



Coating – Fine particles, granules, pellets, tablets
“Expert of Solids” Certification, Seminar 3
June 26 to 28, 2012

Unita



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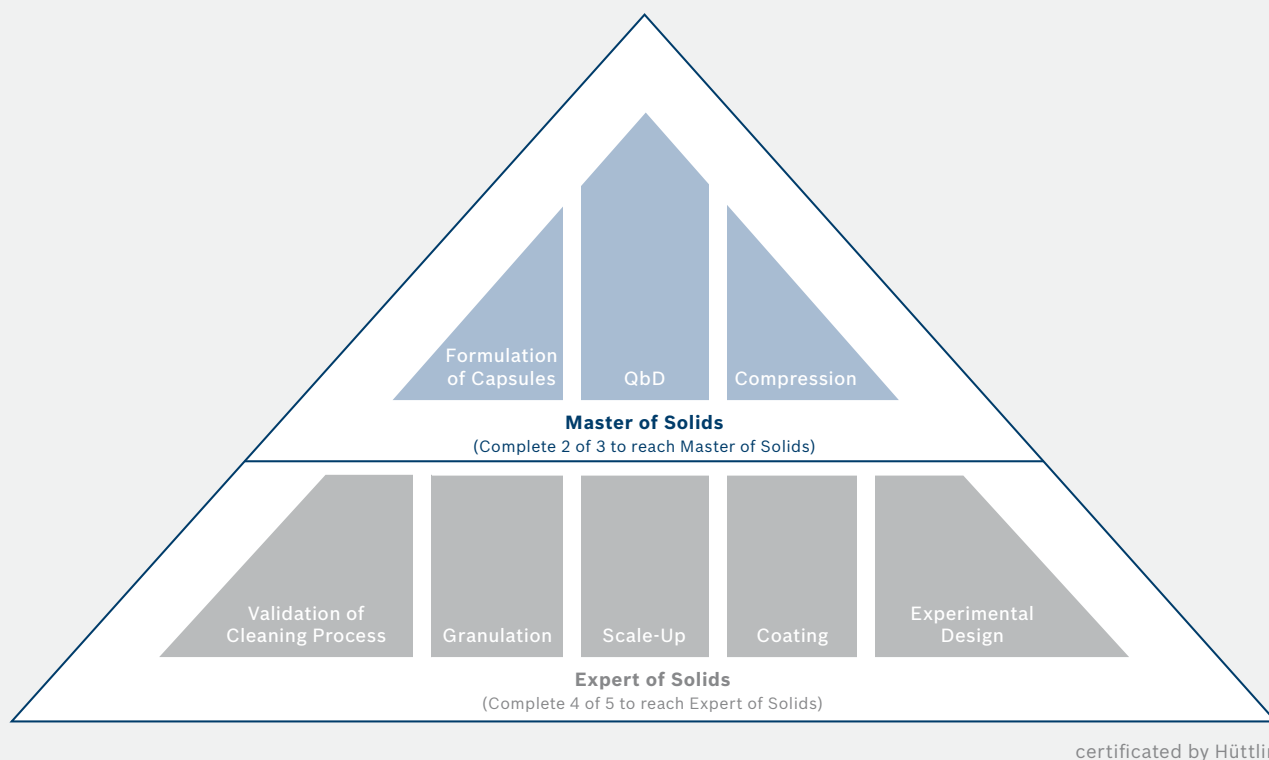
“Expert of Solids” and “Master of Solids” certificated by Hüttlin GmbH

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





Coating – Fine particles, granules, pellets, tablets

Most of today's modern solid dosage production is accompanied by coating. There are many reasons for coating your solid dose, such as colour for marketing reasons or the increase of bioavailability in case of solid dispersion. To develop and maintain an accurate and robust coating process a clear understanding of the technology is necessary.

The first day starts with an introduction to the processes of the fluid bed and drum coater. Also to the excipients which are necessary for the coating process will be highlighted. The day will close with a hands-on coating trial in group sessions.

