Granulation & Tableting

29 September – 01 October 2020,
Prague, Czech Republic

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

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

Speakers

Dr Michael Braun
Boehringer Ingelheim Pharma

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

Dr Harald Stahl
GEA

Prof Dr Karl G. Wagner
University of Bonn

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.

Moderator

Dr Harald Stahl
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 Tabletting 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"
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 Pharma-plan.

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 Tubingen 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.

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.
Date
Tuesday, 29 September 2020, 10.00 to approx. 18.00 h
(Registration and coffee 09.30 – 10.00 h)
Wednesday, 30 September 2020, 08.30 to approx. 17.50 h
Thursday, 1 October 2020, 08.30 to approx. 15.00 h

Venue
Corinthia Hotel Prague
Kongresova 1
14069 Prague 4, Czech Republic
Phone +420 261 191 111
Email prague@corinthia.com

Fees (per delegate, plus VAT)
ECA Members € 1,790
APIC Members € 1,890
Non-ECA Members € 1,990
EU GMP Inspectors € 995

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on three 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 reservation, hotel, organisation etc. please contact:
Mr Niklaus Thiel (Organisation Manager) at +49(0)62 21/84 44 43, or at thiel@concept-heidelberg.de.

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We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

*Please note: You may have to enable pop-ups on the Mobility Partner Program website – otherwise the booking platform window will not open.
General terms and conditions

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   a. We are happy to welcome a substitute colleague at any time.
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      - Cancellation until 2 weeks prior to the conference: 10%,
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   - Cancellation until 2 weeks prior to the conference: 10%,
   - Cancellation until 1 week prior to the conference: 50%,
   - Cancellation within 1 week prior to the conference: 100%.

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