Speakers

Dr Carmen Boix Bernardini
Almirall

Dr Steffen Groß
PEI

Dr Hiltrud Horn
Horn Pharmaceutical Consulting

Dr Line Lundsberg-Nielsen
Lundsberg Consulting

ICH Q8 / ICH Q11 Training Course

From QbD to Process Validation

Live Online Training on 23/24 November 2021

Small & Biotec Molecules will be covered:
Development, Process Validation, Lifecycle Approach (ICH Q12),
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 Q8 and ICH Q11
- ICH Q12: A Lifecycle Approach to Process Validation

Save money and book this live online training course in combination with the „ICH Q12 Training Course - How to use the PACMP in Practice“ on 25 November 2021!

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

Provisional timetable, the actual schedule may vary depending on the situation

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 - 11.00 h QBD for Drug Products

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

11.00 - 11.15 h Break

11.15 - 12.15 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

12.15 - 12.45 h Q&A Session 1

12.45 - 13.45 h Break

13.45 - 15.15 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

15.15 - 15.30 h Break

15.30 - 16.30 h Development of the Drug Substance/ Drug Product (incl. Biotech)

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

16.30 - 17.00 h Q&A Session 2

Programme Day 2

09.00 - 10.00 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

10.00 - 11.00 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)

11.00 - 11.15 h Break

11.15 - 12.15 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

12.15 - 13.00 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 - 13.30 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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Live Online Training Courses

☐ ICH Q8 / ICH Q11 Training Course - From QbD to Process Validation, 23/24 November 2021
☐ ICH Q12 - How to use the PACMP in Practice, 25 November 2021

Title, first name, surname

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Date of the Live Online Training

Tuesday, 23 November 2021, 9.00 to 17.00 h CET
Wednesday, 24 November 2021, 9.00 to 13.30 h CET

Technical Requirements

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Fees (per delegate, plus VAT)

ECA Members € 1,590
APIC Members € 1,690
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ECA Members € 2,290
APIC Members € 2,390
Non-ECA Members € 2,490
EU GMP Inspectorates € 1,440

Registration

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Presentations/Certificate

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Conference language

The official conference language will be English.

Organisation and Contact

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Speakers

Dr Joachim Ermer
Ermer Quality Consulting

Dr Steffen Groß
PEI

Dr Ulrich Kissel
Chair of the EQPA

Dr Lisa Matzen
Boehringer Ingelheim

Luisa Paulo
Hovione,
Member of the ICH Q12 IWG

Dr Ramesh Raghavachari
FDA

ICH Q12 Training Course

How to use the PACMP in Practice

Live Online Training on 25 November 2021

Highlights

- How to implement ICH Q12 in practice
- Views and expectations of assessors (EU & US)
- Examples for Postapproval Change Management Protocols (PACMP) & Established Conditions (ECs)
- Analytical Lifecycle Management
- Strategies to use ICH Q12 effectively for global post-approval change management

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Objectives & Background

The **ICH Q12** topic was endorsed by the ICH Steering Committee in September 2014 and the draft ICH Q12 Guideline on **Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management** was published for comment in December 2017. The final ICH Q12 Post-Approval Changes Guideline including two Annexes has been adopted in November 2019. The guideline aims to promote innovation and continual improvement, and strengthen quality assurance and reliable supply of product, including proactive planning of global supply chain adjustments.

The next phase will be the implementation of ICH Q12 across the ICH regions. However, especially in the EU, revision of local regulations (i.e. the EU Variations Regulation) will have to be performed to fully implement the concepts of Q12 (e.g.: the PACMP can currently be used in the US and in the EU, whereas the ECs are not yet used in the EU).

The new guideline has been developed to complement the existing **ICH Q8 to Q11 guidelines**, especially to enable full realization of more flexible regulatory approaches to **post-approval CMC changes**. The guideline applies to pharmaceutical drug substances and products (both chemical and biological). The guideline also applies to drug-device combination products that meet the definition of a pharmaceutical or biological product and to analytical methods.

In order to ensure a standardized approach, the guidance defines the categorization of Post-Approval CMC changes, Established Conditions (ECs), Post-Approval Change Management Protocols (PACMPs), and Product Lifecycle Management (PLCM) concepts. In particular, the guideline emphasizes the relationship between **Regulatory Assessment and GMP Inspection**.

