Workshop:

SCALE-UP & PROCESS OPTIMIZATION IN ORAL SOLID DOSE MANUFACTURING (OSD)

28 – 30 November 2017
WHY PARTICIPATE?

This newly created workshop wants to fulfil the increasing demand of experts and operators in the industry when it comes to scale-up and optimisation of their solid dose manufacturing processes.

The course covers standard and sophisticated technologies for the relevant solid dose manufacturing steps of granulation, pelletisation and coating in fluid bed, high shear and drum coating equipment.

Besides expert lectures and practical training, the attendees may also exchange their experiences with attending colleagues and speakers in a comforting work atmosphere.

The workshop combines theoretical and regulatory background with practical experiences in the technical and in the GMP lab.

It introduces to the principles of Quality by Design (QbD), late stage Process Analytical Technologies (PAT) and includes case studies from real industry life.

At the end, the attendees shall take with them an enhanced knowledge and also some practical rules to be able to improve their daily work-life.

WHO MAY ATTEND?

Kindly invited are all interested researchers, engineers and operators from pharmaceutical industry and all other industries that deal with oral solid dosing.
PROGRAM

TUESDAY, 28 NOVEMBER 2017

12:00  Transfer from hotel to TTC
12:15  Reception and registration
12:45  Introduction. Klaus N. Moeller

13:00  Principles of scale up of fluid bed granulation & particle coating - Influences of process parameters. Scaling up of fluid bed processes is not magic but based on sound science and process understanding. Defining correct processing parameters is the basis for robust and reproducible commercial production. The key principles of fluid bed granulation and coating scale up will be discussed as well as means to avoid potential obstacles. Norbert Pöllinger

14:00  Regulatory aspects of process changes and scale-up - a hurdle? Providing information on evaluation of the scale-up processes in a marketing authorisation procedure for a drug product - comparison of three different scenarios: classical approach, design space approach and continuous manufacturing. NN

15:00  Coffee break

15:30  Scale-up of tablet coating processes incl. thermodynamic considerations. A profound understanding of the film-coating processes itself is an essential prerequisite for up-scaling. Operators have to know the crucial processing attributes which need to be observed and evaluated in order to implement an up-scaling strategy. Based on some fundamental thermodynamical considerations an up-scaling procedure will be developed for drum coating processes. Various case studies illustrate how to transfer this theory into practice. Thorsten Cech

16:30  Principles in scaling-up high shear wet granulation processes in pharma. Presenting the key process parameters of high shear wet granulation and explaining the fundamentals of scale-up. An overview of common scale-up methods in pharmaceutical industry will be given. Katja Engelhard

17:00  Transfer to hotel
19:30  Workshop dinner
WEDNESDAY, 29 NOVEMBER 2017

08:40  Transfer from hotel to TTC

09:00  QbD case study: How to identify the Critical Process Parameters (CPPs) for the commercial drug product manufacturing process. Introducing into principles of QbD and giving an insight into recent developments. Explaining how manufacturing and quality processes and regulatory implications are influenced. Laura Jerke

09:45  Design of Experiments: Basics and application in pharmaceutical manufacturing. How the principles of Quality by Design can be easily applied to ensure the quick and successful design and optimization of a production process. Philippe Solot

10:45  Coffee break

11:15  Case study: PAT-applications in optimisation of pellet coating (NIR). PAT technologies lead to advanced process understanding to ensure robust production processes and a consistent product quality. Frank Wolters

12:00  Lunch

13:00  The influence of droplet size for scale-up: gambling or rational approach. Presenting an innovative approach in determining nozzle characteristics and evaluating scale-up parameters for different nozzle types used in fluid bed units. Lilia Sprich

13:45  From micro to commercial scale - a look at real world equipment. Discovering the variety of state-of-the-art fluidized bed systems for dedicated applications. Factory tour.

