20 YEARS | ECA Academy
Your GMP/GDP Information Source

Quality Risk Management

An ICHQ9 Training Course

With many practical examples

SPEAKERS:

Timur Güvercinci
Merck Group

Christof Langer
OSConsulting

Aidan Madden
FivePharma

Dr Heinrich Prinz
PDM Consulting

Dr Franz Schönfeld
GMP Inspector

20/21 November 2019, Barcelona, Spain

LEARNING OBJECTIVES:

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

This education course is recognised for the ECA GMP Certification Programme „Certified QA Manager".
Please find details at www.gmp-certification.eu

Quality Risk Management

20/21 November 2019, Barcelona, Spain

Objectives

This ICH Q9 training course deals with the practical implementation of the requirements. Individual examples will support you applying Quality Risk Management (QRM) principles in your company.

Background

After its finalisation, the Guideline ICH Q9 "Quality Risk Management" was implemented in the EU, the U.S. and in Japan.

In the course of implementing ICH Q9, the risk-based approach 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. QRM permits scientifically substantiated decision making based on a previously assessed risk.

Unfortunately many companies limit their whole QRM system only to the implementation of the FMEA method. But it is much more than this and QRM can really 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 improve quality risk management systems.

Moderator

Wolfgang Schmitt

Social Event

In the evening of the first course day, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

Programme

ICH Q9 Quality Risk Management

- Basic Requirements
- Comparison to ISO standards

How to implement Quality Risk Management in a pharmaceutical Company

- The risk-based approach and its impact on key GMP processes
- ICH Q9 in the context of ICH Q8 and ICH Q10
- The implementation of „quality risk management thinking and doing" on management and shop floor level (tools and experiences)

How to realise Quality Risk Management in a GMP Environment

- An overview of the diverse techniques (FMEA, HACCP, FTA etc.)
- Benefit of the tools
- Examples from the production of medicinal products and APIs

How to apply Quality Risk Management in Validation

- Understand why the use of Risk Management in Process Validation is expected
- What is the benefit of using a Risk Management approach versus the traditional 3 batch validation approach?
- What does ICH Q9 mean with respect to Quality Risk Management in Validation
- Benefits
- Exercise

The Inspector's View

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

Workshop:
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
- Events (e. g. deviations, complaints etc.)
- Risk Management Application
- Outputs

Presentation and Workshop on Risk Management in the Supply Chain:

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

- Frequency of Supplier Audits based on Risk Assessment
- Defining risk in the audit program
- Compliance risk assessment

After the workshop you will be able to use or adapt the template to conduct a similar risk profile for your own facilities and third-party operations.

Interactive Session on Case Studies

The term "quality risk management" is used throughout the GMP guidelines. In this session you will get some practical advice and work with scenarios requiring a decision.

Speakers

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.

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 Heinrich Prinz

PDM-Consulting, Germany

Dr Prinz worked with Boehringer Mannheim before he joined Biotest where he was Head of Quality Assurance, responsible for both the pharmaceutical and the medical device division. Since 2003 he works as a freelance consultant.

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.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Quality Risk Management
20/21 November 2019, Barcelona, Spain

☐ Mr ☐ Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

P.O. Number (if applicable)

Street/P.O. Box

City

Zip Code

Country

Phone/Fax

E-Mail (please fill in)

CONCEPT HEIDELBERG
P.O. Box 101764
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D-69007 Heidelberg
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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.
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- until 2 weeks prior to the conference 10 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

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Terms of payment: Payable without deductions within 10 days after receipt of invoice.
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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, 20 November 2019, 09.00 – 18.00 h
(Registration and coffee 08.30 – 09.00 h)
Thursday, 21 November 2019, 08.30 - 15.30 h

Venue

Barcelo Sants Hotel
Pl. Països Catalans, s/n
08014 Barcelona, Spain
Phone +34 93 503 53 00
sants@barcelo.com

Fees (per delegate plus VAT)

ECA Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845

The conference fee is payable in advance after receipt of invoice and includes conference documentation, 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 event. Reservation should be made directly with the hotel.
Early reservation is recommended.

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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For questions regarding reservation, hotel, organisation etc. please contact:
Ms Julia Grimmer (Organisation Manager) at +49(0)6221 / 84 44 44, or per e-mail at grimmer@concept-heidelberg.de.