Furthermore, the guideline describes how ECs are identified as well as what information can be designated as supportive information that would not require a regulatory submission, if changed. Guidance is also included for managing revisions of the ECs over a product's lifecycle.

Presentations, case studies and open discussions will help participants learn more about the lifecycle management of pharmaceutical products / analytical methods and provide a forum for discussing ICH´s new guideline.

Participants will thus have the opportunity to give feedback and ask questions directly to ICH´s Q12 Implementation Working Group (IWG) members on how to move forward with the transition to and implementation of the lifecycle approach.

The meeting will also address topics such as:

- What are "Established Conditions" for Manufacture and Control?
- How could Postapproval Change Management Protocols look like?
- What is the impact of ICH Q12 on analytical method and process validation and transfer?
- What are the views and expectations of assessors and inspectors?

Target Audience

The ECA wishes to actively involve QA personnel dealing with global change management, analytical chemists, QC analysts, R&D scientists, as well as manufacturing scientists (process developers) and managers, and regulatory affairs specialists and regulators.

Programme

Provisional timetable, the actual schedule may vary depending on the situation.

09.00 - 09.15 Welcome and Introduction

09.15 - 10.00
PACMP - Postapproval Change Management Protocol

- What is a PACMP?
- Structure
- Examples

10.00 - 10.45
Views and Expectations of Assessors (EU)

- Current status
- Implementation in Europe
- Application of Q12 tools on post approval changes: Case Studies
- Lessons learned

10.45 - 11.00 Break

11.00 - 12.00
Change Implementation Control now and with ICH Q12

- How we control change implementation today
- How will ICH Q12 influence our future?
- Simplification or new complexity?
- QP considerations

12.00 – 12.30 h
Q&A Session 1

12.30 - 13.30 Break

13.30 - 14.30
Analytical Lifecycle Management

- Overview on EFPIA/PhRMA Paper and the draft USP Chapter <1220>Alignment with manufacturing process
- Analytical Target Profile (ATP)
- Continuous improvement and regulatory flexibility
- ICH Q12, Q2(revision), Q14

14.30 - 15.15
Post-approval CMC Changes -How to Use ICH Q12 effectively

- Global Regulatory Complexity
- Agile post-approval change management within ICH Q12 including examples for
  - Classification of changes
  - Established Conditions / PACMPs / PLCM

15.15 - 15.30 Break

15.30 - 16.30
Drug Product Lifecycle and ICH Q12 - FDA Perspective

- Current status
- Implementation in US
- Application of Q12 tools on post approval changes:
  - PACMP
  - EC
- Lessons learned

16.30 – 17.00 h
Q&A Session 2

Your Benefit

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Speakers

Dr Joachim Ermer,
Ermer Quality Consulting, Germany
Joachim has 30 years of experience in pharmaceutical analytics including global responsibilities as Director of Analytical Processes and Technology, Head of Quality Control, and Head of QC Lifecycle Management (Sanofi, Frankfurt). Since December 2020, he works as a consultant for topics of pharmaceutical analytics and Quality Control. He is member of the USP Expert Committee “Measurement and Data Quality”, and of the Ph. Eur. Chromatographic Separation Techniques Working Party.

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 Ulrich Kissel, European QP Association, KisselPharma-Consulting, Germany
Ulrich is Qualified Person and Chairman of the Board of Directors of the European Qualified Person Association (EQPA). He works as a GMP consultant and contract QP to the Pharmaceutical Industry. Previous to his current role he held leadership positions in Quality and Supply Chain and served for many years as QP for Roche.

Dr Lisa Matzen, Boehringer Ingelheim, Germany
Lisa has held several positions within Boehringer including CMA RA Manager, Office Head CMC RA and Head of Cardiovascular Office (Global Regulatory Affairs). Currently she is Head of the Global CMC RA Group, (Global Regulatory Affairs) at Boehringer.

Luisa Paulo, ICH Q12 IWG Member, Hovione, Portugal
Luisa is Compliance Director at Hovione and Chair of APIC’s Quality Metrics Task Force. Currently she is member of the ICH Q12 Implementation Working Group (IWG) representing APIC.

Dr Ramesh Raghavachari, FDA, USA
Ramesh Raghavachari is currently the Chief of Branch I in the Division of Post-Marketing Assessment I under the Office of Lifecycle Products/ OPQ/ CDER. He has been with the FDA for over 18 years.

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Live Online Training Courses

☐ ICH Q12 - How to use the PACMP in Practice, 25 November 2021
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