ECA Academy
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Speakers

Dr Harald Stahl
GEA

Manufacture of Oral Solid Dosage Forms

Live Online Training on 9 July 2020

GMP & Technology for the Manufacture of Oral Solid Dosage Forms

Highlights

- Fundamentals & Scale-Up of granulation processes
  - Fluidbed-Granulation
  - High-Shear Granulation
- Fundamentals of Commercial Compression Processes
- Critical Process Parameters of a Tableting Process
- Scale-Up of Tableting Processes
- Technology Trends: 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 training is therefore to provide a deeper insight into functional relationships between granulation and tabletting 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.

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 and high-shear granulation are the most commonly used processes. An important part of this training 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. Having the presses run slower should be a last resort after all other options have failed. Therefore Trouble Shooting and solving tableting issues in case of lamination, sticking or weight variances is also part of this training.

Target Audience

This video training is designated for professionals from Pharmaceutical Development, Production and QA/Regulatory Affairs, who are involved in the development, the routine production or the Scale-Up and transfer of tableting processes.

Programme

09.00 – 09.45 h
Introduction – 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

09.45 – 10.40 h
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

10.40 – 11.00 h Break

11.00 – 11.35 h
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

11.35 – 12.20 h
Fluidbed-Granulation: Fundamentals

- 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

12.20 – 12.45 h Questions & Answers

12.45 – 13.30 h Break

13.30 – 14.30 h
Fluidbed Granulation: Scale-Up

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

14.30 – 14.45 h Break

14.45 – 15.25 h
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
- Continuous manufacturing- pros and cons
- Continuous manufacturing- real world examples

15.25 – 15.55 h
Fundamentals and Scale-Up of Tableting

- Physical fundamental of powder adhesion
- Excipients and their selection corresponding to their mechanical compatibility
- Critical Process Parameters
- Parts of tablet presses: their function and their impact on product properties
- Comparison of the different control philosophies
- 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

15.55 – 16.10 h Break

16.10 – 17.00 h
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

17.00 – 17. 30 h Questions & Answers

Speakers

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.

To ensure a high quality transmission the presentations of this seminar were recorded in advance.
Two discussion panels: The seminar includes live Q&A sessions with the speakers (each about ½ hour in the morning and at the end of the event days. This provides the opportunity to ask questions via the chat, which the speakers will then answer.

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Reservation Form (Please complete in full)

Manufacture of Oral Solid Dosage Forms, Live Online Training on 9 July 2020

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Date of the Live Online Training

Thursday, 9 July 2020
09.00 to approx. 17.30 h CEST

Technical Requirements

For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings.
At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer 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 € 790
APIC Members € 890
Non-ECA Members € 990
EU GMP Inspectorates € 445
The conference fee is payable in advance after receipt of invoice. VAT is reclaimable.

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.

Ordering a Recording

Independent from the Live Online Training, you can also order a recording of this training at the same conditions. This recording will be provided on our media server. All you need to watch it is an Internet browser – no additional software. You can book the recording of the Live Online Training at any time at https://www.gmp-compliance.org/gmp-webinars/recorded-gmp-webinars.

Organisation and Contact

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

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