INSTRUCTORS

Dr. Juergen von Frese is the founder of Data Analysis Solutions DA-SOL GmbH. He has been involved in the development and application of advanced multivariate data analysis in industry for more than 14 years. Leading pharmaceutical and biotech companies are among DA-SOL's clients. His focus has been on PAT whole process analysis, data fusion as well as method development for novel kinds of data. He is a board member of the German chemometrics working group and regularly teaches all over Europe and in the U.S.

Assoc. Prof. Frans van den Berg is a member of the Spectroscopy and Chemometrics group in the Department of Food Science, University of Copenhagen, since 2000. He has a PhD in Process Analysis and Chemometrics (University of Amsterdam). His research interests are in Process Analytical Chemistry and Technology for the food and pharma-industry in general and statistical process monitoring and control in particular.

VENUE

The course takes place directly at the scenic Ammersee just south of Munich. The venue can be reached conveniently by commuter rail (S8) from Munich airport or the central station. A room contingent has been reserved at the course hotel for 129 € per night. Please contact the hotel directly **before 15.08.2012**:

AMMERSEE HOTEL
Summerstrasse 32
82211 Herrsching
Germany

www.ammersee-hotel.de
Tel: +49 81 52 96 870
Fax: +49 81 52 53 74
Email: info@ammersee-hotel.de

REGISTRATION

Please register before 15.08.2012 using the registration form or send and informal email inquiry:

First Name _____ Last Name _____

Company _____

Address _____

Postal code, City _____

Telephone _____

Fax _____

Email _____

Date, Signature _____

DA SOL

Data Analysis Solutions DA-SOL GmbH
Kellersgartenstr. 19
86919 Utting, Germany
www.da-sol.com

Tel: +49 8806 95 97 430
Fax: +49 8806 95 97 431
Email: info@da-sol.com

Please note that directly after the course the famous **Oktoberfest** starts in Munich. If you want to stay on, an early room reservation would be advisable.

Integrative Process Analysis and Understanding

An Advanced Course

20.09. - 21.09.2012

Herrsching (near Munich)

Dr. Juergen von Frese
Data Analysis Solutions DA-SOL GmbH

Assoc. Prof. Frans van den Berg
University of Copenhagen

INTRODUCTION

We are faced with more and more complex data from all stages in our production processes. More advanced measurement technologies are available and increasingly used not just in development but on-line or at-line in the production. This data is our most valuable resource for understanding our processes and achieving continuous improvement throughout the production life cycle – thus, fulfilling simultaneously the regulatory requirements and realizing an optimal process performance in an ever more competitive landscape.

Establishing QbD and PAT in a systematic manner requires two complementary approaches:

- → The bottom-up approach leverages existing product and process understanding and allows for an efficient, systematic development using e.g. Design of Experiments (DoE) or the targeted introduction of the most informative at-line or on-line analysis methods and controls.
- → The top-down process analysis investigates the actual data, establishes interdependencies and tries to achieve a holistic, science-based process understanding:
  - How can the process be optimized most efficiently?
  - Which unit operations contribute the most to the overall process variability?
  - How do unit operations influence each other?
  - Which are the most critical risk factors in practice?
  - Troubleshooting: Revealing critical bottlenecks

After a short introduction / reminder of the basics, the course will show how an integrative process understanding can be obtained starting from the individual unit operations to evaluating their interactions and achieving an overall process understanding. We will discuss applications throughout the whole process life cycle from development to continuous improvement. A focus will be on root-cause analysis, troubleshooting and optimization.

The course is based on the instructor's experience in a multitude of industry projects as well as international courses and the PAT MSc. programme at the University of Copenhagen.

AUDIENCE

The course is aimed at scientists, engineers and others involved in process development or production with a basic working knowledge on QbD, PAT and applied data analysis. For beginners a prior attendance of a corresponding introductory course is recommended.

LANGUAGE

The course language is English.

FEE

The course fee is 780 € (+ 19 % VAT) and includes the course material, lunches and all refreshments during the course. Accommodation is not included (see overleaf). Cancellations after the registration deadline cannot be refunded.

AGENDA

Thursday, 20.09.2012 - 10:00 to 18:00

- → ***Introduction / Reminder of Basic QbD/PAT Principles*** *(1.5 h)*
  - QbD and PAT basics (ICH Q8/Q9/Q10)
  - The process life cycle
  - Risk analysis

- → ***Introduction / Reminder of Data Analysis Fundamentals and Methods*** *(1.5 h)*
  - Design of Experiments Basics
  - Univariate Data Analysis, Control Charts
  - Multivariate Data Analysis, Building Predictive Models, MSPC

- → ***Introduction to Integrative Process Analysis*** *(4 h)*
  - The different kinds of process data and their analysis
  - Optimizing and controlling raw materials in development and production
  - Analyzing batch data

Friday, 21.09.2012 - 08:30 to 16:30

- → ***Introduction to Data Fusion*** *(3 h)*
  - Principles of Data Fusion
  - Multiblock Methods
  - Data Fusion in Practice

- → ***Life Cycle Aspects*** *(4 h)*
  - Regulatory Aspects
  - Process Development and Scale-Up
  - Troubleshooting, Root-Cause Analysis and Optimization
  - Calibration Transfer and Maintenance
  - Real time release testing