SPEAKERS:

Dr Wilfried Babel  
Gelita

Dr Carsten Hüttermann  
Dow

Marc Huysmans  
Capsugel

Benedict Kleine-König  
Bosch

Dr Christian Mühlenfeld  
Ashland

Dr Martin Opitz  
Bosch

Claudio Scialdone  
Tillots

Dr Harald Stahl  
GEA

Prof Sven Stegemann  
University of Graz

LEARNING OBJECTIVES:

- From Raw Material to Final Drug Delivery
- Formulation Perspectives
- Scale-up
- Qualification & Validation
- Quality and Trouble-shooting in the Capsule Filling Process
- Containment
- Technology Innovations

8-9 March 2017, Heidelberg, Germany

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

We kindly invite you to the “Capsule Technology School”, an exclusive workshop on state of the art know-how of the different topics of central importance. On the first day, you will get among others an overview of the manufacture and development of hard capsule formulations and raw materials. Day two will be dedicated to the diverse filling technologies and the pharmaceutical application of these techniques. Pharmacists and suppliers will share their expert knowledge in their presentations for example on inhalation products, filling of liquids, containment as well as on the latest capsule filling technologies. Additionally, you will be trained on selected aspects of trouble shooting as well as on the implementation of GMP (Good Manufacturing Practice) in regard of scale-up and Qualification/Validation.

Background

Capsules offer a flexible Drug Delivery System and, thanks to the rapid development in the pharmaceutical industry, there are always new perspectives to be discovered. Especially in the combination of medicinal product and dosage form, many aspects of the manufacture - both technical and economic - play a significant role: expiring patents, increasing health expenditure, economic insecurities characterize the pharmaceutical industry on the one hand. On the other hand, the progress made in research and development - such as the availability of highly-potent APIs and innovative new production processes - are sustainably changing the business area.

Target Group

This course addresses specialists and executives working in the fields of pharmaceutical manufacture, research and development and quality control, as well as engineers, project/facility engineers, especially those involved in the implementation of new monitoring methods, risk-based scale-up models and process technology for capsule filling processes. The conference is also of interest for suppliers of excipients used for capsules.

Moderator

Dr Martin Opitz, Dr Andrea Kühn-Hebecker

Programme

From Raw Material to Final Drug Delivery

Market trends
- Pharmaceutical world market evolution and influencing factors
- Global capsule market development
- Future trends

HPMC - an innovative capsule-polymer
- HPMC is an attractive alternative to gelatin for hard capsules
- Controlled changes in HPMC processing conditions allow targeted changes of morphology & chemical structure leading to desired design of specific properties
- The chemical structure diversity of HPMC provides unique innovative potential for new designs of tailor-made properties for future improvements and new opportunities

Capsules - flexible drug delivery systems
- General characteristics of two piece capsules
- Different capsule polymers and their specific performance parameter
- In-vitro studies of different types of two piece HPMC capsules

Gelatin - a well known capsule-polymer?
- The long way from collagen to gelatin
- Physical characterization of gelatin
- Cross-linking issues of gelatin capsules
- Market and applications of gelatin

Formulation & Characterization

Formulation technologies - review of methods for pellet manufacturing
- Introduction of various processes
- Limitations of the various processes
- Guidance to selection of optimal process
Impact of superdisintegrants in hard capsule formulations

- Superdisintegrants to promote rapid disintegration and dissolution
- Prerequisites for a decreased disintegration time
- Overview about the mostly used superdisintegrants

Formulation development

- Reason & Rational for developing capsules formulations
- Considerations for powder blend capsule formulation
- Selection of excipients in formulation
- Advanced dry capsule formulation

Quality & Troubleshooting in the Filling Process

Capsule filling technologies & Scale-up

- Reproducible dosage possibilities for each solid pharmaceutical Drug

Qualification and Validation - to get the system tested

- Requirements for a capsule filler and the manufacturing process

Trouble shooting in full scale production

- Capsule design
- Defects & Diagnosis on capsule filling machines
- Trouble shooting

Technology & Innovation

Microdosing & New technologies

- Definition and Technologies of Microdosing; DPIs
- Capsule Filling Operations
- Case study of different Lactose types

Containment

- How much containment is required?
- Review of most critical process steps
- Solutions for handling highly potent APIs

Liquid encapsulation and sealing technologies

- Capsule properties
- Liquid fill encapsulation (HGC vs. SGC)
- Challenges of liquid filling
- Lipid-based formulations
- Dosing systems for liquid and semi solid formulations
- Capsule sealing systems and technologies

Speakers

Dr Wilfried Babel, Gelita, Germany
Wilfried Babel is Senior Specialist Pharma in the Research & Business Development Department at GELITA AG in Eberbach, Germany. His responsibilities include product development and technical service for global hard and soft capsule manufacturers. After finishing his doctoral thesis in chemistry at the University of Munich and before joining GELITA AG, he worked for a few years as a post doctoral fellow in the Department of Connective Tissue Research at the Max-Planck-Institute of Biochemistry in Munich. Since then, Dr Babel has held various positions in Pharma, Sales and R&D. He has more than 30 years experience in diverse fields of pharmaceutical gelatine applications.

Dr Carsten Hüttermann, Dow, Germany
Carsten Hüttermann studied Chemistry at the University of Braunschweig, Germany. He started his career in 2002 at Wolff Walsrode AG as project leader (focus: synthesis of new cellulose derivatives). Since 2006 he was head of the laboratory for regulated applications (Food, Pharma). In 2007 Wolff Walsrode AG evolved to Dow Pharma & Food Solutions. At this time Dr Hüttermann was head of development for food additives. Since May 2015 he is working as Senior TS&D Scientist pharma applications responsible for technical support and customer projects in Europe.

