Image: Bosch

Tableting
Equipment, Trouble Shooting & Compliance

10-11 September 2013, Munich, Germany

SPEAKERS:

Dr Afshin Hosseiny
ECA & Tabriz Consulting Limited

Dr Rob Lammens
Technical Services Consult Lammens

Dale Natoli
Natoli Engineering Company, Inc., USA

Dr Harald Stahl
GEA Pharma Systems

PD Dr Karl Gerhard Wagner
Boehringer Ingelheim

LEARNING OBJECTIVES:

- Fundamentals of tableting
- Overview of tablet presses on the market
- Excipients used in tableting
- Tooling
- Trouble shooting: Capping, sticking, variations of content or weight
- Handling highly active compounds
- Validation & cleaning validation
- QA aspects of tablet manufacturing

ECA
EUROPEAN COMPLIANCE ACADEMY

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

Tableting

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Learning Goals

This conference aims at explaining the basics of tableting and presenting the current state of the art in pressing tablets. Another essential topic to be addressed is the handling of issues and deviations within the tableting process.

- Basics of tableting
- Trends for excipients and tablet presses
- Tableting of pellets, multilayer-tablets and effervescent tablets
- Cleaning, validation and QA issues
- Trouble-shooting

Background

Tableting is still the most important pharmaceutical process for the manufacture of medicinal products. Representing about 50% of all dosage forms, tablets have a particular position. Indeed, tablets offer many advantages like low production costs, packagability as well as high stability. Moreover, the medication of tablets is rather easy for patients.
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 in 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. A whole block of the course is dedicated to trouble-shooting and discussions will address such issues. Please bring concrete examples - or send them in in advance.
Furthermore, we will present challenges with new excipients, new control algorithms for tablet presses, laminations, or special matrixes and stamps. In future, through FDA's initiative, Process Analytical Technology (PAT) will increase in importance also for the production of tablets.

Target Group

This event is designated for all managers and executives from Pharmaceutical Development, Production, In-process and Control who would like to deepen and extend their basic knowledge of tableting. It is also designated for experienced professionals who are looking for solutions to their specific problems.

Moderator

Dr Harald Stahl

Programme

Fundamentals of compression

- Mechanism of compaction
- Compaction behaviour of pharmaceutical materials
- The compression cycle

Tablet Presses

- Review on the development of rotary presses
- Operating principle and control algorithm of different commercially available presses
- Difference between constant force and constant volume presses
- Registration of force, strength and weight control and evaluation of in-process data
- Increase of tablet output per time unit
- Use of single punch presses (compaction simulators) for investigating tableting properties of powders
- PAT in tableting

Selection of tableting excipients based on API/excipient mechanical compatibility

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

Image: GEA

Rotary Tablet Press Tooling

- Common Terminology
- Tooling Standards / Specifications
- Common Tool Configurations
- Common Tablet Compression Problems
- Tablet and Tool Troubleshooting
- Tablet Design
- Multi-Tip Tooling

Tableting of highly potent materials
- Fundamentals of containment
- How much containment is required?
- Application examples

Trouble shooting
- Capping- Sticking- Lamination- Weight variations
- Reasons
- How to improve the situation

Tablet manufacturing Validation (granulation & tableting)
- Developing the validation plan
- Defining the critical parameters for:
  - Granulation process
  - Compression
  - Film coating
- Validation protocols
- Data review and reporting
- Few Tips on validation

Cleaning validation
- Approaches to cleaning
- Defining the acceptance criteria
- Sampling and testing
- Reporting of findings
- Revalidation

QA aspects of tablet manufacturing
- What are the key issues for QA?
- How to minimise risk of cross contamination?
- Investigations and root cause analysis
- CAPA process to minimise risk of recurrence

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 Afshin Hosseiny
Tabriz Consulting Limited, Great Britain
Dr Afshin Hosseiny is Managing Director of Tabriz Consulting Ltd. Before working as a consultant, he was Director of Quality Assurance for the Global Supply Network of GlaxoSmithKline

Dr Rob Lammens
Technical Services Consult Lammens
Dr Lammens studied Physical Chemistry and performed his PhD in Pharmaceutical Technology, before he joined the Pharmaceutical Technology Department of Bayer AG at Leverkusen from 1981 till 2004. Since 2001 he is a senior lecturer at the Pharmaceutical Technology Department of the University of Bonn and is running the company Technical Services Consult Lammens.

Dale Natoli
Natoli Engineering Company, Inc., USA
Mr Natoli, President of Natoli Engineering Company, Inc., has over 32 years of troubleshooting experience in the tablet compression industry. Natoli has published articles for major pharmaceutical publications and authored chapters in three books, including the "Tablet Specification Manual", sponsored by the American Pharmaceutical Association. He presents lectures for universities, pharmaceutical associations and tablet manufacturers worldwide.

Dr Harald Stahl
GEA Pharma Systems, Germany
Dr. Harald Stahl worked for 3 years 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 Senior Pharmaceutical Technologist of GEA Pharma Systems. He has published more than 20 papers on various aspects of pharmaceutical production.

PD Dr Karl Gerhard Wagner
Boehringer Ingelheim Pharma GmbH & Co. KG, Germany
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. He still holds the position of an external lecturer at the University of Tübingen with the main research on modified release dosage forms.

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@gmp-compliance.org

Internet:
www.gmp-compliance.org

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

CONCEPT HEIDELBERG
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Fax +49 (0) 62 21/84 44 34

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GERMANY

Reservation Form (Please complete in full)

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Tableting
10-11 September 2013, Munich, Germany
☐ 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

City Zip Code Country

Phone/Fax

E-Mail (please fill in)

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 %
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

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Terms of payment: Payable without deductions within 10 days after receipt of invoice.
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

Tuesday, 10 September 2013, 09.00 to approx. 18.30 h
(Registration and welcome coffee 08.30 - 09.00 h)
Wednesday, 11. September 2013, 08.30 to approx 15.30 h

Venue

Holiday Inn Munich -City Centre
Hochstraße 3
D-81669 Munich
Phone +49 (0)89 - 4803 0
Fax +49 (0)89 – 448 7170

Fees

ECA Members EUR 1,490.- per delegate plus VAT
APIC Members EUR 1,590.- per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members EUR 1,690.- per delegate plus VAT
EU GMP Inspectorates EUR 845,- per delegate plus VAT
The conference fee is payable in advance after receipt of invoice and includes conference documentation, lunch and dinner on the first day 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

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