Granulation – From powder to tablet
"Expert of Solids" Certification, Seminar 2
November 27 to 29, 2012

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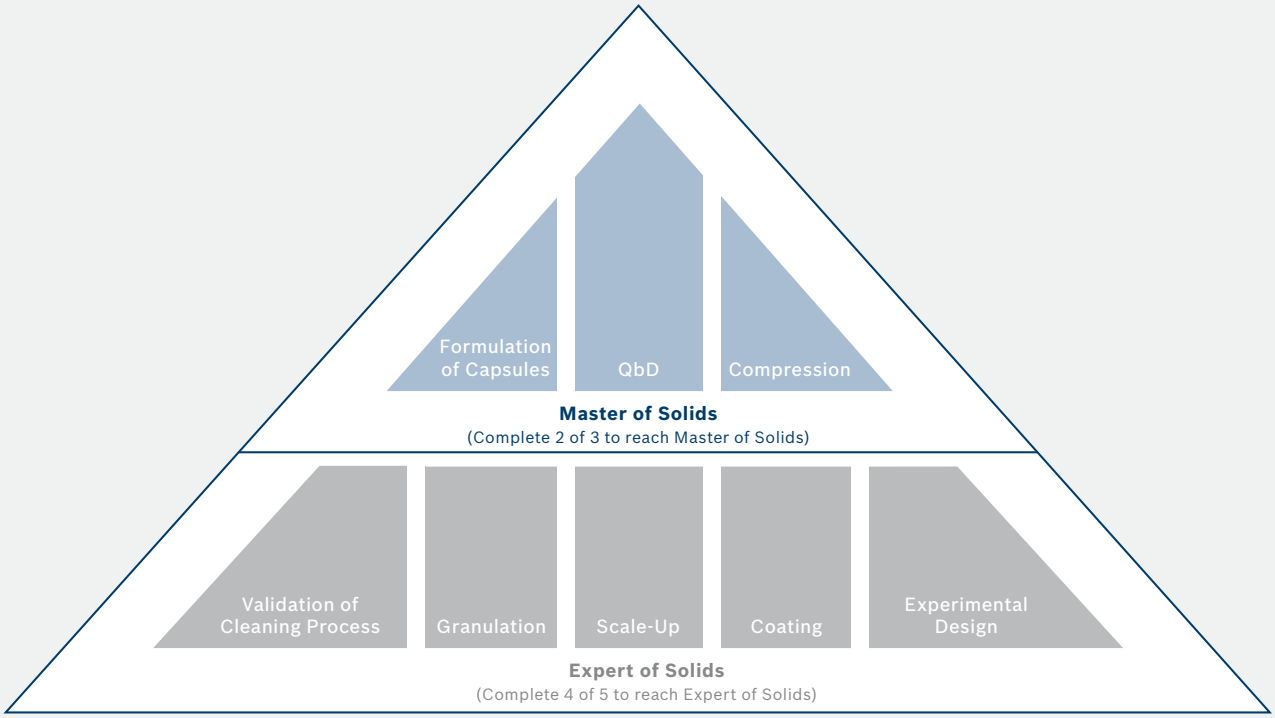
“Expert of Solids” and **“Master of Solids”** certificated by Hüttlin GmbH

The “Expert of Solids” (four seminars, certificated by Hüttlin) is the preliminary stage of the “Master of Solids” (additional two seminars, certificated by Hüttlin).

All aspects of development and production of solid dosage forms will be highlighted from the basis of granulation via the experimental design to the compression of the tablets. An **“Expert of Solids”** will gain detailed knowledge in manufacturing solid dosage forms.

Individual courses on **“Expert of Solids”** can be taken.

Seminars and trainings – Leadership through knowledge



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Granulation – From powder to tablet

Today granulation is still the core process in the production of solid dosage forms. For this reason the second seminar of “Expert of Solids” is focused on drying and granulation.

On the first day participants are introduced to the granulation process, flow properties and critical parameters will be explained. Participants will have the opportunity to familiarise themselves with the equipment for wet granulation.

Day two begins by focusing on analytic and excipients used for granulation and the link to compression of the granules. After lunch participants sign in special interest groups and are working on small granulation projects.

The third day will start on with the topic trouble shooting and a case study about granule properties. The seminar will close with a presentation of the group results.