14:45  Coffee break

Practical Session: The hands-on experience with pellets in GMP and technical lab environments

15:00  Intro practical demonstrations. Lilia Sprich

15:15  Practical Demonstrations: Innovation Center
- Lab trial 1: Granulation – Mini Glatt with at-line measurement of particle size distribution
- Scale-up 1: Pilot granulation – GPCG 10 including moisture monitoring with microwave
- Process optimization: Pellet - Wurster Coating – GPCG 2 including online monitoring of particle size increase
- Lab trial 2: High shear granulation process in a TMG
- Scale-up 2: High shear granulation in a VG 400 in production scale

Claudio Cortazzo, Björn Haepp

17:30  Transfer to hotel

19:30  Workshop dinner
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<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tr>
<td>08:40</td>
<td>Check-out from hotel and transfer to TTC</td>
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<tr>
<td>09:00</td>
<td><strong>Simulation methods for scale-up of fluidized bed spray granulation process.</strong> Presenting various solutions for process visualization and optimization, such as Discrete Element Modeling (DEM), population balance modeling, flow-sheet simulation and shortcut-methods. <em>Stephan Heinrich</em></td>
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<td>09:45</td>
<td><strong>Considerations in equipment design and performance in scale-up.</strong> Discussion of technical design options for fluidized bed equipment. Summary of technical and process parameters to be considered in scale-up procedures. Explanation of scale-up principles and procedures using case studies. <em>Michael Jacob</em></td>
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<td>10:30</td>
<td>Coffee break</td>
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<td>11:00</td>
<td><strong>Case study: PAT-applications in dry powder layering with rotor technology in fluid bed.</strong> Online moisture control as tool for process development, scale-up activities and routine production during powder layering processes. <em>Kathrin Lange</em></td>
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<td>11:45</td>
<td><strong>Case study: Oral solid processing in continuous mode monitored by on-line measurement of particle size and distribution.</strong> <em>Mike Mulcahy</em></td>
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<td>12:30</td>
<td>Summary</td>
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<td>12:45</td>
<td>Snack Buffet and Log Out</td>
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<td>13:00</td>
<td>Transfer to Basel, German Railway Station (Badischer Bahnhof), Swiss Railway Station (SBB) and EuroAirport</td>
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**SPEAKERS**

Thorsten Cech  
BASF SE, Germany

Katja Engelhardt  
Glatt Systemtechtechnik  
Dresden, Germany

Prof. Dr. Stephan Heinrich  
Technische Universität  
Hamburg-Harburg, Germany

Dr. Michael Jacob  
Glatt Ingenieurtechnik GmbH  
Weimar, Germany

Laura Jerke  
F. Hoffmann-La Roche Ltd., Switzerland

Dr. Kathrin Lange  
Takeda, Germany

Mike Mulcahy  
Innopharmalabs Ireland, Ireland

Dr. Norbert Pöllinger  
Glatt GmbH, Germany

Dr. Philippe Solot  
AICOS Technologies AG, Switzerland

Lilia Sprich  
Glatt GmbH, Binzen

Dr. Frank Wolters  
Boehringer Ingelheim, Germany

**MODERATION**

Klaus N. Moeller, Technology Training Center, Germany

**DETAILS**

>> The participation fee is € 1490,− (exclusive of VAT).

>> This fee includes participation, accompanying course notes, daytime catering and dinner. Any other expenses are to be borne by the attendee.

>> Free attendance granted to a limited number of students.

>> Participation is limited. Registrations will be confirmed on a first come first serve basis.

>> Courses taking place in Germany are subject to Value Added Tax (VAT).

>> Each participant will receive a certificate of attendance at the end of the course.

>> Registration deadline: 12 October 2017
ORGANIZATION AND LOCATION

TTC - Technology Training Center
Regina Bernstein / Klaus N. Moeller / Bianca Nowak
Werner-Glatt-Straße 1, 79589 Binzen, Germany
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E-mail ttc@ttc-binzen.de

For further information or online registration please visit us on

www.ttc-binzen.de

REGISTRATION

Workshop:
SCALE-UP AND PROCESS OPTIMIZATION IN ORAL SOLID DOSE MANUFACTURING (OSD)
28 – 30 November, 2017

Name
Company
Dept.
Function
Address

Phone
Fax
E-mail

☐ Yes, I want to receive information about future TTC workshops.

Signature

☐ Accommodation required from

Check-in day: 
Check-out day: = nights
(Approx. 74,00 €/night incl. breakfast)