SQT

TRAINING THAT DEVELOPS *REAL* CAPABILITY

Pharmaceutical Quality Risk Management and ICH Q9

LS041

Pharmaceutical Quality Risk Management and ICH Q9

Quality Risk Management is a cornerstone of any effective pharmaceutical Quality System, ensuring product quality and achieving compliance with regulations. This highly interactive one-day course introduces risk management principles and demonstrates their application across pharmaceutical manufacturing, testing and distribution. The course is delivered by expert tutors who combine theory with practical scenarios to make ICH Q9 requirements accessible and actionable.

By attending this course, delegates will obtain the tools and skills necessary to carry out risk assessments designed to implement a risk management system in line with ICH Q9. Learners complete practical exercises covering real life situations so that they can be confident of completing risk assessment when they return to the workplace.

We can tailor the training to meet your specific training needs and incorporate examples from your processes and procedures into the training programme as required.

Duration & Price

Duration: 1 day
Public Virtual Training: €425
Delivery mode: This programme is available In-Company, and via Public Virtual Training

Dates & Locations

Date	Venue	
15 Oct 2026	Virtual	Book Date

In-Company Training

Please contact us for more information on our In-Company training options

What's covered?

The course provides a practical framework for implementing Quality Risk Management in line with ICH Q9. It combines discussion with hands-on activities to ensure learners can apply the methods directly in their workplace.

Topics include:

- Understanding the need for Risk Management
- Key requirements of ICH Q9
- Relationship to deviations and change control
- Identifying possible hazards and sources of risk
- Estimating and reducing risk while minimising subjectivity
- Risk management techniques: FMECA, HAZOP and Preliminary Hazard Analysis
- Applying risk management principles to all aspects of quality and service provision
- Practical risk assessment exercises

The training involves practical exercises covering all relevant topics, with learners encouraged to work on examples from their own workplace as part of these practical exercises. If required, content may be tailored to reflect your organisation’s specific processes, risk profile and regulatory setting.

Who should participate?

This course is designed for anyone in the pharmaceutical sector who requires a solid foundation in the principles and practice of Quality Risk Management. It is particularly beneficial for those involved in:

- Quality and Compliance
- Production
- Engineering
- Research and Development
- Management and supervisory roles

A good standard of written and spoken English is important to engage effectively with this programme.

What will I learn?

On successful completion of this course, learners will be able to:

- Explain the key requirements of ICH Q9.
- Identify, evaluate and quantify risks using structured methodologies.
- Apply techniques such as FMECA, HAZOP and Preliminary Hazard Analysis.
- Assess and determine the acceptability of risks.
- Apply risk assessment principles to deviations and change controls.
- Reassess risks following corrective and preventive actions.
- Correctly apply company-specific risk management procedures and documentation.

These outcomes ensure that learners return with the practical skills and knowledge necessary to conduct effective risk assessments and embed ICH Q9 principles in their daily work.

How do we train and support you?

Our training approach is practical, highly interactive and discussion-based, with flexibility to meet organisational needs

- Pre-training consultation for in-company courses to tailor content to organisational needs
- Emphasis on industry specific application through practical exercises, case studies and group activities that reinforce key concepts and encourage active participation.
- Access to comprehensive course material that is regularly reviewed and updated to reflect the latest industry standards and guidance.
- Live training is available virtually or delivered onsite to suit the needs of the team
- Real-time support from expert tutors

Class sizes are generally limited to 12-15 participants to support personalised learning and individual support.

How can you progress?

Learners who complete this course often continue to deepen their skills in:

- Mastering CAPA in the Pharmaceutical Industry
- Process Validation and Equipment Validation
- GMP for Manufacturers of APIs
- GMP for Manufacturers of Finished Pharmaceuticals
- Technical Writing Skills

Tutors

John Lafferty
View Profile

Majella McEnroe
View Profile

What Our Learners Say

We believe in excellence through transparency and continuous improvement. That's why we invite all our delegates to share their experiences on CourseCheck.com, an independent platform dedicated to genuine, unfiltered feedback. Learner insights help us not only to enhance our training programmes but also empower potential learners to make informed decisions. Click on the link below to read firsthand experiences and testimonials from past learners.

Click Here

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SQT provide a unique combination of high quality, accredited, practical training delivered by leading industry experts and supported by the most up to date learning technology and tools

LEAN SIX SIGMA, PROCESS & PROJECT MANAGEMENT

- Lean Six Sigma
- Join our Lean Six Sigma Network
- Continual Process Improvement
- Project & Programme Management

COMPLIANCE, STANDARDS & AUDITING

- Quality
- Environment & Energy Management
- Health & Safety
- Food Safety
- Life Sciences
- Laboratory
- Integrated Management Systems

LEADERSHIP & PERSONAL DEVELOPMENT

- Leadership & Personal Development
- Train the Trainer

QQI AWARD | IEMA - APPROVED - | CompEx Part of the JTL Group | FSPCA FOOD SAFETY PREVENTIVE CONTROLS ALLIANCE | CQI IRCA APPROVED TRAINING PARTNER | Chartered Institute of Environmental Health

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