Seminar 2 – “Expert of Solids” certificated by Hüttlin
November 27 to 29, 2012

Agenda	Day One: November27, 2012
8.00 – 8.15	**Registration**
8.15 – 8.30	**Introduction and Welcome** – Dr. M. Knöll, ***Hüttlin***
8.30 – 9.30	**Introduction, definitions and methods of tablet production with focus on wet granulation** – Prof. Dr. Dr. h.c. A. A. Sakr, ***USA/Egypt*** The ideal characteristics of compressed tablets and the “intelligent” choice of tablet excipients for specific tablet properties will be discussed. A brief comparison between the technologies of tablet manufacturing will be conducted with special emphasis on wet granulation.
9.30 – 10.45	**Tablet development and the role of excipients** – Dr. E. Stoyanov, ***ISP GmbH*** The presentation describes some of the most used tablet excipients and their advantages and disadvantages in the tablet development, differences in wet granulation and direct compression as well as some case studies.
10.45 – 11.00	**Coffee Break**
11.00 – 12.00	**Basics of Hüttlin technology and process selection** – Dr. M. Knöll, ***Hüttlin*** Basics of the function of the fluid bed and high shear mixer. Thermodynamical basics of drying and of the fluid bed. Comparison between fluid bed and dry oven. Comparison between fluid bed and high shear mixer granulation. Advantages and disadvantages of both methods and how to select the right process.
12.00 – 13.00	**Lunch Break**
13.00 – 14.30	**Process parameters of high shear and fluid bed granulators** – Dr. M. Knöll, ***Hüttlin*** Parameters influencing the granulating process and how to use them for process control.
14.30 – 14.45	**Coffee Break**
14.45 – 17.45	**A practical introduction to the granulation process using a high shear mixer and a fluid bed combined with analytical methods** – Dr. M. Knöll, R. Sill, M. Frank, ***Hüttlin*** The participants will be divided into several groups and will be introduced to the wet granulation process, the analysis and the compression of the granules.
17.45	**Transfer to hotel**

Agenda	Day Two: November 28, 2012
8.45 – 9.15	**Capsule filling as an alternative to direct compression** – E. Sternberger-Rützel, ***Bosch*** Capsule filling is an easy and straight forward process and thus a viable alternative to direct compression. Encapsulation provides an easy alternative to direct compression because a wide variety of formulations, even at higher API levels, can be handled and dosed on a capsule filler with excellent dosing accuracy and uniformity. Fundamentals starting from the process to formulations will be introduced during the presentation.
9.15 – 09.45	**In Process Control (IPC)** – Prof. Dr. Dr. h.c. A. A. Sakr, ***USA/Egypt*** Process Analytical Technology includes systems for continuous analysis and control of manufacturing processes via rapid measurements during processing, of quality and performance attributes of raw and in-process materials and processes to assure acceptable end product quality at the completion of the Process. The presentation will describe the application of on-line Raman spectroscopy to evaluate the effect of blending time on low dose, 1%, blend uniformity of azimilide dihydrochloride.
09.45 – 10.30	**Tablet manufacturing by direct compression** – J. Croenlein, ***Colorcon*** This presentation provides an overview of direct compression as one of the simplest and cheapest methods of tablet manufacture. A comparison is made of the formulations produced by both fluid bed and high shear granulation to the direct compression approach using an amlodipine besylate formulation. Two DC case studies are also discussed for cyclobenzaprine hydrochloride and sucralfate formulations.
10.30 – 11.00	**Coffee Break**
11.00 – 12.00	**Tabletting and compression** – Dr. F. Oprach, ***Sandoz*** The calculation and use of dwell times for production and validation in compressing of solid dosage forms. The use of compression hardness profiles for a better process understanding, set-up of compressing machines and justification of process limits. Impacts of the filling curve and the rotary feeder on the product quality of the tablets.
12.00 – 13.00	**Lunch Break**
13.00 – 13.45	**Benchmark of binders for wet granulation** – T. Cech, ***BASF*** The focus of the presentation is to show, using the most popular wet granulation techniques (bowl and fluid bed), the performance of the most commonly used pharmaceutical wet granulation binders. Since the properties of the filler material has a strong impact on the granulation process, model filler materials such as Lactose, Ca-Phosphate and Microcrystalline cellulose were used in the placebo formulations.
13.45 – 17.45	**Special interest groups for different granulation processes** – ***All*** Every participant can sign in a special interest group for the granulation process, likewise for fluid bed granulation or high shear mixer granulation.
17.45	**Transfer to hotel**

