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# Capsule Technology 2017

## Innovations and Future Requirements

Complete overview of the latest  
developments in capsule  
processing

### 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*



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8-9 March 2017, Heidelberg, Germany

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### 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



# Capsule Technology 2017

8-9 March 2017, Heidelberg, Germany

## Objectives

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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

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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

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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

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Dr Martin Opitz, Dr Andrea Kühn-Hebecker

## Programme

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### 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; DPLs
- 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 trail 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.

## 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](mailto:info@concept-heidelberg.de)

 **Internet:**  
[www.gmp-compliance.org](http://www.gmp-compliance.org)

### Date

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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

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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)

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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

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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

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Via the attached reservation form, by e-mail or by fax message. Or you register online at [www.gmp-compliance.org](http://www.gmp-compliance.org).

### Conference Language

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The official conference language will be English.

### Organisation and Contact

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

CONCEPT HEIDELBERG  
P.O. Box 10 17 64  
69007 Heidelberg, Germany  
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[info@concept-heidelberg.de](mailto:info@concept-heidelberg.de)  
[www.concept-heidelberg.de](http://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](mailto:kuehn@concept-heidelberg.de).

### For questions regarding reservation, hotel, organisation etc.:

Mr Ronny Strohwalde (Organisation Manager)  
at +49-62 21/84 44 51, or per e-mail at  
[strohwalde@concept-heidelberg.de](mailto:strohwalde@concept-heidelberg.de).

### Social Event

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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

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#### Airport Shuttle Service PCS

<http://www.pcs-hd.de/>  
Phone: +49 (0)6221 – 16 46 64, [pcs@pcs-hd.de](mailto:pcs@pcs-hd.de)

#### TLS Airport Shuttle Service Heidelberg

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#### 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](mailto:info@frankfurt-airport-shuttles.de)

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

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Reservation Form (Please complete in full)

**Capsule Technology 2017**

8-9 March 2017, Heidelberg, Germany

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

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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 %  
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**Terms of payment:** Payable without deductions within 10 days after receipt of invoice.

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**Privacy Policy:** By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing

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