ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Pharmaceutical Development Manager

Speakers

Dr Carmen Boix Bernardini
Almirall

Dr Steffen Groß
PEI

Dr Hiltrud Horn
Horn Pharmaceutical Consulting

Dr Dominique Kummli
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 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 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

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

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

Interactive Sessions: QBD for Drug Products

- 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)

- 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)

- 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

- 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 Quimica (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 Dominique Kummli Novartis Pharma AG, Switzerland

Dominique holds a PhD in physical chemistry from the University of Bern. He started in pharmaceutical industry more than 10 years ago as a project leader for PAT. He is currently working as PAT / Statistics Lead within local manufacturing science and technology group of Novartis Pharma Stein AG, where he is responsible for the implementation of real-time release tests (QbD / PAT concepts) for the sites in the Basel area.

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.

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GERMANY

Reservation Form (Please complete in full)

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

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)

General terms and conditions
If you cannot attend the conference you have two options:
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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
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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.

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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