Agenda

Day Three: November 29, 2012

8.30 – 9.30	**Trouble shooting** – M. Frank, ***Hüttlin*** Typical problems in fluid bed and high shear processes are shown and different solution methods are presented.
9.30 – 10.30	**A Case Study: Influence of the design of the granulation equipment and process parameter on the granule properties** – Dr. J. Müller, ***Hüttlin*** The presentation describes the influence of the design of the granulation equipment and process parameter on the granule properties by using a DoE.
10.30 – 10.45	**Coffee Break**
10.45 – 11.15	**Preparation of the presentation** – ***All***
11.15 – 12.00	**Presentation of results from the project groups and wrap up** – ***All***
12.00 – 13.00	**Lunch**

Objective of this seminar

Following the seminar the participant will have a clear understanding of the granulation process and the critical issues. The participant will be able to perform a granulation process in the high shear mixer, in the fluid bed and in its combination.

Who should attend?

Professionals engaged in development or production of solid dosage forms.

Your speakers

Dipl.-Ing. (FH) Joerg Croenlein, Colorcon, Germany
Joerg Croenlein holds a degree in Chemistry from Technical College Fresenius, Wiesbaden/Germany. Parallel to his studies, from 1990 to 1994, he gained experience in analytics at Fresinus Institute, Taunusstein. From 1995 to 1999 he worked for Boehringer Ingelheim in the Pharmaceutical Development department. Since 1999 he has been working for Colorcon GmbH as Head of Laboratory and is currently holding the position Area Technical Manager and Modified Release Technologies.

Dr. Frank Oprach, Sandoz, Switzerland
Frank Oprach studied Pharmacy in Braunschweig (Germany) and made his theses with a topic in Pharmaceutical Biology (1987). He joined the former Ciba-Geigy in Wehr (Germany) in the same year. Frank headed from 1987 to 1995 different departments for QA/QC (Raw Materials, Analytical Control of Finished Dosage Forms, Analytical Development) and took over increased responsibilities as Qualified Person, as well as for the Microbiological Labs. From 1995 Frank became Department Head for Solid Dosage Forms, Liquids and Semi Solids. From 2000 to 2002 Head of Pharmaceutical Development. From 2002 to 2006 Project Team Leader for launches of solid dosage forms in Stein (Novartis Pharma, Switzerland). Since 2006 Manager for Pharmaceutical Processes for Sandoz AG, Basle.

Thorsten Cech, BASF SE, Germany
Thorsten Cech studied process technology (with a focus on pharmaceutical technology) at the University of Applied Sciences in Bingen/Germany. During five years at Knoll AG, he was consigned for the development of solid oral dosage forms using melt extrusion technology. Subsequently, he worked for five years in the R&D development of OTC products at Boehringer Ingelheim Pharma GmbH & Co. KG. Since 2005, he has been responsible for the European Pharma Application Lab of BASF SE in Ludwigshafen/Germany. His responsibility is the application support concerning customers requests in the European region.

Prof. Dr. Dr. h. c. Ahmed Adel Sakr,
University of Cincinnati, USA; Future University, Egypt
Ahmed Adel Sakr is Emeritus Professor of Industrial Pharmacy & Pharmaceutics, and Director of the Industrial Pharmacy Graduate Program at the College of Pharmacy, University of Cincinnati Medical Centre and Board of Trustees Chair Assistant for Graduate Studies, Research & International Affairs, Future University, Egypt. His primary areas of interest include the design and optimization of immediate and modified release tablet formulation and manufacturing processes. He has more than 50 years of international academic and industrial experience, more than 160 internationally published research papers and has presented more than 450 conference presentations, invited presentations and/or workshops.
Prof. Sakr is an elected Fellow of the American Association of Pharmaceutical Scientists, FIP Fellow and Graduate Fellow of the University of Cincinnati. He is the recipient of the Distinguished Faculty Achievement Award of the University of Cincinnati, Emeritus Congress Chair, FIP-Industrial Pharmacy Section, the recipient of the 2008 AAPS Outstanding Educator Award and the 2011 AAPS Research Achievement Award in Manufacturing Science and Engineering.

