ECA Academy
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GMP Certification Programme
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Speakers

Dr Christian Palmes
Bayer AG, Germany

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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

- A short introduction round
- Objectives of the training

Basics of DoE Planning: Part A

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

First Optimization Example

- 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

- 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

- 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

- 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)

Excercise: 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:

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GERMANY

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 | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

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If you cannot attend the conference you have two options:
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German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

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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E-Mail: hyperion.berlin@h-hotels.com

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 search and register directly at www.gmp-compliance.org under the number 21810.

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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