Marc Huysmans, Capsugel, Belgium
Marc Huysmans started at CAPSUGEL Belgium in 1986 as a technician in the Capsule Printing Department. 1999, he moved to the Quality Department and became a Technical Service Engineer. This job gives him the opportunity to visit customers & focus on optimizing their capsule filling process. Regions of responsibility are Germany (Pharma) and South Africa.

Benedict Kleine-König, Bosch, Germany
Benedict Kleine-König studied Pharmaceutical Technology and made his Bachelor theses in Pharmaceutical Chemistry. Before he joined Bosch in the position of Project Manager engineering pharmaceutical service in August 2016, he worked 3 years in different pharmaceutical companies as an expert for qualification and validation. After that 3 years for different pharmaceutical machine companies (focus: Capsule filler) as project manager Qualification and product manager. Today he has the responsibility for customer machine trial and support for product transfers, as well as the development of new filling technologies with the focus of pharmaceutical manufacturing.

Dr Christian Mühlenfeld, Ashland Inc., Germany
Dr Mühlenfeld obtained his PhD from the University of Düsseldorf, Germany, where he specialized in manufacturing and characterization of solid dispersions for solubility enhancement. He joined Ashland in 2013 as a Technical Service Manager/Pharmaceutical Scientist. Currently he is head of the European Pharma Application Laboratory at Ashland. His role involves support for Ashland's excipients, advice on formulation and process development, scale-up, and technical transfer especially for solid dosage forms, film coatings, and solubilization technologies.
Dr Martin Opitz, Bosch, Germany
Martin Opitz studied Chemistry in Bonn (Germany) and made his doctoral theses in Pharmaceutical Chemistry in 1997. Before he joined Bosch in the position of a Senior Market Expert in August 2013, he worked 9 years for Capsugel and 3 years for Colorcon in different kind of business development functions. Today he has the responsibility of a global trend scout in Pharma Solid, cooperation management and scientific support function for capsule applications.

Claudio Scialdone, Tillotts Pharma AG, Switzerland
Claudio Scialdone is Senior Manager for Contract Services & Business Development and joined Tillotts Pharma AG 19 years ago. He has extensive expertise in hard shell capsules liquid filling technology, project management, logistics and interdisciplinary team management. During his time at Tillotts he has managed several development and commercial products including Colpermin®. Before joining Tillotts Claudio worked for 11 years at Ciba/Novartis in Basel in different technical functions in production and engineering departments.

Dr Harald Stahl, GEA, Germany
Dr Harald Stahl is the Group Director Pharma Application and Strategy Management at GEA. He has held various positions at GEA since 1995 and previously worked for Schering AG, Germany. His main fields of interest within Pharmaceutical Solid Dosage Technology are: Granulation, Drying, Coating, Tableting, Process Scale up and Containment technologies. With a diploma in physics and a PhD in chemical engineering, Harald is an experienced trainer, presenter and author, having published more than 100 papers on various aspects of pharmaceutical processing.

Prof Sven Stegemann, Graz University of Technology, Austria
Dr Sven Stegemann is director, pharmaceutical business development at Capsugel, and professor of patient centric drug design and manufacturing at the Graz University of Technology, Austria. Over the course of his career at Capsugel, Dr Stegemann has worked as an advisor to major pharmaceutical companies on ways to improve the design, development and manufacture of pharmaceutical products. In his academic role, Dr Stegemann’s focuses his research on the rational development of patient centric drug products and their associated manufacturing technologies. Dr Stegemann is the founder and chair of the AAPS Focus Group on Patient-Centric Drug Development, Product Design, and Manufacturing as well as the founder and President of the Geriatric Medicine Society.
Date
Wednesday, 8 March 2017, 9:00 – 17:30 h
(Registration and coffee 8:30 – 9:00 h)
Thursday, 9 March 2017, 9:00 – 16:00 h

Venue
NH Hotel Heidelberg
Bergheimer Strasse 91
69115 Heidelberg, Germany
Phone +49 (0)6221 1327 0
Fax +49 (0)6221 1327 100

Fees (per delegate plus VAT)
ECA Members € 1,490
APIC Members € 1,590
EU GMP Inspectorates € 845
Non-ECA Members € 1,690

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/POG when you have registered for the course. 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.

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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.:
Mr Ronny Strohwald (Organisation Manager) at +49-62 21/84 44 51, or per e-mail at strohwald@concept-heidelberg.de.

Social Event
In 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.

Heidelberg – Optimal Accessibility via Frankfurt

Airport Shuttle Service PCS
http://www.pcs-hd.de/
Phone: +49 (0)6221 – 16 46 64, pcs@pcs-hd.de

TLS Airport Shuttle Service Heidelberg
www.tls-heidelberg.de, Phone +49 (0)6221 77 00 77, info@tls-heidelberg.de

Lufthansa Bus Airport Shuttle
http://www.transcontinental-group.com/en/frankfurt-airport-shuttles, Phone +49 (0)6152 – 97 69 099, info@frankfurt-airport-shuttles.de

Train: You can get on the train directly at the airport. Trains leave up to two times per hour and it takes less than one hour to get to Heidelberg. www.bahn.de
**Reservation Form (Please complete in full)**

**Capsule Technology 2017**  
8-9 March 2017, Heidelberg, Germany

- **Mr**  
- **Ms**

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**Phone/Fax**

**E-Mail (please fill in)**

**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 up to 2 weeks prior to the conference: 10 %  
   - cancellation up to 1 week prior to the conference: 50 %  
   - cancellation within 1 week prior to the conference: 100 %

**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 non-appearance or lack of payment. 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).  

**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/doc/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.

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