Speakers

Dr Carmen Boix Bernardini
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ICH Q8 / ICH Q11 Training Course

From QbD to Process Validation

Live Online Training on 8/9 October 2020

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

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 and ICH Q11.**

During this live online training elements and methodologies associated with ICH Q8 and ICH Q11 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 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 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/Q11 elements.

Programme Day 1

09.00 - 09.15 h Welcome and Introduction

09.15 - 10.15 h 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

10.15 - 10.30 h Coffee Break

10.30 - 11.45 h 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

11.45 - 12.15 h Q&A Session 1

12.15 - 13.15 h Lunch

13.15 - 14.00 h
QBD for Drug Products

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

14.00 - 15.00 h 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

15.00 - 15.15 h Coffee Break

15.15 - 16.45 h 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

16.45 - 17.15 h Q&A Session 2

Programme Day 2

08.30 - 09.30 h QbD for Drug Products: Typical Points of Discussions within Teams

- Keypoints and potential pitfalls
- Ways to success for the submission of the dossier
- Typical questions from regulators

09.30 - 10.30 h 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)

10.30 - 10.45 h Coffee Break

10.45 - 11.45 h 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

11.45 - 12.30 h 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

12.30 - 13.00 h Q&A Session 3

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

Hiltrud 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 Line Lundsberg-Nielsen Lundsberg Consulting Ltd., UK

Line is a scientist and runs her own consultancy business focusing on applying a science and risk based approach for pharmaceutical development, process design, technology transfer, qualification and process validation. She 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. Line is an active ISPE member and has had different chairing roles and is a well-recognized international speaker and instructor

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ICH Q8 and Q11 Training Course
Live Online Training on 8/9 October 2020

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Date of the Live Online Training
Thursday, 8 October 2020, 9.00 to 17.15 h CEST
Friday, 9 October 2020, 8.30 to 13.00 h CEST

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ECA Members € 1,590
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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.

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

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PE/0909020