ECA Academy
Your GMP/GDP Information Source

Speaker

Dr Peer Schmidt
AbbVie

The ICH Q9 Training Package - What is behind it?

Live Online Training on 19 June 2024

Highlights

- Overview about the changes caused by the ICH Q9-Revision
- Details of the chapters of the ICH Q9 Training Package
- Discussions

What is behind the ICH Q9 Training Package?

Objective

The first revision of the ICH Q9 guideline on risk management has provided further clarification on Quality Risk Management (QRM). Topics specifically addressed by the revision are subjectivity, formality and risk-based decision-making in QRM. In addition, the revision clarifies why the risk management process starts with hazard identification rather than risk identification, and how QRM can support medicinal product availability. The ICH Q9(R1) training package provides in-depth information on all these topics, and has an additional chapter on risk review. The aim of the event is to give you a compact overview of the 9 slide sets with over 300 slides of the ICH Q9(R1) training package.

Addressed are:

- Changes in Revision 1 of the ICH Q9 Guideline
- Hazard identification vs risk identification
- Formality according to ICH Q9(R1)
- Risk-based decision making
- Availability of medicinal products
- Risk review
- Reduction of subjectivity in risk management

As a member of the Expert Working Group (EWG), the speaker is a co-author of the ICH Q9(R1) guideline.

Background

Since 2005, the ICH Q9 guideline has been the state of the art when it comes to quality risk management. It found its way into the EU GMP guidelines, initially as Annex 20 and was then incorporated into Part III, where it is still to be found today. In addition, an ICH Q9 briefing package was also developed and then made available on the ICH website. This briefing package was intended to clarify the guideline.

At the end of 2020, the ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) announced that it would revise the ICH Q9 guideline. After several years of work, the final revision was released as "R1" at the beginning of 2023. Changes were mainly made in four areas

- Subjectivity in risk assessment and QRM results
- Management of product availability risks
- Understanding how much formality is required for risk management
- Clarity on risk-based decision making

In addition, training material on risk review and hazard identification as the first step in QRM has been produced. Detailed training material on all these areas was published in October 2023; it consists of nine files totaling over 300 slides and some case studies.

Target Audience

The event is aimed at people who want to familiarise themselves with the topic of risk management in accordance with ICH Q9(R1) and in particular with the changes introduced by Revision 1.

Programme

The ICH Q9 Training Package Part I

Overview of the ICH Q9 revision

Hazard Identification instead of Risk Identification

- Explanation of the change
- QRM tools for hazard identification
- Product development case study
- How hazards can be considered in the FMEA
- Human error

Formality according to ICH Q9(R1)

- Influencing factors
- Case study: Process development
- Case study: Change to the tablet press

Risks in Drug Availability

- Case study: Fictitious cancer drug
- Case study: Combination Product

The ICH Q9 Training Package Part II

Risk-based Decision-making - a daily Task

- Examples of approaches to risk-based decision-making
- Case study: integrating different approaches to decision-making

Dealing with Subjectivity

- Background and examples of subjectivity
- Tips for identifying and managing it
- Case study: Subjectivity in data integrity

The Risk Review

- Implementation
- Examples: Tablet cross-contamination, impurities, contamination control

Speaker

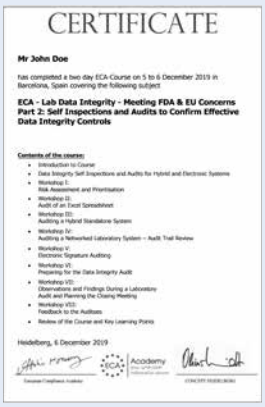
Dr Peer Schmidt
AbbVie

Peer Schmidt brings more than 20 years of experience in the development, manufacturing, registration and supervision of Medicinal Products, Medical Devices and Combination Products. The Director Global Quality Systems also acts as EU Authorized Representative for AbbVie´s Medical Devices. Dr Schmidt holds a Ph.D. in Molecular Biology and was previously the Head of Quality Assurance at Abbott Biotechnology Germany. He is a member of the ICH Q9 Revision 1 Expert Working Group.

Your Benefits

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 seminar in detail and with which you document your training.



CERTIFICATE

Mr John Doe

has completed a two day ECA-Course on 5 to 6 December 2019 in Barcelona, Spain covering the following subject

ECA - Lab Data Integrity - Meeting FDA & EU Concerns Part 2: Self Inspections and Audits to Confirm Effective Data Integrity Controls

Contents of the course:

- Introduction to Course
- Data Integrity Self Inspections and Audits for Hybrid and Electronic Systems
- Workshop I: Risk Assessment and Prioritisation
- Workshop II: Audit of an Excel Spreadsheet
- Workshop III: Auditing a Hybrid Standalone System
- Workshop IV: Auditing a Networked Laboratory System – Audit Trail Review
- Workshop V: Electronic Signature Auditing
- Workshop VI: Preparing for the Data Integrity Audit
- Workshop VII: Observations and Findings During a Laboratory Audit and Planning the Closing Meeting
- Workshop VIII: Feedback to the Auditees
- Review of the Course and Key Learning Points

Heidelberg, 6 December 2019

ECA Academy

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  - Medicinal Products
  - Biopharmaceuticals
- Quality Assurance
- Quality Control
- Validation/Qualification
- Regulatory Affairs
- Sterile Manufacturing
- IT / Computer Validation
- Good Distribution Practice (GDP)
- Data Integrity
- Packaging
- Medical Devices
- Technical Operations

You will find a time schedule for each training course at https://www.gmp-compliance.org/training/gmp-gdp-in-house-trainings

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GERMANY

Reservation Form (Please complete in full)

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Live Online Training on 19 June 2024

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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- Cancellation until 2 weeks prior to the conference 50 %
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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 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 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

Wednesday, 19 June 2024, 13.30 - 17.30 h
All times mentioned are CEST

Technical Requirements

We use Webex for our live online training courses and webinars. At 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 EUR 590,-
APIC Members EUR 640,-
Non-ECA Members EUR 690,-
EU GMP Inspectorates EUR 345,-
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.

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