Dr. Joshua Müller, Hüttlin, Germany
Joshua Müller studied Pharmacy from 2001 until 2005 at the Free University of Berlin/Germany. After his graduation he worked in the Pharmacy in Berlin before he started in August 2007 as a Ph.D. student in the group of Prof. Peter Kleinebudde at the Heinrich-Heine-University in Düsseldorf. The topic of his Ph.D. study was the “Feasibility of Raman spectroscopy as PAT tool in coating” which was performed in cooperation with L. B. Bohle and Kaiser optical systems. Furthermore he has experience in multivariate data analysis which is a necessary tool for the inline measurements and the PAT approach regarding the FDA Guidelines. In September 2010 he joined Hüttlin and works in the Pharma Service as Senior Scientist.

Dr. Edmont Stoyanov, ISP Global Technologies, Germany
Edmont Stoyanov graduated Pharmacy at the Medical University in Sofia/Bulgaria. He holds his Ph.D. in the field of Organic and Pharmaceutical Chemistry focused on the synthesis design, isolation and analysis of novel biologically active substances. He worked five years as senior assistant professor in the industrial pharmacy department at the Medical University of Sofia and published over 30 papers in the field of organic and pharmaceutical chemistry. As Alexander von Humboldt Research Fellowship holder, realized Mr. Stoyanov an own project about a new microwave-assisted method for the preparation of organic compounds. Edmont holds several patents on different subjects like poly-functional formulating agents, ionic liquids and new application of solid dose excipients. He worked for JRS Pharma, Germany from 2006 to 2011 as senior scientist and expert in the Technical Competence Center. Stoyanov joined in May 2011 ISP Global Technologies as EMEA Technical Director Pharmaceuticals.

Dr. Elke Sternberger-Rützel, Bosch, Germany
Elke Sternberger-Rützel studied pharmacy at the FU Berlin and the Eberhard-Karls-University of Tübingen. After that she did her PhD in Pharmaceutical Technology at the Karl-Ruprechts-University of Heidelberg. She worked as a head of laboratory at Grünenthal GmbH for stability studies, packaging development and clinical supplies. After that she changed to Catalent Pharma Solutions, Germany, as a packaging development manager with focus on microdosing and interims head of R&D. In her current position she works at the Robert Bosch GmbH, Packaging Technology – Business Unit Pharma as a Pharma Trendscout.

Manfred Frank, Hüttlin, Germany
Manfred Frank has a degree in Engineering of Technical Physics and worked for more than nine years as Project Engineer in R&D at AEG and Endress+Hauser. Since 1990 he is the Head of Laboratory at Hüttlin, Schopfheim/Germany and has more than 20 years of experience in the field of solid dosage forms. He is an expert in development of formulations and processes for granulation and coating. Manfred Frank combines knowledge of R&D with production.

Dr. Marcus Knöll, Hüttlin, Germany
Marcus Knöll is a pharmacist and graduated from Philipps Universität Marburg/Germany. After a six months research internship at University of Florida/USA he accomplished his doctoral thesis „Enteric coated Mucoadhesive Micropellets in Rotary Agglomeration Process for Wet Spheronization“ (2002 – 2005). He is Head of Pharma Service at Hüttlin, Schopfheim/Germany since 2005 with six co-workers.

Registration Form Course No. 8-GRA-0212

Granulation – From powder to the tablet – Seminar 2 in Schopfheim

Please sign up to the seminar by e-mail.

Surname	First Name	Title
Position	Department	
Company	Industrial Sector	
Street / P.O. Box		
Postcode	Location, Country	
Phone	Fax	
E-mail		
Date, Signature		

- ◯ Please book _____ single / double room(s) for _____ night / nights from _____ to _____.
- ◯ Please organize a taxi transfer from the airport to the hotel / to Hüttlin and back (Flight information will be forwarded to Hüttlin as soon as possible.).
- ◯ I will arrive by car.

The reservations are limited. Reservation is confirmed when we receive full payment.

Price for Seminar

1.250€ (excl. VAT), 10% reduction for participants from a previous course
(Inclusive: lunches and beverages during the seminar and dinner on the first and second day)

As soon as we receive your registration form we will send an invoice to you with our banking details and more detailed information on the seminar.

Your Contact Person
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