The second day is focused on modern technologies likewise the compression of pellets, increasing the bioavailability by solid dispersions and using the hotmelt process for demanding formulations. Later the participants enrol in special interest groups and work with coating projects.

To gain a full understanding the audience will be introduced to bio relevance of certain dissolution media and the trouble shooting from the coating process at the last day. The seminar will be finished by result presentations of each working group.

Seminar 3 – „Expert of Solids“ certificated by Hüttlin

June 26 to 28, 2012

Agenda

Day One: June 26, 2012

8.30 – 8.45	Registration
8.45 – 9.00	Introduction – Dr. M. Knöll, <i>Hüttlin</i>
9.00 – 9.30	Basics of coating and the involved equipment – Dr. M. Knöll, <i>Hüttlin</i> Basics of coating and the corresponding equipment, the comparison between the equipments and their benefits will be highlighted. Reasons for coating and the basis of the process and the thermodynamic will be explained.
9.30 – 10.30	Excipients for film coating processes – W. Weisbrod, <i>Evonik Industries AG</i> Filmcoating formulations contain beside the functional polymer additional excipients, which are important for the coating process or the functionality of the coating. The presentation handles excipients and their use for the formulation.
10.30 – 10.45	Coffee Break
10.45 – 11.30	Critical physico-mechanical properties of ethylcellulose films influencing the performance of coated multiparticulate systems – J. Croenlein, <i>Colorcon GmbH</i> An overview is given as an introduction. The most frequently used polymer for barrier membrane coating is Ethylcellulose (EC). A comparison of organically applied EC and the aqueous dispersion (Surelease) regarding formulation, application and film properties will be discussed in this presentation.
11.30 – 12.30	Advancements in tablet film coating (PAT) – B. A. Helsdon, <i>Bosch Packaging Technology</i> Tablet coating advancements using side-vented pan technology from laboratory scale to large scale production batches. The importance and the relationship between the coating equipment and process variables in successful film coating. On-line inspection using Terahertz technology which examines critical quality criteria such as density, coating thickness, moisture content and temperature during the manufacturing process in the tablet coater.
12.30 – 13.30	Lunch Break
13.30 – 14.30	Process parameters of fluid bed coating – Dr. M. Knöll, <i>Hüttlin</i> Presentation of parameters influencing the coating process and their application during the process control.
14.30 – 17.15	Practical introduction to the coating process – Dr. M. Knöll, <i>Hüttlin</i> The participants will be divided into several groups and will be introduced to the coating process, the compression and the analysis.
17.15 – 17.30	Wrap up – All
17.30	Transfer to hotel

Agenda

Day Two: June 27, 2012

8.30 – 9.45	The use of biorelevant dissolution test methods to predict the in vivo performance of MR formulations – Prof. Dr. S. Klein, <i>University of Greifswald</i> Simulation of gastrointestinal conditions is essential to adequately predict the in vivo behaviour of drug formulations. This presentation will focus on how to develop predictive in vitro studies for all types of oral MR formulations.
9.45 – 10.15	Compression of enteric coated particles to disintegrating tablets – T. Rupp, <i>Evonik Industries AG</i> Compared to monolithic dosage forms, multiparticulate formulations show less variation and less food effects in the GIT, the compression to disintegrating tablets can reduce the manufacturing costs. To achieve such disintegrating tablets, several factors are important for a good functionality and reproducibility.
10.15 – 10.30	Coffee Break
10.30 – 11.15	Taste masking of active ingredients – T. Cech, <i>BASF</i> A new trend in solid dosage development, tablets which are administered orally without the use of water: To achieve a high rate of patient compliance for such medicine, a neutral or pleasant taste in the mouth is necessary. This presentation will cover the fundamentals of applying different polymer coatings detail the relationship of pH value dependent solubility for masking the active ingredient taste. Real case studies will underline the presentation's main point, for the audience to recognize potential solutions in their research applications.
11.15 – 12.00	Preparation of solid dispersion by the solvent method to increase the bioavailability – A. Mauler, <i>Hoffmann-La Roche</i> , Dr. C. Timpe, <i>Novartis</i> Solid dispersions are recently becoming more and more attractive in drug delivery for overcoming poor solubility and bioavailability issues of new drug candidates. The historic reluctance of the pharmaceutical industry until recently to apply organic solvent based manufacturing processes for making these formulations was based on the arguments of using large volumes of organic solvents (ecological, ecotoxicological aspects). The presentation will give an insight on how to efficiently apply a novel solvent-based wet granulation process using a Hüttlin spray granulator for preparing solid dispersions with superior powder properties. Scaling-up possibilities and details of the process steps will be discussed on the basis of a poorly soluble drug candidate project giving an outlook about possible future applications.
12.00 – 13.00	Lunch Break
13.00 – 13.45	Trouble shooting of the equipment – M. Frank, <i>Hüttlin</i> Typical problems in fluid bed coating and different solution methods are presented.
13.45 – 17.00	Special interest groups for different coating processes – All Every participant can enrol in a special interest group for the coating process: powder layering, taste masking, compression of pellets.
17.00	Transfer to hotel

