ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Pharmaceutical Development Manager

## Speakers

Dr Steffen Groß
PEI, Germany

Dr Line Lundsberg-Nielsen (invited)
NNE, Denmark

Dr Martin Maus
Boehringer Ingelheim, Germany

Dr Christian Palmes
Bayer, Germany

Dr Andrea Staab
Boehringer Ingelheim, Germany

# ICH Q8 Training Course

## From QbD to Process Validation

Live Online Training on 10/11 April 2024


**Development, Process Validation, Lifecycle Approach, Control Strategy / PAT / RTRT**

## Highlights

- Quality by Design (QbD)
- Quality Target Product Profile (QTPP)
- Critical Quality Attributes (CQA)
- Critical Process Parameters (CPP)
- DoE Examples
- Design Space (DS)
- Control Strategy
- Process Analytical Technology (PAT)/RTRT
- ICH Q12: A Lifecycle Approach to Process Validation

# Programme

## Objectives

You will be updated on the latest regulatory developments and learn how to apply the respective paradigms in Pharmaceutical Development to be better able **to design strategies for the implementation of Quality by Design (QbD) according to ICH Q8.**

During this Live Online Training elements and methodologies associated with ICH Q8 will be discussed. **All this will be illustrated with examples and case studies.**

## Background

The impact of ICH Q8, Q9, Q10, and Q11 is changing both the regulatory expectations and the strategies of Pharmaceutical Development, and **this impact will continue to grow, especially in view of the new ICH Q12 Guideline.**

**The QbD concept described in ICH Q8 and ICH Q11 have to be seen as an overarching paradigm and an interdisciplinary approach across the product lifecycle.** It also systematically emphasises enhanced product and process understanding throughout the product lifecycle.

Ideally, application of ICH Q8 and ICH Q11 elements already starts in the early design phase of a drug product where both patients needs and process design are considered. The QbD concept requires a comprehensive understanding of the chemical and physical nature of the individual active substance(s) and excipients, and of the way their attributes interact in the formulation and how they bare impacted by the manufacturing process. During the design phase, it is important to establish the Quality Target Product Profile (QTPP), determine the Critical Quality Attributes (CQAs), identify Critical Process Parameters (CPPs) and Material Attributes (material CQAs) and to understand how the process parameters and material attributes affect the CQAs. The relationship between process inputs (material attributes and process parameters) and the CQAs is described in the Design Space and ensured during manufacturing with an enhanced control strategy, leading to improved process understanding, greater operational flexibility and opportunities for more efficient life cycle management activities.

**ICH Q8 combined with the new Q12 will open the door to a powerful era of refined, modern and efficient pharmaceutical development and optimization for those companies who are ready to invest in this new paradigm.**

## Target Audience

This Live Online Training is designed for all scientists, engineers, managers and executives from Pharmaceutical and Biotech Development units and support functions to Manufacturing, including Quality Assurance and Technical/CMC Regulatory Affairs, who are involved in the implementation of ICH Q8 elements.

## Programme Day 1

### Introduction to QbD – setting the Scene

- Drug product development at a glance – from first in man to marketing authorization
- Pharmaceutical QbD: Quo vadis?
- Application of QbD principles to drug product development

### QbD - Regulatory Perspective

- Current state of PAT & QbD implementation and regulatory challenges
- Quality by on-line (PAT) measurements
- Real time release testing: general considerations
- Going forward: ICH Q12 / Q13 / Q14

### QbD Toolbox: DoE, PAT, Basic Statistics

- Value-added use of QbD tools – generic approaches and tailored solutions
- Examples for different unit operations

Q&A Session 1

Case Study DoE

- Why we use DoE in the pharmaceutical development
- Example: DoE for formulation selection / optimization
- Example: DoE for manufacturing process optimization
- DoE vs "traditional" approach – when to use which

### Quality Risk Management and Control Strategy

- Objectives of Quality Risk Assessment (QRA) as part of development
- Overview on risk assessment tools
- Introduction to Process Risk Map
- Introduction of risk-based control strategy development

