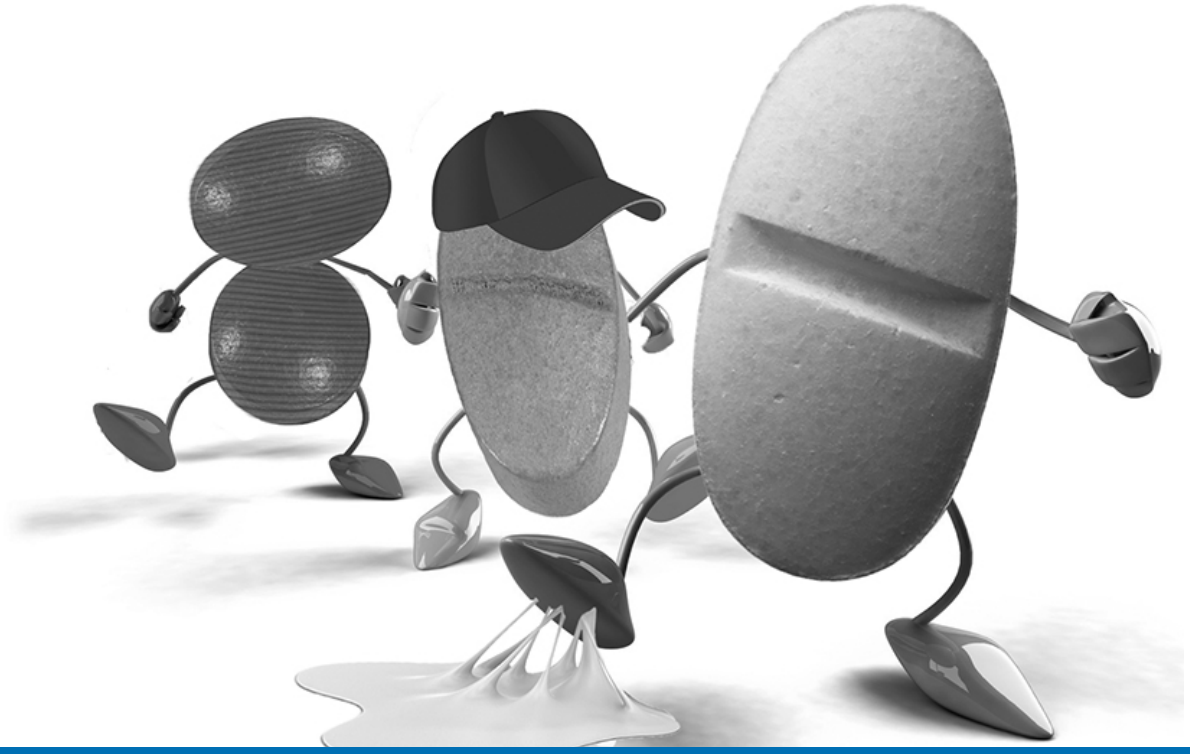

Sticking - Capping - Lamination

Tableting problems from Development to full-scale Production

7-8 October 2015, Berlin, Germany

SPEAKERS:

Dr Michael Braun
Boehringer Ingelheim Pharma

Michael Van den Bossche
GEA

Prof Dr Karl G. Wagner
University of Bonn

LEARNING GOALS:

- Avoiding tableting problems during development
  - Mechanical compatibility of excipients and APIs
  - Prerequisites for successful tableting
  - Critical Process Parameters and Critical Quality Attributes
- Avoiding tableting problems during scale-up
  - Scale-up principles
  - Usage of CPPs & CQPs
  - Transfer strategy
- Trouble-Shooting in full-scale production
  - Reasons for capping and what to do
  - Reasons for sticking and what to do
  - Reasons for lamination and what to do
  - Reasons for variations in weight, failing in hardness and disintegration

ECA ACADEMY

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

This course aims at explaining were problems in the tableting process come from and how these issues can be avoided or solved. This includes optimisation and **trouble-shooting** during:

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

Background

Tableting ranks among the most important pharmaceutical manufacturing processes. Representing about 50% of the total pharmaceutical market, tablets have a particular position. Yet, although tableting is wide spread and used since the invention of the stamp/matrix principle in 1843, there are still open questions and problems in the daily routine which often appear during scale-up or transfer from development. Also in the daily routine with validated processes, issues may arise like for example tablets which suddenly start capping or sticking, or tablets with decreasing hardness or with fluctuations of the content.
Many of these problems originate from the development phase of the tablet and only become visible after transfer to the commercial plant, were usually much bigger and faster presses are used.

The development process should be a holistic approach which takes into account the requirements of a high speed rotary tablet press on its feed materials. The definition of critical process parameters, the selection of excipients based on the mechanical compatibility of API/excipient and the formulation itself must be seen in the full context.