Agenda

Day Three: June 28, 2012

8.30 – 9.45

Hotmelt – Dr. D. Marchaud, *Gattefossé GmbH*

Hotmelt coating is still a niche in the pharmaceutical production, but it can be a key for finding solutions in a demanding market. The lectures will deal with the physio-chemical properties of lipid excipients and their functionality in the field of solid dosage forms. At the end case studies of different model drugs and rules for process optimization will be given.

9.45 – 10.30

Troubleshooting in film-coating processes – W. Weisbrod, *Evonik Industries AG*

Besides problematic process parameter settings, the used raw materials can be responsible for troubles during the coating process or unexpected results in functionality. This presentation highlights some aspects with the focus on polymers, usual excipients used for film-coating formulations and basic process settings.

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

12.30 – 13.00

Lunch

13.00

Transfer to hotel

Objective of this seminar

Providing solutions to all types of challenges you face in day-to-day coating business. Answers to the topics of taste masking, preparation of solid dispersion, coating of pellets, coating of tablets and the dissolution of these dosage forms will be given. The participant will be able to perform hands on coating processes on the Hüttlin equipment.

Who should attend?

Professionals engaged in the development or production of solid dosage forms.



Your speakers

Wolfgang Weisbrod, Evonik Industries, Germany

Wolfgang Weisbrod made an education as chemical assistant at Röhm GmbH, Darmstadt/Germany. Afterwards he worked at the technical service laboratory for EUDRAGIT® polymers, in development of particle coating technology with pharmaceutical polymers using fluidized bed technology and was responsible for controlled release solid pharmaceutical dosage forms. Then he was Technical Supervisor and since 2006 he is Principal Scientist and deputy Regional Tech Manager EUDRAGIT® for Europe, Middle East, South America and regular speaker at workshops and conferences in Europe, America and Asia. He published several papers and posters on the application of pharmaceutical methacrylates in formulation of solid dosage forms and is co-inventor of several patents.

Thomas Rupp, Evonik Industries, Germany

Thomas Rupp is Senior Scientist in Tech. Service EUDRAGIT® since 2004 in the group of East Europe, Middle East, Africa and South America at Evonik Industries AG, Darmstadt. Prior to that he has been at the Company Bayer and Novartis where he was responsible for Adalat GITS and Carbamazepine GITS production in function of master craftsman.

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 Fresenius 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.

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.

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 Spherization“ (2002–2005). He is Head of Pharma Service at Hüttlin, Schopfheim/Germany since 2005 with six co-workers.

Prof. Dr. Sandra Klein (Ph.D.), Ernst-Moritz-Arndt-University, Germany

Sandra Klein is currently a Professor of Pharmaceutical Technology at the Ernst-Moritz-Arndt-University in Greifswald/Germany. She got her pharmacist's license and her Ph.D. from the Goethe University of Frankfurt, was a postdoctoral fellow at Eastman Chemical Company in Kingsport/TN/USA and a senior research associate at the Goethe University of Frankfurt.

