

QbD/PAT: Whole Process Analysis

**DATA ANALYSIS SOLUTIONS
DA-SOL GmbH**

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QbD/PAT: WHOLE PROCESS ANALYSIS

Introductory Half-Day Course

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The increasing availability of comprehensive data throughout production processes as well as the growing number of PAT applications and QbD filings have led to a strategic importance of chemometrics for the pharma and biotech industry. Thorough process understanding plays a key role for regulatory approval as well as an efficient operation and a continuous process improvement. Chemometric analyses of comprehensive, heterogeneous data from raw material characterisation, through process control and batch modelling to real time release testing require a diverse toolset beyond PCA and PLS and a good understanding of how the various tasks can be approached in a systematic manner.

The course will provide a straightforward introduction and overview over the essential topics in whole process analysis:

- QbD/PAT Concepts
- Regulatory Aspects, Guidances & Standards
- Design of Experiments
- Univariate Analyses, Control Charts
- Multivariate Methods and Good Modelling Practice
- Calibration Transfer and Maintenance
- Data Fusion
- Analysis of Batch Data
- Influence of Raw Materials

Audience: No prior knowledge of whole process analysis is required, although a basic familiarity with chemometric methods and concepts is assumed.

About: Data Analysis Solutions is a services & consulting company helping its clients to make the most out of their data through smart, tailored analysis solutions.

It is based on more than 14 years of experience of its founder, Dr. Juergen von Frese, in industrial chemometrics and bioinformatics. He has given numerous talks and industrial courses all over Europe and in the U.S. He has worked extensively on analyzing comprehensive process data for a blockbuster drug including the development of new algorithms and whole process analysis software.