But even after a transfer to the commercial plant, there are some possibilities to get rid off tableting problems, besides lowering the speed of compression. Using coatings, special matrices and stamps or changing the relative humidity or tempering of the tablet press are some amongst others, we are going to talk about. Also the optimisation of upstream processes such as granulation often allows a significant improvement of the subsequent tableting process.

Target Group

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

Programme

Development & Formulation

Mechanical compatibility of excipients and APIs

- Basics on the deformation and cohesion in tablets
- Determination of the deformation characteristics using compression analysis
- Explanation of the most relevant excipients
- Classification of excipients in deformation classes
- Finding the right API and excipient combination
- Case studies

Development of a formulation for tableting - or – the development point of view

In this presentation it is shown, how an early formulation is developed corresponding to given parameters like API, content and tablet hardness. Usually equipment available in the development department is used, which often differs to the equipment used in production-scale. This example formulation will be used and further developed in the following presentations.

Prerequisites for successful tableting

Making compressible mass – or -what is essential for successful tableting?

- Mechanism of compaction
- Compaction behavior of pharmaceutical materials
- Granulation
  - Mechanisms of agglomeration
  - The different granulation types and their influence on the granules' characteristics
  - Influence of liquid and energy input, geometry of equipment etc. on the compressibility
- The compression cycle

Tablet presses in production scale

- Why formulations from development often make problems
- Modern instrumentation of tablet presses
- The differences of 'old' and 'new' presses
- Effects of changing the filling time, compression time, circulation speed...
- The influence of tooling

Transfer and Scale-Up

Theory
In this presentation the developed formulation is given to production. Will it work?

Scale-up and transfer from development to production: The Real World
In this session a systematic approach, following QbD principles for scale-up and transfer from development to production will be presented. Case studies focusing on the scale-up of the compression step will illustrate how this can be realized in practice and further look into technical issues and solutions

- Identification and evaluation of Critical Process Parameters and Critical Attributes and link to Drug Product Quality Attributes
- Scale-up principles and transfer strategy
- Case studies

Debugging – make it work

Re-formulation
In this presentation, the initial formulation is re-designed by using the knowledge gained through the presentation. Revealing of parameters which should have been defined earlier:

- Critical quality attributes
- Critical process parameters
- Linkage of CQAs and CPPs for the example formulation

Trouble-Shooting
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:

- Reasons for capping and what to do
- Reasons for sticking and what to do
- Reasons for lamination and what to do
- Reasons for variations in weight and what to do
- Reasons for failing in hardness and what to do
- Reasons for failing in disintegration and what to do

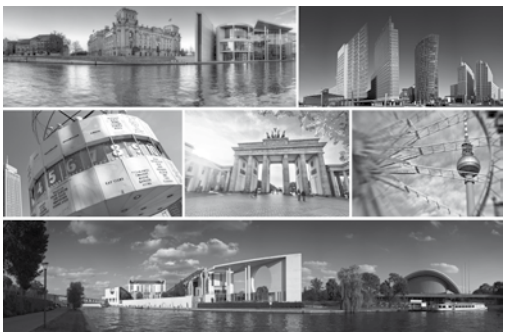
Speakers

Dr Michael Braun
Boehringer Ingelheim Pharma GmbH
Dr Michael Braun studied Pharmacy and is head of process development at Boehringer Ingelheim in Biberach. He is responsible for the 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.

Michael Van den Bossche
GEA
Michael holds a master in biochemical engineering. 10 years ago he joined GEA, where he promoted the GEA compression equipment. Currently he is part of the GEA continuous team, which is covering all activities related to the development and positioning of the ConsiGma™ technology within the OSD manufacturing landscape.

Prof Dr Karl G. Wagner
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.

Social Event



On October 7 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.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

If the bill-to-address deviates from the specifications on the right, please fill out here:

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Sticking - Capping - Lamination
7-8 October 2015, Berlin, Germany

☐ Mr ☐ Ms

Title, first name, surname

Company Department

Important: Please indicate your company's VAT ID Number **PO Number if applicable**

Street/P.O. Box

City Zip Code Country

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P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

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GERMANY

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees: Cancellation
- until 2 weeks prior to the conference 10 %
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Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012)

Date

Wednesday, 7 October 2015, 10.00 to approx. 18.15 h
(Registration and coffee 09.30 – 10.00 h)
Thursday, 8 October 2015, 08.30 to approx. 14.15 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
Phone +49 (0)30 212 7 - 0
Fax +49 (0)30 212 7-799

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, lunch and dinner on the first day, lunch snack on the second day 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 when you have registered for the event. Please use this form for your room reservation to receive the specially negotiated rate for the duration of your stay. 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

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

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