

## Speakers



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# Introduction to Statistical Design of Experiments in the Pharmaceutical Industry

23/24 September 2025 | Berlin, Germany



*Case Studies: Optimization of a Granulation Process & HPLC Robustness Assessment*

## Highlights

- DoE by Hand Calculations in Excel: Main Effects and Interactions
- Get familiar with DoE in Minitab (Introduction to DoE in Minitab)
- DoE Theory explained: Analysis of Variance (ANOVA) and Predictive Modeling
- Classical and Modern Designs for: Screening, Robustness and Optimization
- Optimization with Response Surface Methodology (RSM)
- Guidelines covered: ICH Q8, Q11, Q14 and Pharm. Eur. (Supplement 11.7)

Highly Interactive Training: Hands-On  
Demonstrations with Numerous Exercises

## Objective

Our DoE course offers a clear, hands-on introduction to planning and analyzing experiments using Minitab. The course features four case studies presented in a completely click-through manner. All examples are set in a pharmaceutical context.

DoE theory is covered at a practical level to ensure participants understand the concepts and can accurately interpret software outputs, ultimately leading to correct conclusions.

- **Day 1:** Focuses on the planning stage of DoE
- **Day 2:** Focuses on the analysis of DoE results

The course covers a broad range of classical and modern DoE designs, including full and fractional factorial, Plackett-Burman, central composite (RSM), D-optimal and mixture designs.

## Background

Design of Experiments (DoE) is a powerful statistical method used in Quality by Design (QbD) to gain insights into the characteristics of processes and products. It provides a scientific basis for selecting process parameter ranges in regulatory submissions and helps identify key parameters affecting product quality, while minimizing the number of experiments and associated costs.

In the planning step, a minimal number of experiments is selected to representatively cover the experimental space. In the analysis step, a multivariate empirical model is fitted to the measurements to describe the relationship between process parameters and quality attributes of interest. This model is then used to predict product quality with the desired level of certainty and to establish operational ranges that ensure compliance with specification limits.

The importance of the DoE methodology in the pharmaceutical development is further emphasized by various regulatory guidelines, including the Quality ICH Guidelines (Q8, Q11, and the newer Q14) and, more recently, the European Pharmacopoeia (Supplement 11.7).

## Target Audience

This course is ideal for employees in development, quality control labs, process engineering, and quality assurance departments who are currently using DoE or plan to use it in the future. It is also suitable for GMP auditors, inspectors, and validation personnel involved in DoE review or other submission processes. Requirements: Basic math skills/understanding and strong intrinsic motivation.

## Additional Supplement

As an additional supplement one DoE case study will be provided as homework to test and reinforce your newly acquired knowledge.

**The number of participants is strictly limited due to the workshops.**

## Programme

### Day 1

#### Welcome and Setting Up the Scene

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- A short introduction round
- Objectives of the training

#### Basics of DoE Planning: Part A

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- Why DoE?
- One-Factor-at-a Time (OFAT) vs. DoE
- The DoE workflow
- Experimental goals
- Main, interaction and quadratic effects

#### First Optimization Example

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- Get familiar with DoE in Minitab
- Plan and evaluate a factorial experiment in Minitab
- Calculate main and interaction effects in Excel

#### Basics of DoE Planning: Part B

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- Randomization, blocking and replication
- Power and sample size
- Orthogonality
- Fractional factorial designs: resolution III, IV and V
- Plackett-Burman and central composite designs
- Special designs: D-optimal and mixture designs

#### A Pharmaceutical Optimization Problem: Planning

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- Plan a full-factorial design in Minitab
- Assess signal to noise, correlation and effect-sizes
- Employ Minitab's DoE planning tool

#### Exercise: Hands-On DoE Planning

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- Plan a DoE on your own
- Case Study 1: Optimization of a granulation process
- Case Study 2: HPLC robustness assessment

## Day 2

### Statistical Modeling and Prediction

- Effect selection
- Analysis of variance (ANOVA)
- Model building
- F-test, t-test, p-value
- Confidence, prediction and tolerance intervals
- Data and model visualizations with Minitab

### Interpreting Model Diagnostics

- Goodness of fit and prediction
- Curvature
- Predicted values and residuals
- Transformations (Box-Cox)

### A Pharmaceutical Optimization Problem: Analysis

- Effect selection for model building
- Interpretation of model diagnostics
- Derivation and Assessment of Sweet Spot and Proven Acceptable Ranges (PARs)

#### Exercise: Hands-On DoE Analysis

- Analyze the HPLC and Granulation DoEs
- Derive a Sweet Spot and Design Space

### Supplementary Material: Design Augmentation

- Questions with answers (elaborated sample solutions)
- Simultaneous optimization of 3 responses with 2 factors
- Design augmentation to incorporate quadratic effects
- Circumscribed central composite designs in Minitab
- Design Space and Sweet Spot derivation using overlay plots



Each participant should bring a laptop with Excel and Minitab in a current version. A time limited free-trial Minitab program is available from <http://www.minitab.com>. This program should be downloaded on a laptop a few days before the beginning date of the course and verified that it works on the laptop.

## Speakers



**Dr Christian Palmes**  
Principal CMC Statistician  
Bayer AG, Germany

Christian previously led the Statistics Department for Laboratory Diagnostics at Siemens Healthineers in Marburg. Prior to that, he worked as a senior statistical expert at Boehringer Ingelheim in Biberach. Currently, he is with Bayer AG in Wuppertal, where he applies Design of Experiments (DoE) and multivariate data methodologies on a daily basis within the context of Quality by Design. Christian holds a PhD in Applied Mathematics from TU Dortmund, Germany.



**Dr Raluca Ilinca Schmitt**  
Senior Principal CMC Statistician  
Bayer AG, Germany

Ilinca holds a doctoral degree in Statistics from the TU Dortmund, Germany. She started her career with machine learning in the biomarker field at Roche Diagnostics and worked as a lead and senior biostatistician at Genzyme and Bayer, respectively. Since 2014 she provides statistical consulting as senior expert statistician for the chemical and pharmaceutical development at Bayer AG. Her daily business focus lies today on CMC statistics consulting, e.g., for DoE applications in the QbD frame, method validation and stability studies.

## Social Event

On 23 September 2025, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.



If the bill-to-address deviates from the specifications on the right, please fill out here:

Reservation Form (Please complete in full)

Introduction to Statistical Design of Experiments in the Pharmaceutical Industry  
23/24 September 2025, Berlin, Germany

Title, first name, surname

Department

Important: Please indicate your company's VAT ID Number

City

Phone / Fax

E-Mail (Please fill in)

Company

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D-69007 Heidelberg  
GERMANY

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In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed!) (As of January 2012).  
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Date

Tuesday, 23 September 2025, 09.00 – 17.30 h  
(Registration and coffee 08.30 – 09.00 h)  
Wednesday, 24 September 2025, 08.30 – 17.00 h

Venue

HYPERION Hotel Berlin  
Prager Straße 12  
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Fees (per delegate, plus VAT)

Non-ECA Members EUR 2,190  
ECA Members EUR 1,990  
APIC Members EUR 2,090  
EU GMP Inspectorates EUR 1,095  
per delegate plus VAT.  
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments.  
VAT is reclaimable.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at [www.gmp-compliance.org](http://www.gmp-compliance.org).

Conference language

The official conference language will be English.

GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.  
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