Statistical Design Space Development – from Design of Experiment to granules

"Expert of Solids" Certification, Seminar 4
April 24 to 25, 2012

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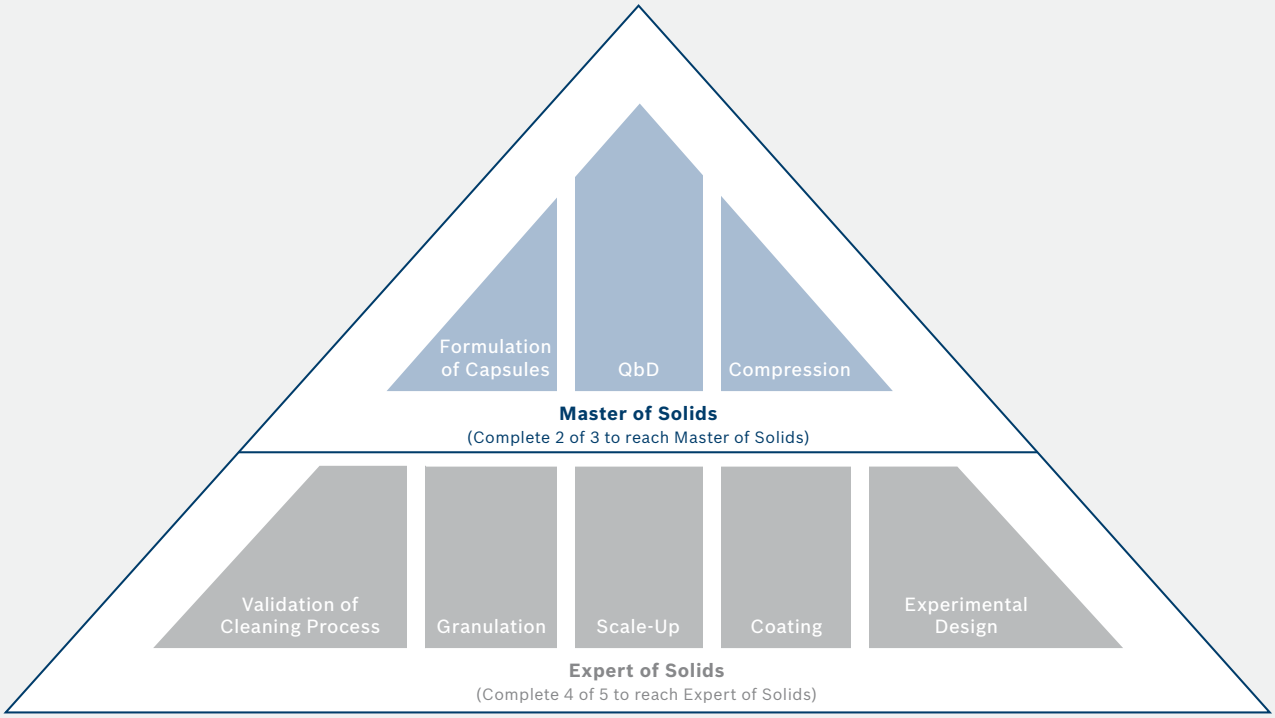
“Expert of Solids” and **“Master of Solids”** certificated by Hüttlin GmbH

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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Statistical Design Space Development – from Design of Experiment to granules

How to get the maximum knowledge out of your process with the minimum effort of time and manpower? Design of Experiment (DoE) is a structured, organized and effective method for determining complex relationships between multi-dimensional factors that may impact a process.

The first day will cover the fundamentals of DoE including mathematical and statistical analysis along with an in depth introduction to full factorial designs. Actual run granulation trials following a DoE plan will be analysed with the state-of-the-art software package Umetrics' MODDE.

The second day will be addressed to the analysis of the granulation trials and develop corrective actions. The power of using DoE combined with Analysis of Variance (ANOVA) as the Six Sigma's "power tool" will lead to cost effective manufacturing principles.

Seminar 4 – “Expert of Solids” certificated by Hüttlin
April 24 to 25, 2012

Agenda — Day One: April 24, 2012

8.15 – 8.30	**Registration**
8.30 – 9.00	**The new concept of Quality by Design** – Prof. P. Wehrlé, *University of Strasbourg* ICH guidelines for a maximal efficient, flexible, manufacturing sector which reliably produces high-quality drugs without extensive regulatory oversight will be presented.
9.00 – 9.45	**DoE – What is it?** – Prof. P. Wehrlé, *University of Strasbourg* Design of Experiments to optimize and validate pharmaceutical processes and formulations – theory and overview.
9.45 – 10.00	**Coffee Break**
10.00 – 10.30	**Selection of influencing process factors and responding product properties for granules** – Dr. M. Knöll, *Hüttlin* For a reliable DoE a basic knowledge about the process is mandatory. In the short time a rough overview about the fluid bed granulation is given under application of FMEA (Failure Mode and Effects Analysis).
10.30 – 11.15	**Full factorial designs, the basis for DoE** – Dr. E. Johansson, *Umetrics* Full factorial designs are the basis for DoE and we will go through these in detail as a preparation for the practical exercise.
11.15 – 11.30	**Coffee Break**
11.30 – 12.30	**Creation of a DoE for the case study; Reworking the FMEA into a practical design (DoE)** – *All* Bringing theory into practice, the given knowledge of the morning should be transfered now into a DoE. The participants will create with the software MODDE their own DoE case study.
12.30 – 13.30	**Lunch Break**
13.30 – 16.30	**Performing of experiments in the fluid bed** – *All* The participants will be divided into several groups. Every group will run a part of the DoE on a laboratory fluid bed granulator.
16.30 – 16.45	**Coffee Break**
16.45 – 18.00	**Analysing the granules** – *All* The granules’ characteristics will be used as response variables for the evaluation of the DoE. The groups will analyse their produced granules.
18.00	**Transfer to hotel**
19.30	**Dinner**

