20 YEARS ECA Academy Your GMP/GDP Information Source

Granulation & Tableting

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

Solving sticking, capping & lamination problems

SPEAKERS:

Dr Michael Braun
Boehringer Ingelheim Pharma, Director Late Stage Drug Product Development

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

Dr Harald Stahl
GEA, Group Director Application & Strategy Management

Prof Dr Karl G. Wagner
University of Bonn, Professor for Pharmaceutical Technology at the University of Bonn

10-12 September 2019, Vienna, Austria

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

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

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Objectives

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 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

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

- Fundamentals of Fluidbed Granulation (process & technology)
- Which process parameter influences which product quality attribute
- How to scale-up?
- Consequences for the quality critical attributes

High Shear Granulation: Fundamentals and Scale-Up

- Plant geometry and design
- Process parameters (degree of filling, torque-speed, humidity, time)
- Methods of drying
- Special Case: Single-Pot-Granulation
- Scale-Up: influence of impeller speed, dosing speed

Wrap-Up: Overview and comparison of the different granulation techniques

- How to choose the right one?
- 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

Fundamentals of tableting/compression and tablet-presses

- Physical fundamental of powder adhesion
- Compressibility and compactibility of different materials
- How to quantify these properties?
- How to handle materials with unfavourable compression properties?
- Parts of tablet presses: their function and their impact on product properties
- Special cases: effervescent tablets
- Comparison of the different control philosophies

Excipients for tableting: their selection corresponding to their mechanical compatibility

- Fundamentals of deformation and cohesion of tablets
- Measurement of the deformation behaviour by compression analysers
- Overview and characterisation of the most important excipients used for compression
- Practical task: selection of appropriate API and excipient combinations
- Case Studies

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
- Case studies

Global 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

Validation of a tableting process

- Main Pharmacopoeial descriptions for tablets
- 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
- Writing a clear and trustful report
- Following tablets stability issues
- Conclusion

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

Continuous manufacturing

- Factors for a 6-sigma granulation process
- Which optimisation is possible by using continuous granulation
- Control of continuous processes
- The Consigma Systems as one example for continuous manufacturing equipment
- PAT

Trouble shooting in tableting processes: Sticking, Capping & Lamination

- Reasons for tableting problems
- Possible changes in upstream processes
- How to improve compression properties
- Tips and tricks for production: possible changes within the existing equipment and registration environment

Trouble-Shooting: Discussion

Final part of the course is an open discussion where you will find help for your special cases. Bring your questions/problems/troubles with you to the course or send them beforehand so that the speakers can prepare themselves for finding answers. Send your cases to eicher@concept-heidelberg.de, subject: "Trouble-Shooting Tableting"

Moderator

Dr Harald Stahl

Social Event

On 10 September 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.

Speakers

Dr Michael Braun
Boehringer Ingelheim Pharma, Director Late Stage Drug Product Development
Dr Michael Braun studied Pharmacy and is Director Late Stage Drug Product Development at Boehringer Ingelheim Pharma in Biberach. He is responsible for process development, scale-up and products transfers for oral solid dosage forms, sterile and inhalation products. He is also experienced in formulation development, non-clinical development and R&D project management.

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 during many years at various positions including Quality Assurance, Production Management, Engineering and GMP Consulting. He has also been auditor of the International Red Cross. Now he has been member of the ECA advisory board and works for Pharmaplan.

Dr Harald Stahl
GEA, Group Director Application & Strategy Management
Dr Harald Stahl worked in the Pharmaceutical Development of Schering AG in Germany. At that time his main interest was the aseptic production of pellets. 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. He has published more than 20 papers on various aspects of pharmaceutical production.

Prof Dr Karl G. Wagner
University of Bonn, Professor for Pharmaceutical Technology at the University of Bonn
Karl G. Wagner studied pharmacy and gained his PhD in pharmaceutical technology. After an academic scholarship at the University of Texas he worked at the University of Tübingen at the institute for pharmaceutical technology. 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.

Easy Registration

Reservation Form:
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69007 Heidelberg
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Reservation Form:
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e-mail:
info@gmp-compliance.org

Internet:
www.gmp-compliance.org

Date

Tuesday, 10 September 2019,
10.00 to approx. 18.00 h
(Registration and coffee 09.30 – 10.00 h)
Wednesday, 11 September,
08.30 to approx. 17.50 h
Thursday, 12 September 2019,
08.30 to approx. 15.00 h

Venue

Radisson Blu Park Royal Palace Hotel Vienna
Schlossallee 8
1140 Vienna, Austria
Phone +43 (1) 891 10 - 0
info.parkroyalpalace.vienna@radissonblu.com

Fees (per delegate plus VAT)

ECA Members € 1,790
APIC Members € 1,890
Non-ECA Members € 1,990
EU GMP Inspectorates € 995
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on all three days and all refreshments. VAT is reclaimable.

Accommodation

CONCEPT 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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eicher@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc. please contact:
Mr Niklaus Thiel (Organisation Manager) at
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We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

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Reservation Form (Please complete in full)

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☐ Mr ☐ Ms

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **P.O. Number (if applicable)**

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German law shall apply. Court of jurisdiction is Heidelberg.

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