ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Assurance Manager

Speakers

Alexandra Bauloye
Johnson & Johnson Innovative Medicine, Belgium

Christof Langer
OSConsulting, Austria

Aidan Madden
FivePharma, Ireland

Dr Franz Schönfeld
GMP Inspector, Germany

Quality Risk Management

An ICH Q9 Training Course

03/04 September 2025 | Hamburg, Germany

Highlights

- ICH Q9 Implementation
- Expectations of the Inspector
- QRM Tools
- Documentation
  - Risk Description/ Statement
  - Quality Risk Register
- Workshops and Examples
  - Event Management
  - Problem Assessment
  - Decision Making
  - Quality Risk Register
  - Bow Tie Method

With many practical examples

Objectives

This ECA 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 course 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)

Programme

ICH Q 9 - Quality Risk Management: an Overview

- QRM in non-GxP industries
- QRM in pharma
- Historical GMP situation
- ICH Q9: current revision
- QRM tools and techniques

The Inspector's View

- 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

- The term "quality risk management" is used throughout the GMP guidelines. In this session you will get some practical advice on how implement QRM
- SOPs needed
- Auditing

Interactive Session: Applying Principles of QMR after an Incident has happened

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

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

Build a good Risk Description/ Statement: Bow Tie Method

- Distinguish causes and consequences
- What is the difference between hazard and risk
- Use the bow tie method to categorise the pieces of the puzzle and get a clear risk statement

Case Study: Quality Risk Register

- What is it, how to develop it and which type of risks to include
- What to show to authorities?
- The way to business continuity
- Examples

QRM Tools in Practice

- How to implement Quality Risk Management in a pharmaceutical Company
- Using ICH Q9 and other Norms (with takeaways for Pharma)
- Examples

Social Event

On 03 September you are cordially invited to a social event (city tour and dinner). This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Testimonials

"I learned a lot and I'm really happy that I came." | Iris Saevarsdottir, Alvotech Iceland hf

"Great course, great speakers. Thank you!" | V. Adriaensen, Huvepharma, Belgium

"Very good presentations and speakers. Really like implementation of real-life cases for better understanding. Really will recommend to colleagues and other people from pharma area to join courses." | B. Stankovic, Seagen International, Switzerland

"Very interesting course, learned a lot!" | K. Vreys, Center for Clinical Pharmacology, Belgium

Speakers

Alexandra Bauloye
Johnson & Johnson Innovative Medicine, Belgium

Alexandra Bauloye is Business Enterprise Risk Management Lead. Before that she was Senior Director and Global Process Owner for Risk Management within GSK.

Christof Langer
OSConsulting, Austria

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.

Aidan Madden
FivePharma, Ireland

Aidan Madden is CEO of FivePharma, a Quality Services Company founded in 2003. Aidan held senior quality positions in Wyeth Pharmaceuticals, Baxter Healthcare and Fort Dodge Laboratories.

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. German member of the GMP/GDP Inspectors Working Group at EMA.

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 acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

If the bill-to-address deviates from the specifications on the right, please fill out here:

_____

_____

_____

_____

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
03/04 September 2025 | Hamburg, Germany

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 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
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 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
Wednesday, 03 September 2025, 09.00 – 17.15 h
(Registration and coffee 08.30 – 09.00 h)
Thursday, 04 September 2025, 08.15 - 15.30 h

Venue
Barceló Hotel Hamburg
Ferdinandstraße 15, 20095 Hamburg, Germany
Tel. +49 (0) 40/22 63 62 0
Fax +49 (0) 40/22 63 62 999
E-mail: hamburg@barcelo.com

Fees (per delegate, plus VAT)
ECA Members EUR 1.890.-
APIC Members EUR 1.990.-
Non-ECA Members EUR 2.090.-
EU GMP Inspectorates EUR 1,045.-
The course fee is payable in advance after receipt of invoice and includes dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

Registration
Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 21941.

Presentations/Certificate
The presentations for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. 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.
CONCEPT HEIDELBERG
P.O. Box 10 17 64 | D-69007 Heidelberg
Phone: +49(0) 62 21/84 44 0 | Fax +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 reservation, hotel, organisation etc. please contact:
Ms Julia Grimmer (Organisation Manager) at
+49 (0) 62 21/84 44 44, or per e-mail at
julia.grimmer@concept-heidelberg.de