Agenda

Day Two: April 25, 2012

8.15 – 9.15	**SPC and "Six- Sigma"** – Prof. P. Wehrlé, *University of Strasbourg* Control charts, Capability indices; Ishikawa diagram to control and quantify variability will be presented as tools for continuous quality improvement.
9.15 – 10.45	**Screening and optimisation designs** – Dr. E. Johansson, *Umetrics* Fractional factorial designs are used for screening or robustness testing / Design Space validation and RSM designs are used for optimisation.
10.45 – 11.00	**Coffee Break**
11.00 – 12.00	**Postulated model of an Enalapril granulation as a complex process using DoE** – Dr. A. Hartung, *Novartis Pharma* Demonstration of real process data. The advantages of DoE with detection of unexpected parameter interactions are shown. The result is increased process knowledge.
12.00 – 13.00	**Lunch Break**
13.00 – 15.00	**Evaluation of raw data from case study and model interpretation** – Dr. E. Johansson, *Umetrics* A live demonstration / exercise of the data from day one to investigate if we have a "Design Space"
15.00 – 15.15	**Coffee Break**
15.15 – 16.45	**Evaluation of case study and presentation of the group results** – *All* The groups will present their results and the discussion is opened.
16.45 – 17.00	**Wrap up**

Objective of this seminar

The target of this seminar is to combine the theory of DoE (statistical and mathematical aspects) with a practical workshop (production of granules). We combine theoretical knowledge with data from real granulation trials. As a result of this seminar the participant will feel confident in things such as QbD, Design Space, Six Sigma and Capability – quality systems for their operations improvement.

Who should attend?

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

Your speakers

Dr. Erik Johansson, Umetrics, Sweden
Erik Johansson is the senior application specialist of Umetrics. He has a long and broad experience from using DOE and MVDA in the Pharma and Biotech industries. After graduating from the University of Illinois and Umeå University in 1984, Dr. Johansson in 1985 joined AstraHässle (today part of AstraZeneca) on a specialist mission to focus on QSAR and PAT. After six years with AstraHässle, Dr. Johansson was recruited to Umetrics as a senior application specialist. In this role, he has provided consulting expertise to clients like AstraZeneca, GSK, Novartis, Pfizer and Roche. Erik Johansson is a frequently engaged external lecturer and has conducted training classes on DOE/MVDA for MPA, EMEA and EUFEPS. Presently, his focus is on helping Pharma and Biotech companies to fulfill the objectives of Design Space estimation under the quality by design (QbD) umbrella.

Dr. Marcus Knöll, Hüttlin, Germany
Marcus Knöll is a pharmacist and graduated from Philipps Universität Marburg/Germany. After a six month 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 leads the Pharma-service at Hüttlin, Schopfheim/Germany since 2005 with six co-workers.

Prof. Dr. Pascal Wehrlé, University of Strasbourg, France
Pascal Wehrlé is a pharmacist and professor at the Faculty of Pharmacy of Strasbourg where he is teaching pharmaceutical technology. He is a graduate of the University of Paris and the University of Strasbourg. In his research and development activities, dealing mainly with solid dosage forms he is studying and using mathematical and statistical multifactorial methods to rationalize pharmaceutical processes and drug formulations. Professor Pascal Wehrlé is also President of the French Association of Academic Professors in Pharmaceutical Technology and Expert at the French Agency for the Safety of Medical Products (AFSSAPS).

Dr. Andrea Hartung, Novartis, Switzerland
Andrea Hartung studied Pharmacy from 2003 till 2007 at the Johann Wolfgang Goethe University of Frankfurt/ Germany. After her graduation she started as a Ph.D. student in the group of Prof. Peter Langguth at the Johannes Gutenberg University of Mainz/Germany in cooperation with Hüttlin, Schopfheim/Germany. Her Ph.D. study was on granulation and tabletting processes using statistical applications e.g. DoE to optimize them. Furthermore she is experienced in Process Analytical Technology, using timely controlled “inline” measurements for controlling critical process parameters such as moisture and other particle attributes. In 2011 she joined Novartis PharmOps Switzerland as Process Expert. In this role she is responsible for production processes of several Novartis blockbuster.

Registration Form Course No. 2-DOE-0412

Statistical Design Space Development – Seminar 4 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

984€ (excl. VAT), 10% reduction for participants from a previous course
(Inclusive: lunches and beverages during the seminar and dinner on the first 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.

Requirement

Please bring your own laptop with you to the seminar and install the free demo version of MODDE (available at: www.umetrics.com)

Your Contact Person
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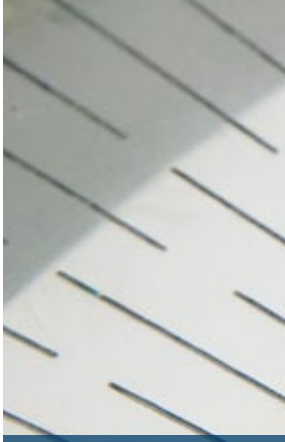

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