

SPEAKERS:



Dr Michael Braun
*Boehringer Ingelheim
Pharma*



Dr Harald Stahl
GEA



Image: GEA Pharma Systems

23-24 May 2017, Barcelona, Spain

HIGHLIGHTS:

- Fundamentals of
 - High Shear Granulation
 - Fluid Bed Granulation
 - Dry Granulation
- Critical process and product parameters
- Selection of the right process
- Scale up of
 - High Shear Granulation
 - Fluid Bed Granulation
 - Dry Granulation
- Trouble shooting: solving process and technology problems



Granulation

23-24 May 2017, Barcelona, Spain

Objectives

This course aims at providing you a deeper understanding of the different granulation techniques: Fluid Bed Granulation, High Shear Granulation and Roller Compaction.

This includes optimisation and trouble-shooting during:

- The development phase
- The scale-up and transfer phase
- The routine and full-scale production

Background

Granulation is one of the most important manufacturing processes in the pharmaceutical and food industry. In the manufacture of pharmaceutical drugs, APIs and excipients are granulated before compression to tablets. This enhances flowability and adhesion of the powdery particles.

Different demands regarding the properties of granulates require different techniques. Today, fluid bed granulation, roller compaction, high shear granulation and spray drying are the most important techniques. Knowing how processing parameters influence product properties is essential for obtaining a product which meets the quality specification and requirements for further processing. In fact, most of the problems occurring in the compression step are caused by inappropriate granulation. A deeper understanding of the different granulation techniques is essential.

In addition to scale up aspects of the different granulation techniques this will be the main focus of this course.

- Fluid Bed Granulation
- High Shear Granulation
- Dry Granulation
- How to select the right technique
- How to manage the different processes
- Trouble shooting

Another highlight is the implementation of PAT in continuous granulation processes. This technology and most of all the process understanding help controlling varying process parameters and influences from raw materials. It also allows minimizing time and costs for scale up projects.

Target Audience

This event is designated for all professionals from Development and Production, who are responsible for the development, the routine production or the scale-up and transfer of granulation processes.

Moderator

Dr Harald Stahl

Programme

Fundamentals - what is a good granulate

Even there is a recent trend to use often dry methods in the production of solid dosage forms granulation remains for 2 reasons to be one of the most important unit operations. First it allows the use of simpler and cheaper excipients which is of paramount importance if large volume products have to be produced and second granulation can massively improve the compression behaviour of materials.

- Overview of granulation methods
- Theory of granulation
- Benefits and limitations

Fundamentals - high shear granulation

High shear granulation is a popular granulation method. It is a robust granulation technique capable of handling most APIs, to produce granules of intermediate densities, between roller compacted and fluid bed processed granules. Operationally, control of the shear energy input for granulation is by changing the impeller speed. Design of the impeller and feed load have their effects on the granulation process. Thus, together with the impeller speed, the method and rate of liquid addition are also important critical process attributes to control the granulation process.

Fundamentals - fluid bed granulation

Fluid beds were first adopted by the pharmaceutical industry for drying granules after wet massing. Later, fluid bed granulation was introduced, to produce free flowing, spherical and porous granules direct from powders. The fluid bed granulator depends entirely on the fluidising air to lift and dry particles. The liquid addition rate and method of delivery system are important control determinants of the granulation rate. Various innovative changes have improved the fluid granulation processors. A discussion of the fluid bed technique and innovations to the fluid bed granulation processor will be provided.

Dry Granulation / Roller Compaction

Dry granulation is a common unit operation in solid dose manufacture. Small footprint, fast process development and scale-up, together with the option for continuous manufacturing are compelling arguments why roller compaction has become even more important for pharmaceutical industry nowadays.

Enhanced product and process understanding, following a Quality by Design approach, is key for a successful technology transfer to operations and smooth implementation in routine manufacture.

The session will cover following topics:

- Introduction and basic principles of roller compaction
- Scale-up and process monitoring
- Case studies

Even high shear granulation processes are already in use for many decades still scale up is often done by trial and error. In this session more scientific approaches are introduced.

- Theory of high shear granulation
- Identification and scale up of CPPs
- The role of the end point- review of available technologies
- The importance of suitable equipment and instrumentation

Scale-up fluid bed granulation

By their nature fluid bed processes can be much easier described by scientific models than high shear processes. However often these possibilities of science based scale up approaches have been ignored.

- Theory of fluid bed processes
- Identification and scale up of CPPs
- The importance of suitable equipment and instrumentation

Scale Up of wet granulation processes: Practical aspects

Wet granulation processes, like fluid-bed and high shear granulation, have been widely applied for decades in pharmaceutical industry. Although multiple scale-up models and approaches are described in literature, mechanistic process understanding is still not yet mature. This session will focus on translation and relevance of different scale-up models into practice.

- High shear and fluid-bed granulation: theoretical scale-up considerations
- Case study: Scale-up of a high shear process
- Case Study: Scale-up of a fluid-bed process

New Trends in Granulation: PAT, continuous manufacturing, etc.

Continuous processing is widely used in other industries such as food or chemicals. Over recent years also the pharmaceutical industry showed an increasing interest as well as authorities pushing for a wider use.

- Why go continuous?
- Examples of installations
- Regulatory situation
- Control strategy

Trouble-Shooting Workshop

In this interactive session, all the key elements of the preceding lectures are brought together. A systematic approach is presented and discussed with regards to the extent, trouble shooting measures have to be escalated: what can be done on the operator level, what can be done on the supervisor level, what must be done by development.

Speakers



Dr. Michael Braun, *Boehringer Ingelheim Pharma GmbH*

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 project management in R&D.



Dr Harald Stahl, *GEA*

Dr Harald Stahl worked in the Pharmaceutical Development of Schering AG in Germany. Since 1995 he served within GEA Process Technology. 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.

Social Event

In the evening of the first 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.



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Reservation Form (Please complete in full)

Granulation

23-24 May 2017, Barcelona, Spain

Mr Ms

Title, first name, surname

Company Department

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

Street/P.O. Box

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Date

Tuesday, 23 May 2017, 09.00 to approx. 17.30 h
 (Registration and coffee 08.30 - 09.00 h)
 Wednesday 24 May 2017, 08.30 to approx. 15.00 h

Venue

Barceló Sants Hotel
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Fees (per delegate plus VAT)

ECA Members € 1,490
 APIC Members € 1,590
 Non-ECA Members € 1,690
 EU GMP Inspectorates € 845
 The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both 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 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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