

## Speakers



Dr Carmen Boix Bernardini  
Almirall



Dr Steffen Groß  
PEI



Dr Hiltrud Horn  
Horn Pharmaceutical Consulting



Dr Lorenz Liesum  
Novartis Pharma AG



Dr Antonio Peinado Amores  
Novartis Pharma AG

# ICH Q8 / ICH Q11 Training Course

From QbD to Process Validation

26/27 May 2020 | Vienna, Austria



## Highlights

- Quality by Design (QbD)
- Quality Target Product Profile (QTPP)
- Critical Quality Attributes (CQA)
- Critical Process Parameters (CPP)
- Design Space (DS)
- Control Strategy
- Process Analytical Technology (PAT)/RTRT
- ICH Q8 and ICH Q11
- ICH Q12: A lifecycle approach to Process Validation

Small & Biotec molecules will be covered:

- Development
- Process Validation
- Lifecycle Approach (ICH Q12)
- Control Strategy / PAT / RTRT

## Objective

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 and ICH Q11.

In workshops, you will discuss elements and methodologies associated with ICH Q8 and ICH Q11. 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 emerging 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 patient 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 are 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 coming 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 training course 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/Q11 elements.

## Programme

### QbD for Drug Products: Background and Practical Aspects

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- Essentials to know about QbD
- Steps for defining QTPP/CQA/ CPP
- Benefits of the QbD Approach
- Practical Examples

### QbD - Regulatory Perspective

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- 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



### Interactive Sessions: QbD for Drug Products

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- QTPP – CQA – CPP for different kinds of formulations, e.g. Oral formulations (Tablets, vs. Biotech vs. Vaccines)
- Typical points of discussions within teams

### Development of the Drug Substance (Focus on Biotech)

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- Strategies to consider for development
- Key points and potential pitfalls
- Ways to success for the submission of the dossier
- Typical questions from regulators

### Development and launch of a QbD process (Drug Product)

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- Lab and pilot phase investigations for criticality assessments and design space definition
- Verification of the design space and the RTRT methods at full scale
- Post approval activities and the use of a post approval change management protocol

### From the design board to the implementation in the manufacturing plant: Practical examples of PAT in small and large molecules

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- PAT Toolbox
- PAT as an enabler of Process Understanding and Quality Assurance
- Main milestones in the implementation of PAT for RTRT: Example in small molecules
- The big opportunities lurking around: Examples of development of PAT solutions for large molecules



### Case examples: Control strategy options for a QbD process

- Case example for solid dosage form process with Real Time Release Testing (RTRT) enabled by PAT and a Design Space approach
- Case example for an small molecule API manufacturing process with PAT and SPC (Statistical Process Control) elements
- The PAT toolbox for pharmaceutical manufacturing and launches

### DoE examples for API development

- DoE theory:
  - Resolution and confounding
  - Overview of available DoE designs
  - Basic statistics – understanding my software analysis
  - Intuitive interpretation of the design: mapping
- Practical approach to DoE aimed to reduce the number of experiments:
  - Risk assessment: Fishbone (Ishikawa) diagram; FMEA (failure Mode Effect Analysis) and RPN analysis (Risk Priority Number)
  - Choosing the design
  - Practical tips for execution

### Continuous Process Verification and lifecycle approach of a QbD process

- Differences to the traditional validation approach
- Case example of an NDA using the alternative validation approach
- Draft ICH Q12: Life cycle management of a QbD process in the framework of ongoing process verification



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

*"Excellent speakers!"*

Gordana Savi, Croatian Agency for Medicinal Products and Medical Devices

## Speakers



**Dr Carmen Boix Bernardini, Almirall, Spain**  
Carmen received her PhD in Organic Chemistry from the University of Valencia (Spain). After two years as Marie Curie post-doctoral Fellow (University of Nottingham), she joined the GSK Operations (UK) in 1999 as process chemist for new APIs, where she had her first contact with QbD. She has over 20 years of experience in development and optimization of chemical processes by QbD methodology. Currently, she is responsible for the industrialization of APIs in Ranke Química (Almirall chemical plant) in Barcelona.



**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 Hiltrud Horn, Horn Pharmaceutical Consulting, Germany**

Dr Hiltrud Horn is managing director of HORN Pharmaceutical Consulting with focus on CMC, GMP and Regulatory Affairs (EU and US). She started in pharma industry in 1990 and held several managerial positions within Hoffmann-La Roche and Knoll (now Abbott) with global responsibility within QC / QA / Regulatory Affairs / Project Management / Medical Writing. She was consultant for the biotech and life science industry at Cap Gemini Ernst & Young prior to starting her own business.



**Dr Lorenz Liesum, Novartis Pharma AG, Switzerland**

Since more than 10 years Dr Liesum is working in the field of Process Analytical Technology and was involved in regulatory QbD filings. He is leading the Statistics and PAT group within global Manufacturing Science and Technology in Novartis Technical Operation supporting the production sites globally for all statistical relevant topics and managing PAT and QbD implementation with a strong focus on advanced control strategies based on NIR spectroscopy and multivariate statistical process control.



**Dr Antonio Peinado Amores, Novartis Pharma AG, Switzerland**

After receiving his Ph. D. from the University of Barcelona, Spain, Antonio started his industrial career as Chemometrician in R&D at GSK. Since 2011 he is working for Novartis as Global Technology Expert supporting the manufacturing operations of small and large molecules in terms of PAT and data analysis. Antonio is currently the Pharmaceutical Editor of NIRnews and is leading a team in the US supporting the late-phase process development of Cell and Gene therapies.

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

Reservation Form (Please complete in full)

ICH Q8 / ICH Q11 Training Course | 26/27 May 2020, Vienna, Austria

Title, first name, surname

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Department

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Important: Please indicate your company's VAT ID Number

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#### General terms and conditions

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2. If you have to cancel entirely we must charge the following processing fees:
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  - Cancellation until 1 week prior to the conference 50 %
  - Cancellation within 1 week prior to the conference 100 %

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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 26 May 2020, 9.30 h – 17.15 h  
(Registration and coffee 9.00 h – 9.30 h)  
Wednesday, 27 May 2020, 8.30 h – 15.30 h

## Venue

Radisson Blu Park Royal Palace Hotel Vienna  
Schlossallee 8  
1140 Vienna, Austria  
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## Fees (per delegate, plus VAT)

ECA Members € 1,590  
APIC Members € 1,690  
Non-ECA Members € 1,790  
EU GMP Inspectorates € 895

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.



## Social Event

In the evening of the first day of the course 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.

## 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.

## Organisation and Contact

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

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