ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Regulatory Affairs Manager

Speakers

Dr Joachim Ermer
Ermer Quality Consuting, Germany

Dr Rainer Gnibl
GMP Inspector for EMA and Local Government, Germany

Dr Steffen Groß
PEI, Germany

Dr Ulrich Kissel
Chair of the EQPA, Germany

Dr Lisa Matzen
Boehringer Ingelheim, Germany

Dr Bianca Omasreiter
Roche, Germany

Luisa Paulo
Hovione, Member of the ICH Q12 IWG, Portugal

Dr Ramesh Raghavachari
FDA, USA

ICH Q12 Training Course

How to use the PACMP in Practice

Live Online Training on 15/16 November 2022

Highlights

- How to implement ICH Q12 in practice
- Expectations and experiences of assessors & inspectors (EU & US)
- Examples for Post-approval Change Management Protocols (PACMPs) & Established Conditions (ECs)
- Analytical Lifecycle Management
- Strategies to use ICH Q12 effectively for global post-approval change management
- Practical aspects to consider in submissions

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.

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 (with reference to ICH Q14).

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) documents. 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, practical examples 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.

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 expectations and experiences 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 Day 1

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

Views and Expectations of Assessors (EU)

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

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

Q&A Session 1

Analytical Lifecycle Management

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

PACMP - Postapproval Change Management Protocol

- What is a PACMP?
- Structure
- Examples

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

Q&A Session 2

Programme Day 2

How Quality Systems have to support the ICH Q12 Vision

- ICH Q10 Pharmaceutical Quality System (PQS)
- Importance of Quality Metrics
- Interplay between the PQS and Regulatory Affairs
- QP experience

From the ICH Q12 Concept to CMC Documentation

- Considerations for translating the EC concept into a PLCM document
- Considerations for PACMPs describing complex post-approval changes

Views and Expectations of Inspectors (EU)

- Interfaces between ICH Q12 & GMP
- Intentions, preconditions & the Inspector´s expectations
- Challenges

Q&A Session 3

Your Benefit

Internationally Acknowledged Certificate from ECA Academy


CERTIFICATE

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 acknowledge participant certificate, which lists the contents of the Live Online Training in detail and with which you document your training.

This could be of interest for you as well

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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 Rainer Gnibl, GMP Inspector for EMA and local Government, Germany
Rainer is pharmacist and GMP Inspector for the District Government of Upper Bavaria and the EMA and performs GMP-inspections worldwide. Before that, he was working for the Bavarian Ministry of Environment and Health. Rainer Gnibl also holds a lectureship at the University Erlangen-Nurnberg.

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.

Dr Bianca Omasreiter, Roche, Germany
Bianca studied Biology at the University Würzburg, Germany, and received her PhD in Neurobiology. She joined Roche in 2009 to start her career as a regulatory professional in the department of technical regulatory affairs and is currently working as a people leader. Bianca is passionate about new regulatory strategies and has also been working on regulatory concepts like PACMPs and ECs according to ICH Q12.

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 almost 20 years.

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CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

ICH Q12 Training Course - How to Use the PACMP in Practice
Live Online Training on 15/16 November 2022

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:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
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- Cancellation within 2 weeks prior to the conference 100 %.

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Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.
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 July 2022).
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 https://www.gmp-compliance.org/privacy-policy). 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
Tuesday, 15 November 2022, 9.00 to 17.00 h CET
Wednesday, 16 November 2022, 9.00 to 13.00 h CET

Technical Requirements
We use Webex Events for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT 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 € 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.

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.

You cannot attend the Live Event?
We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

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

CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany
Phone +49(0)62 21/84 44-0
Fax +49(0)62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Dr Andrea Kühn-Hebecker (Operations Director) at
+49(0)62 21/84 44 35, or at
kuehn@concept-heidelberg.de.

For questions regarding organisation please contact:
Ms Sarah Schmidt (Organisation Manager) at
+49(0)62 21/84 44 16, or at
s.schmidt@concept-heidelberg.de.