier (Organisation Manager)
Phone +49 (0) 62 21 / 84 44 46
e-mail: weidemaier@concept-heidelberg.de

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Reservation Form (Please complete in full)

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Pharma Packaging 2013, Budapest, Hungary, 25-27 November 2013
☐ Part 1: Printed Packaging Materials, 25-26 November 2013
☐ Part 2: Plastic Packaging Materials, 26-27 November 2013
(Please mark)

☐ Mr ☐ Ms

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number / Purchase Order Number, if applicable

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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 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

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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)