



## Speakers



Dr Michael Braun  
Boehringer Ingelheim Pharma



Dr Jean-Denis Mallet  
Former Head of the French Pharma-  
ceutical Inspection Dpt. AFSSAPS



Dr Harald Stahl  
GEA



Prof Dr Karl G. Wagner  
University of Bonn

### NEWS

Stay informed with the GMP  
Newsletters from ECA

The ECA offers various free of charge  
GMP newsletters for which you can sub-  
scribe to according to your needs.

To subscribe, simply scan the  
QR code on the right or visit  
[www.gmp-compliance.org/  
gmp-newsletter](http://www.gmp-compliance.org/gmp-newsletter)



# Granulation & Tableting



Live Online Training  
from 14-16 October 2025



*GMP Compliance and Technology for the Manufacture of Oral Solid Dosage Forms*

## Highlights

- Fundamentals & Scale-Up of granulation processes
  - Fluidbed-Granulation
  - High-Shear Granulation
  - Roller Compaction
- Fundamentals of commercial compression processes
- Global GMP requirements for the manufacture of oral solid dosage forms
- Set-up and features of modern tablet presses
- Excipients and their impact on compression
- Scale-Up of tableting processes
- Handling of highly active materials
- Validation of tableting processes according to EU & US requirements
- Continuous Manufacturing
- Trouble Shooting: how to solve tableting problems

How to solve sticking, capping &  
lamination problems

## Objective

A thorough root cause analysis often reveals that compression issues such as **capping, sticking and weight variations** are related to the upstream granulating process. The objective of this intensive training is therefore to provide a deeper insight into functional relationships between granulation and tableting in order to avoid such problems from the very beginning.

The training also conveys a deeper understanding for tableting and granulating processes, including Scale-Up, which helps in avoiding problems or solving them in practice. This also complies with the GMP principle of understanding and controlling the critical parameters of manufacturing processes. An introduction to the different GMP requirements for manufacturing solid dosage forms worldwide is therefore also subject of this course.

## Background

Granulation and tableting are considered the most commonly used manufacturing processes in the pharmaceutical industry. Of course, a direct compression process is most preferred; in practice, however, an upstream granulation is usually required to obtain a favourable particle size distribution, flowability and compactibility. Different requirements for granulates call for different procedures or technologies. Nowadays, fluid bed, high-shear or dry granulation are the most commonly used processes. An important part of this course is therefore to introduce the different granulation methods, their basic principles and Scale-Up approaches. A deeper insight into process parameters and their influence on product properties is also part of the programme.

The holistic approach to granulation and tableting therefore aims at avoiding issues from the very beginning and to overcome problems at an industrial scale through in-depth process insights. A separate block of this seminar is dedicated to the issue of **Trouble Shooting**. Please bring your questions concerning manufacturing problems with you or send them in beforehand. These challenges are met by new excipients, new control algorithms for tablet presses, laminations as well as special punches and dies. Having the presses run slower should be a last resort after all other options have failed.

Further topics of this training are the tableting of highly active materials, the implementation of recent validation requirements based on the example of tablet manufacturing as well as continuous manufacturing.

## Target Audience

This intensive course is designated for all professionals from Pharmaceutical Development, Production and QA/Regulatory Affairs, who are responsible for the development, the routine production or the Scale-Up and transfer of tableting processes.

## Programme

### Fundamentals of Granulation – what is a good Granulate?

---

- Reasons for granulation
- Overview of the different granulation processes
- Impact of the single processes on the granulate properties
- Understanding the mechanisms of agglomeration
- Characterisation of granulates
- Excipients for granulation and their impact on product properties

### Fundamentals of Fluidbed-Granulation

---

- Design aspects and working principle of a modern fluidbed-dryer
- Basic principle and advantages of fluidbed-granulation
- Impact of process parameters on product properties
- Process insights: how to run, control and design the process

### Scale-Up of Fluidbed Granulation

---

- Which process parameter influences which product quality attribute
- How to scale-up?
- Consequences for the quality critical attributes

### High Shear Granulation: Fundamentals

---

- Plant-geometry and -design
- Process parameters (degree of filling, impeller speed, liquid saturation, process time)
- Methods of drying
- Special Case: Single-Pot-Granulation

### High Shear Granulation: Scale-Up

---

- Influence of impeller speed, liquid addition rate and wet massing time
- Review of end point detection methods
- Scale up trouble shooting

### Fundamentals of Roller Compaction / Dry Granulation

---

Dry granulation is gaining more and popularity in the pharmaceutical industry as it may offer advantages like fast development and Scale-Up, usability in continuous manufacturing operations and improved process control

- Design aspects of a modern roller compactor
- Impact of process parameters like compaction force, gap, roll speed, roll surface, roll width and side seal system on ribbon properties
- Principles of densification: solid fraction as critical material attribute
- Scale-Up

## Wrap-Up: Overview and Comparison of the different Granulation Techniques – An Outlook

---

- Which technique for which kind of product: viewpoint of development
- Which technique for which product portfolio: viewpoint of production
- Comparison of direct and indirect cost: viewpoint of management
- Continuous Manufacturing

## Tableting: Process, Equipment and Formulation

---

- Physical fundamental of powder adhesion
- Compressibility and compactibility of different materials
- How to handle materials with unfavourable compression properties?
- Parts of tablet presses: their function and their impact on product properties
- Comparison of the different control philosophies
- Measurement of the deformation behaviour by compression analysers
- Overview and characterisation of the most important excipients used for compression

