ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Regulatory Affairs Manager

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

Save money and book this live online training course in combination with the „ICH Q8 / ICH Q11 Training Course - From QbD to Process Validation“ on 23/24 November 2021!

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

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...“. This is why you receive an acknowledged participant certificate, which lists the contents of the Live Online Training in detail and with which you document your training.


CERTIFICATE

This could be of interest for you as well

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Take advantage of the wide range of „on demand“ training opportunities offered by the ECA Academy. You can use various online offers at any time without software installation. There is an extensive selection of courses available. Simply book online - with a certificate of completion, of course.
Find out more at https://www.gmp-elearning.com and https://www.gmp-compliance.org/recordings

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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Reservation Form (Please complete in full)

Live Online Training Courses

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

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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2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 2 weeks prior to the conference 10 %,
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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).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date of the Live Online Training

Thursday, 25 November 2021, 9.00 to 17.00 h CET

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer 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 € 990
APIC Members € 1,040
Non-ECA Members € 1,090
EU GMP Inspectorates € 545

The conference fee is payable in advance after receipt of invoice.

Would you like to save money?

If you book the live online training courses "ICH Q12 Training Course - How to use the PACMP in Practice" and "ICH Q8 / ICH Q11 Training Course - From QbD to Process Validation" on 23/24 November 2021 simultaneously the fee reduces as follows:

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

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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