Quality by Design (QbD) means that, starting from the very first development step, products and processes are designed in a way to ensure a high level of quality and reliability. One of the main QbD tools is statistical Design of Experiments (DoE), which enables to perform the necessary experiments in an efficient and structured way. This constitutes the most effective manner to identify the Critical Process Parameters (CPP's) and Material Attributes (CMA's) that, together, influence most the quality characteristics of highest concern, the so-called Critical Quality Attributes (CQA's). Of course, the methodology can also be applied to optimize existing products or processes.

The training gives a comprehensive introduction to statistical Design of Experiments (DoE): on the one hand, the statistical background is explained, on the other hand, the methods are illustrated with examples from the pharmaceutical and chemical industry, and their application is trained with many exercises based on real-world case studies using a DoE software tool. A part of the last afternoon is reserved for discussing the participants’ own applications. The practical aspects are addressed at regular intervals throughout the whole course duration, so that the course overall proposes a balanced combination of methodological knowledge and practical aspect.

**ABOUT CfPIE**

Learn from the Leader

In a life sciences industry that has faced nearly $15 billion in fines and compliance-related settlements over the last several years, The Center for Professional Innovation & Education (CfPIE) is a better alternative for maintaining high standards, protecting industry reputations, and enhancing personal growth. Since 2001, we have embraced a singular goal—to provide the highest quality education to life science professionals. Today, as the global leader in quality life sciences training, we offer the largest range of course options for professional development in pharmaceutical, medical device, biotech, and skin/cosmetics disciplines. We are dedicated to enriching that reputation by conveying content relevant to the needs of individuals and organizations facing intense scrutiny in those highly technical disciplines.

**HOW TO REGISTER**

1. Go to http://www.cfpie.com
2. Go to “REGISTER HERE” and select your course.
3. Create an account and register for your course.

**COURSE DESCRIPTION**

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**PAYMENT**

$2650.00 PER PERSON (INCLUDES BREAKFAST & LUNCH)

**EARLY BIRD DISCOUNT**

If you register at least thirty days in advance you will receive a $200 discount on the course.

**ADDITIONAL DISCOUNTS**

Contact us at 610-648-7550 or info@cfpie.com for information regarding partnership discounts or how your organization can become a partner with CfPIE.

**CANCELLATION POLICY**

All cancellations must be in writing and are subject to a $350.00 cancellation fee. If cancellations are made more than 30 days prior to the course, a refund less the cancellation fee will be provided. If cancellations are made less than 30 days prior to the course, a voucher good for attendance at an upcoming course will be provided. The voucher, which can be used by the registrant or anyone else within his/her company, will be valued at the registration fee minus the $350.00 cancellation fee.

If a registered attendee does not cancel and fails to attend, neither a refund nor voucher will be issued. All course cancellations must be in writing and emailed sent to info@cfpie.com. Registrants are responsible for contacting the hotel and canceling their room reservations.

CfPIE reserves the right to alter the venue, if necessary.

*Substitution Policy - Classroom Courses*

Substitutions are accepted at no penalty with written notification from the original registrant in advance of course. All substitution requests must be in writing and emailed to info@cfpie.com.

CfPIE also offers on-site courses for 10 or more attendees. Contact us at info@cfpie.com.
INSTRUCTOR CREDENTIALS

Dr. Philippe Solot is Chief Executive Officer of AICOS Technologies, a company which he co-founded in 1997 and which is specialized in facilitating the use of statistical methods by scientists active in the process industry. He previously served five years as Consultant in the Scientific Services department of Ciba-Geigy Ltd., the multinational chemical-pharmaceutical company that merged with Sandoz to form Novartis.

Dr. Solot looks back at more than 20 years of industrial expertise. His specialization is mathematical optimization, in particular its application in improving development and production processes in the pharmaceutical and chemical sectors. He regularly teaches courses on Design of Experiments, data visualization and analysis, Six Sigma and Statistical Process Control. He also gives lectures at Swiss and French universities and is the author of approximately 20 scientific publications in journals such as the International Journal of Production Research and INFOR.

Dr. Solot holds a PhD from the EPFL, the Swiss Federal Institute of Technology in Lausanne, Switzerland. For his doctoral thesis he was awarded the Robert Faure Prize in France by the French AFCET. From 2001 to 2005, he was president of the Swiss Operations Research Society.

Dr. Stefanie Feiler works as Senior Consultant in Applied Statistics at AICOS Technologies since 2005.

Her tasks include consulting and data analysis, as well as teaching. In a multitude of diverse projects that she in particular executes for the pharmaceutical industry, she regularly uses a broad range of statistical methods. Her areas of specialization are statistical Design of Experiments (DoE), Six Sigma, and data mining using CART. In training, her main concern is on the applications of the methods in the participants’ typical working situations.

Dr. Feiler studied mathematics and chemistry at the university of Tübingen, Germany. During her exchange year in Besançon, France, she received a master’s degree in pure mathematics. She obtained her PhD degree as member of the Statistics Group of the Institute for Applied Mathematics at the University of Heidelberg, Germany.

FIRST DAY

Background
• Importance of Quality by Design (QbD) as part of an efficient QA strategy
• Role of QbD / DoE within the Six Sigma framework
• Regulatory aspects

Concepts of Statistical Design of Experiments
• Introduction
• DoE vs. one-factor-at-a-time
• Strategic approach in phases: screening, modelling, optimization

DoE in Practice
• User input: definition of response variables and factors
• Effects and interactions

Modelling
• Full and fractional factorial designs
• Selection of an appropriate design
• Analysis of the experimental results with multiple linear regression
• Graphical visualization and interpretation

SECOND DAY

Modelling (cont.)
• Numerical and graphical assessment of the model quality
• Analysis conclusions

Specific Issues with Formulation Problems
• Concepts and definition of restrictions
• Designs for formulation problems
• Result analysis and interpretation

Optimization
• Optimization designs
• Building response surface models to identify best settings, graphical interpretation
• Confirmatory experiments

THIRD DAY

Screening
• Selection among many factors
• Screening designs
• Analysis with the half-normal plot

Simultaneous Optimization of Several Response Variables
• Target optimization
• Determining the best compromise and the Design Space with the desirability function

Accounting for Real-World Challenges
• Experimental restrictions, trend
• Handling of violated factor settings
• Unsuccessful experiments

Practical Recommendations

Discussion of the Participants’ Own Applications
• Questions & Answers

HOTEL INFORMATION

The Hilton LAX, Los Angeles, CA (CfPIE room rate of $167/night if booked 3 weeks in advance of the course date)
The Desmond Hotel & Conference Center, Malvern, PA (CfPIE room rate of $141/night if booked 3 weeks in advance)
Club Quarters Hotels, Boston, MA (CfPIE room rate of $255/night if booked 4 weeks in advance)
DoubleTree by Hilton London - Victoria (CfPIE room rate of £199.00/night if booked 4 weeks in advance)