## Scale-Up of Tableting Processes

---

- Compression issues during Scale-Up and Transfer Quality by Design helps to overcome Scale-Up issues
- Scale-Up and optimisation of compression processes
- Constant dwell time as Scale-Up approach: theory and practice

## Global GMP Requirements for OSD Operations

---

- OSD Quality Attributes: from homogeneity to dissolution
- Pharmacopoeias and OSD: main monographs
- Requirements from the main guides: US, EU/PICS & WHO
- Requirements from special chapters: US, UK and France

## Handling of highly potent Materials – Containment for Tableting Processes

---

- How much containment is really needed
- Identification of critical operations (with regards to exposition)
- Comparison of different containment concepts
- Examples of existing equipment

## Validation of a Tableting Process

---

- What are the main validation requirements
- Tablets Quality Attributes and Tableting Critical Parameters
- Establishing a protocol not forgetting intermediate steps
- Running the process not neglecting secondary operations
- Following tablets stability issues

## Trouble Shooting in Tableting Processes: Sticking, Capping & Lamination

---

- Reasons for tableting problems
- Possible changes & improvements in upstream processes
- Tips and tricks for production: possible changes within the existing equipment and registration environment

## Speakers

### Dr Michael Braun, Boehringer Ingelheim Pharma

*Head Solid State Sciences and API Engineering*

Dr Michael Braun studied Pharmacy and has been Director Late Stage Drug Product Development at Boehringer Ingelheim Pharma in Biberach where he was responsible for process development, scale-up and product transfers for oral solid dosage forms, sterile and inhalation products. He also was Head of Clinical Trial Manufacturing and is now Head Solid State Sciences and API Engineering.

### Dr Jean-Denis Mallet, *Former Head of the French Pharmaceutical Inspection Dpt. AFSSAPS*

Jean-Denis Mallet is a pharmacist. He was previously the Head of the Pharmaceutical and Cosmetics Inspection Department at the French Health Products Regulatory Agency (Afssaps=ANSM). He also used to work in or with the pharmaceutical industry at various positions including QA, Production, Engineering and GMP Consulting. He has also been auditor of the International Red Cross. Now he works for Pharmaplan.

### Dr Harald Stahl, GEA

*Group Director Application & Strategy Management*

Dr Harald Stahl worked in the Pharmaceutical Development of Schering AG. Since 1995 he served within GEA Process Technology in various positions. Presently he owns the position of a Group Director Application & Strategy Management of GEA.

### Prof Dr Karl G. Wagner, University of Bonn

*Professor for Pharmaceutical Technology at the University of Bonn*

Prof Karl Wagner gained his PhD in pharmaceutical technology and worked at the University of Texas and at the University of Tübingen. Later he joined Boehringer Ingelheim and became head of the laboratory for galenic research, modified release. Since 2013 he is professor for Pharmaceutical Technology at the University of Bonn.



#### Participants' comments:

*„Nice presentations: easy understanding, quite visual.“*

Susana Manrique Manrique, Boehringer Ingelheim España, S.A.

*„Great speakers, a lot of experience and sharing.“*

Felipe Gonzalez Perez, Mucos Emulsionsgesellschaft mbH

*„I loved the case studies presented, and how the presenters answered all the questions well.“*

Tammy Morrison, Jazz Pharmaceuticals Ltd., Great Britain



# Live Online Training: Granulation & Tableting

14-16 October 2025

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

---

---

---

---

---

Title, first name, surname

Department

Company

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

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

ZIP Code

City

Country

D-69007 Heidelberg  
GERMANY

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 until 4 weeks prior to the conference 10 %  
- Cancellation until 3 weeks prior to the conference 25 %  
- Cancellation until 2 weeks prior to the conference 50 %  
- Cancellation within 2 weeks 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 July 2022).  
German law shall apply. Court of jurisdiction is Heidelberg.

**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 [www.gmp-compliance.org/eca\\_privacy.html](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 of the Live Online Training

Tuesday, 14 October 2025, 09.00 to approx. 16.30 h  
Wednesday, 15 October 2025, 09.00 to approx. 16.15 h  
Thursday, 16 October 2025, 09.00 to approx. 16.00 h  
All times mentioned are CEST.

## Technical Requirements

We use Webex for our live online training courses and webinars. At [www.gmp-compliance.org/training/online-training-technical-information](http://www.gmp-compliance.org/training/online-training-technical-information) you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

## Fees (per delegate, plus VAT)

ECA Members EUR 2,090.-  
APIC Members EUR 2,190.-  
Non-ECA Members EUR 2,290.-  
EU GMP Inspectorates EUR 1,145.-  
The conference fee is payable in advance after receipt of invoice.

## Registration

Via the attached reservation form, by e-mail or by fax – **or search and register directly at [www.gmp-compliance.org](http://www.gmp-compliance.org) under the number 21849.**

## Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

## Conference language

The official conference language will be English.

## You cannot attend the Live Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand“ – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at [www.gmp-compliance.org/recordings](http://www.gmp-compliance.org/recordings).

## Organisation and Contact

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

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](mailto:info@concept-heidelberg.de)  
[www.concept-heidelberg.de](http://www.concept-heidelberg.de)

For questions regarding content please contact:  
Dr Robert Eicher (Operations Director) at  
+49(0)62 21/84 44 12, or per e-mail at  
[eicher@concept-heidelberg.de](mailto:eicher@concept-heidelberg.de)

For questions regarding organisation please contact:  
Mr Niklaus Thiel (Organisation Manager) at  
+49(0)62 21/84 44 43, or at  
[thiel@concept-heidelberg.de](mailto:thiel@concept-heidelberg.de)