

# Smart Data: Design of Experiments

DATA ANALYSIS SOLUTIONS SLU
Carrer de la Costa 29
07589 Capdepera
Spain
Dr. Jürgen von Frese
jvf@da-sol.com

#### **Smart Data: Design of Experiments**

#### From Novice to Specialist in 8 half-day sessions

Big data is all the rage. However, in development data is costly and scarce. The best we can achieve is to make our data "smart", i.e. to conduct experiments most efficiently, so that they provide the maximal information possible in a way that allows for unambiguous conclusions. That is what Design of Experiments is all about.

This Online-Course aims at creating future DOE specialists in the pharmaceutical industry with two modules lasting four half-days each. The course is valuable both for complete novices with only basic data analysis knowledge who want to master DOE for their (or their colleagues') applications, but also for seasoned statisticians who want to profit from a systematic and effective approach for applying DOE in a pharmaceutical setting.

#### Module 1: Developing a Design (4 x 4 hours)

- Principles of DOE
- The Workflow for Establishing a Designed Experiment
- Different Design Types
- Evaluating the Suitability of Designs

The focus is on getting a conceptual understanding on where and how to use design of experiments (DOE) and how to obtain the best and most efficient designs.

Prior knowledge would be advantageous but is not necessary. The course does not contain any equations, but still provides a solid basis for becoming a qualified DOE specialist and covers all aspects required in a pharmaceutical setting. The examples are from pharmaceutical applications. Hands-on exercises are performed in Design Expert.

#### Module 2: Analyzing DOE Data (4 x 4 hours)

- Principles for Obtaining Valid Models
- The Workflow for Analyzing DOE Data
- What can we learn from DOE models?
- Establishing Design Spaces

This course provides a step-by-step understanding on how to analyze DOE data by systematically building a valid model, how to evaluate the quality of an obtained model and how to draw conclusions from that model. As a specific application in the pharmaceutical setting the development of a design space is discussed. Like in the first block, the course provides a solid conceptual understanding but does not contain any equations. Hands-on exercises are performed in Design Expert based on pharmaceutical data.

Although both modules are self-contained, it is highly recommended that all participants take part in both modules.



#### Add-on Module "Formulation / Mixture Design" (2 x 4 hours)

Whenever our experiments involve ingredients/components for which only relative amounts (%) matter, e.g. in a typical formulation setting, this requires very particular experimental designs and analysis approaches also known as mixture designs. This one-day add-on course to our two-part "Smart Data: Design of Experiments" course enables its participants to understand the relevant principles and methods, enabling them to design and successfully analyze mixture designs (also including those with additional process factors). Hands-on exercises are performed in Design Expert.

### Add-on Module "Robust Parameter Design" (4 hours)

When using Design of Experiments (DOE), we generally focus on the predicted means of our responses and try to optimize them according to our needs. But it is also possible to consider and minimize the future variability of the responses. Corresponding approaches have initially been introduced by G. Taguchi into the quality culture, but more powerful methods are available now. This course is a half-day add-on module to our "Smart Data: Design of Experiments" course and will enable its participants to understand the principles for designing and analyzing robust parameter designs and thereby optimizing CQAs and KPIs while simultaneously minimizing their variability. Hands-on exercises are performed in Design Expert.

## Strategic Seminar: Smart Data versus Big Data: Low versus High-Cost (2 hours)

Pharmaceutical companies are investing large amounts into big data/AI approaches. But generating data is generally costly in pharmaceutical R&D. – Big data/AI approaches require at least hundreds if not 1000s to 10.000s of training examples and are primarily predictive black boxes that do not improve our understanding. Thus, in particular in a pharmaceutical R&D context, additional approaches are needed which can maximize the information content and interpretability of small, cost-efficient datasets. Silently, behind the scenes, such approaches for generating and exploiting "smart data" (a.k.a. "Design of Experiments" (DOE)) have proven their value in numerous industries for decades and have enabled their proponents to outclass their competitors. But there have also been substantial improvements in recent times which led to higher efficiencies and much easier applicability of DOE. This two-hour strategic seminar will show and discuss how a "smart data" strategy can complement existing big data/AI initiatives and lead to substantial additional business benefits.

