ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers

Richard M. Bonner
ECA

Timur Güvercinci
Merck Group

Christof Langer
OSConsulting

Dr Franz Schönfeld
GMP Inspector

Quality Risk Management

An ICH Q9 Training Course

Live Online Training on 14/15 October 2020

Highlights

- ICH Q9 Implementation
- Expectations of the Inspector
- QRM Tools
- Workshops and Examples
  - Validation
  - Event Management
  - Supplier Qualification
  - Problem Assessment
  - Decision Making

With many practical examples

Objectives

This ICH Q9 live online training course deals with the practical implementation of Quality Risk Management (QRM). You will learn how to implement and use QRM approaches to increase efficiency and to meet the expectations of the regulators.

Background

The ultimate responsibility for the performance of a medicinal product over its lifetime, its safety, quality and efficacy, lies with the marketing authorisation holder (MAH). To achieve the quality objective, "there must be a comprehensively designed and correctly implemented system of Quality Assurance incorporating Good Manufacturing Practice, Quality Control and **Quality Risk Management.**" **[EU-GMP Guidelines, Part 1, Chapter 1]**.

QRM was formally introduced to the pharmaceutical industry with the **ICH Q9 Guideline**, which has been incorporated in the **EU-GMP Guidelines, Part 3**. In the course of implementing ICH Q9, risk-based approaches increasingly gained in importance. Before that, it was often the case that processes were defined, implemented and documented to the latest detail. Now, based on risk assessments, more flexibility is possible, allowing implementing and controlling processes more efficiently. Decisions can be made based on evaluated risks. Unfortunately many companies limit their whole QRM system to the implementation of the FMEA method only. But it is much more than this and QRM can support the pharmaceutical industry in improving their processes and performance.

Target Audience

This live online training is designed for members of staff in pharmaceutical, biopharmaceutical and API industry's production and quality units, who establish, manage and use quality risk management systems.

Moderator

Wolfgang Schmitt
CONCEPT Heidelberg (on behalf of ECA)

GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance.

Programme

ICH Q 9 - Quality Risk Management: an Overview

- QRM in non-GxP industries
- QRM in pharma
- Historical GMP situation
- Current rules and regulations
- QRM tools and techniques

The Inspector's View on QRM

- Expectations
- Integration in the Pharmaceutical Quality System
- Examples for good and not so good practice

How to realise Quality Risk Management in a GMP Environment

- Integration
- SOPs
- Applications
- Commissioning
- QP Dispositioning

Applying Principles of QMR after an Incident

A problem has occurred – how to perform a sound Risk Assessment of the situation and come to an appropriate decision.

How to apply Quality Risk Management in Validation

- Application of Risk Assessment for Process ValidationRisk Assessment over the Product Life Cycle Risk based Quality by Design (QbD) approach
- Examples

Design of an Event Handling System based on a Quality System and Quality Risk Management Approach

- QRM in the Quality System
- Design of an Event Handling system based on QRM and Management Review
- Use of QRM in the evaluation of events
- Examples

Presentation and Exercise on Risk Management in the Supply Chain

An interactive session to establish where to best concentrate your resources to maximise the assurance of a reliable supply chain:

- Requirements
- Life cycle of the supplier relationship
- Frequency of Supplier Audits based on Risk Assessment
- Defining risk in the audit program
- Compliance risk assessment

How to implement Quality Risk Management in a pharmaceutical Company

- QRM Tools made practicable in daily QRM life
- Comparison of ICH Q9 with other Norms and takeaways for Pharma
- Strength of practical DMAIC methodology
- QRM culture: principles and examples
- Cost of Quality/Compliance

Speakers

Richard M. Bonner
U.K.

Richard M. Bonner is the former Chairman of the EQPA Board of Directors and former Chair of the ECA Executive Board. He has more than 30 years experience within the pharmaceutical industry and was a Senior Quality Adviser for Eli Lilly and Company.

Timur Güvercinci
Merck Group, Germany

Timur Güvercinci is Director of QA Chemical Pharmaceutical Development.

Christof Langer
OSConsulting

Christof Langer is a certified Risk Manager, Lean Six-Sigma Black Belt and independent consultant. Before that, he was Managing Director at Baxter BioScience (now Shire) in Switzerland and the Czech Republic.

Dr Franz Schönfeld
District Government of Upper Franconia, Germany

Dr Franz Schönfeld is a GMP inspector at the centralised inspectorate for medicinal products of the government of Upper Bavaria. He is head of the expert working group for APIs at the Central Authority of the Federal States for Health Protection.

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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)

Quality Risk Management
Live Online Training on 14/15 October 2020

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:
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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
Wednesday, 14 October 2020, 08.30 – 17.00 h
Thursday, 15 October 2020, 08.30 - 15.00 h

Technical Requirements
For our 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 € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845
The course 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.

Conference language
The official conference language will be English.

Ordering a Recording
Independent from the Live Online Training, you can also order a recording of this training at the same conditions. This recording will be provided on our media server. All you need to watch it is an Internet browser – no additional software. You can book the recording of the Live Online Training at any time at https://www.gmp-compliance.org/gmp-webinars/recorded-gmp-webinars.

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

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg
Telefon +49(0) 62 21/84 44 0
Telefax +49(0) 62 21/84 44 34
E-Mail: info@concept-heidelberg.de
www.concept-heidelberg.com

For questions regarding content:
Mr Wolfgang Schmitt (Operations Director) at
+49(0) 62 21/84 44 39, or per e-mail at
w.schmitt@concept-heidelberg.de.

For questions regarding organisation please contact:
Ms Julia Grimmer (Organisation Manager) at
+49 (0) -62 21/84 44 44, or per e-mail at
grimmer@concept-heidelberg.de.