Her research is focussed on developing biorelevant in vitro models to predict drug bioavailability from oral and vaginal delivery systems and on improving the bioavailability of poorly soluble drugs. She has more than 10 years experience in biorelevant dissolution testing, is (co-)author of various original manuscripts and book chapters, member of the CRS board of scientific advisors and has been an invited speaker at international dissolution workshops of AAPS, APV, CRS, FIP and WHO amongst others.

Dr. Delphine Marchaud, Gattefossé, France

Delphine Marchaud is Technical Applications Manager for the Pharmaceuticals division of Gattefossé SAS based in St. Priest/France. She designs and oversees research projects involving the optimization of melt techniques (hotmelt coating, melt granulation, spray cooling) with lipid excipients and the characterization of the resulting powders and granules. She has authored many publications, developed innovative processes and patented drug delivery systems and delivers the Gattefossé Lipid School – a training programme for pharmaceutical industry formulators on how to use lipid excipients in drug delivery. Her technical background is in biochemistry, physical chemistry and formulation science; before joining Gattefossé she worked at Sanofi (Sanofi-aventis) USA and in France in their formulation development teams.

Brian A. Helsdon, Bosch Packaging Technology, UK

As an engineer with over 40 years experience of Manesty products, Brian Helsdon has an extensive knowledge of the tableting equipment gained for many years of working within the production and engineering departments at Manesty in a number of senior roles. In his current position he is responsible for Manesty's customer training worldwide. He also lectures on tablet compression technology, tablet coating equipment and tablet tooling.

Arnaud Mauler, Novartis Pharma, Switzerland

Arnaud Mauler graduated successfully from the Ecole Nationale Supérieure de Chimie de Mulhouse/France as an engineer specialized in chemistry and material science. He has recently been awarded a business engineering degree from Strasbourg's Management School. Since 2003 he's working as formulation scientist in the pharmaceutical development department at Novartis Pharma AG focussing on solid oral dosage forms and special delivery systems for poorly soluble drugs.

Dr. Carsten Timpe, F. Hoffmann-La Roche, Switzerland

Carsten Timpe was born in Hannover/Germany, studied pharmacy at the Technical University in Braunschweig/Germany. He completed his Ph.D. thesis at the Philipps University of Marburg/Germany in the group of Prof. Dr. Klaus Hartke in Pharmaceutical Chemistry ("Synthesis and Properties of novel 1,3-Dithiols with anellated Cyclopentadiene Ring"). From 1992 until 2000 he served as a group leader for formulation development of oral solid dosage forms (with ultra-low doses) at the Jenapharm GmbH in Weimar/Germany (affiliate of Schering AG). Subsequently he joined Eli Lilly in Hamburg/Germany in May 2000 where he worked after two promotions as "Principal Research Scientist" until February 2007 in the formulation development area of new drug candidates with a special focus on technologies to overcome poor aqueous solubility of small molecules. He has joined Novartis in Basel in early 2007 as "Fellow" scientist in the Special Delivery Systems group in Pharmaceutical Development, St. Johann and becoming also a project leader was then promoted in 2010 to "Senior Fellow". Since January 2012 he works at Hoffmann-La Roche company in early drug development in Basel. Timpe is inventor/co-inventor of several international formulation patents and invited speaker to several drug delivery conferences in Europe, has been many years an active member of the APV focus group "Pharmatechnik" in Germany and since 2008 of the focus group "Drug Delivery".

Registration Form Course No. 4-COA-0612

Coating – Fine particles, granules, pellets, tablets – Seminar 3 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 by receipt of full payment.

Price for Seminar

1.250€ (additionally 19% VAT), 10% reduction for participants of a previous course
(Inclusive: lunches and beverages during the seminar and dinner on the first as well as 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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Seminar Coordination

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