Q&A Session 2

### GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. This training course is the first element for your additional certification. 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. Please find more information at www.gmp-certification.org

# Programme Day 2

## Reports and Documentation

- Development Reports
- Transfer protocols and reports
- Control Strategy and link to the submission dossier

## How the QbD derived Control Strategy defines Process Validation

- QbD and PAT as an enabler for gaining Process Understanding and designing the process and the control strategy, PV stage 1 (establishing the control strategy)
- Different approaches to PV/PPQ depending on the type of control strategy, PV stage 2 (traditional, continuous process verification or hybrid approach used to verify the control strategy)
- Ongoing/Continued Process verification, PV stage 3 (verifying the validity and robustness of the control strategy)

## Process Validation - Case Study (Small Molecule Drug Product)

Case study related to the previous presentation (PV stage 1 and 2)

- Case example of a solid dosage form process enabled by a QbD approach
- Establishing the control strategy: Examples of the application of PAT/RTRT
- Validation of the process – verification of the control strategy

## Ongoing Process Verification and Lifecycle Approach of a Process established from QbD Principles

- Continuous process verification versus continued/ongoing process verification (PV stage 3)
- Case study – the continuation of the example from above (PV stage 3)
- ICH Q12, performance-based control and the link to PAT
- Life cycle management of the product, process and control strategy opportunities for a product developed using of a QbD principles

## Q&A Session 3



# Speakers

**Dr Steffen Groß, Paul-Ehrlich-Institut (PEI) Federal Institute for Vaccines and Biomedicines, Germany**

Steffen Groß received his PhD degree from the Max Planck Research Unit Molecular Cell Biology Jena, Germany. Today, he is Head Section Monoclonal and Polyclonal Antibodies and Scientific Assessor (Quality, Pre-clinic) at the Paul-Ehrlich Institute (PEI).

**Dr Line Lundsberg-Nielsen (invited), NNE, Denmark**

Line has many years of experience within the pharmaceutical Industry and has a theoretical as well as practical approach to QbD, PAT and RTRT from working at Novo Nordisk and Lundbeck before being a consultant. She is an active ISPE member and has had different chairing roles and is a well-recognized international speaker and instructor.

**Dr Martin Maus, Boehringer Ingelheim Pharma GmbH, Germany**

Martin is a Principal Scientist at Boehringer Ingelheim in Biberach where he is working in late stage product development of solid oral dosage forms.

**Dr Christian Palmes, Bayer AG, Germany**

Christian is currently CMC Design Space Expert (Statistical Expert) in the Department of Digital Transformation in CPD, Pharmaceuticals, at Bayer. Previously he was Head of Statistics & Data Sciences (leadership and management of the department of statistics for laboratory diagnostics) at Siemens Healthineers and CMC Senior Statistician (statistical inference for large molecule biopharmaceutics) at Boehringer Ingelheim.

**Dr Andrea Staab, Boehringer Ingelheim Pharma GmbH, Germany**

Andrea worked in different functions within Pharmaceutical Development at Aventis and Boehringer Ingelheim, covering drug product development work from early formulation to late stage process development. Since 2012, she is head of Process Science and QbD Support within Late Stage Drug Product Development. Her responsibilities cover the documentation of the drug product development strategy and development work from risk-based experimental planning to submission for marketing authorization.

**Participant's comment from the May 2018 course:**

*"Excellent speakers!"*
Gordana Savi, Croatian Agency for Medicinal Products and Medical Devices

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Reservation Form (Please complete in full)

## ICH Q8 Training Course | Live Online Training on 10/11 April 2024

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### Date of the Live Online Training
Wednesday, 10 April 2024, 9.00 to 17.00 h CEST
Thursday, 11 April 2024, 9.00 to 13.30 h CEST

### Technical Requirements
We use Webex for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

### Fees (per delegate, plus VAT)
ECA Members € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
The conference fee is payable in advance after receipt of invoice.

### Registration
Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org

### Presentations/Certificate
The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

### Conference language
The official conference language will be English.

### You cannot attend the Live Event?
We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

### Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this event.

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