



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

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Granulation & Tableting



Live Online Training
from 17-19 September 2024



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 of Clinical Trial Manufacturing

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. Now he is Head of Clinical Trial Manufacturing.

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:

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

Tammy Morrison, Jazz Pharmaceuticals Ltd., Great Britain

„Very useful presentations for a non-engineer professional working in the pharma industry. We were given solid foundations on OSD processes and troubleshooting.“

Elena Ojeda, Janssen, Netherlands

„Very professional, excellent speakers.“

Tamas Levay, P&G Health Austria GmbH & Co. OG, Austria



Live Online Training: Granulation & Tableting 17-19 September 2024

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Date of the Live Online Training

Tuesday, 17 September 2024, 09.00 to approx. 16.45 h
Wednesday, 18 September 2024, 09.00 to approx. 16.30 h
Thursday, 19 September 2024, 09.00 to approx. 16.00 h
All times mentioned are CEST.

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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 message. Or you register online at www.gmp-compliance.org.

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.

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Organisation and Contact

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

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