



TRAINING THAT DEVELOPS  
*REAL CAPABILITY*



**Pharmaceutical Quality Risk  
Management and ICH Q9**

LS041

# Pharmaceutical Quality Risk Management and ICH Q9

Quality Risk management is an essential element of any pharmaceutical Quality System designed to assure product quality and achieve compliance with regulations. This course covers risk management principles and good risk management practice as applied to all aspects of pharmaceutical manufacturing testing and distribution. The course is based on the requirements of ICH Q9.

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. Practical exercises will be completed throughout the day covering real life situations so that delegates can be confident of completing risk assessment when they return to the workplace.

## Duration & Price

Duration: 1 day

Delivery mode: This programme is available In-Company

## Dates & Locations

*In-Company training programmes are customised for your organisations specific needs. Most In-Company training is now delivered virtually.*

## In-Company Training

Please [contact us](#) for more information on our In-Company training options

## What's covered?

- Understanding the need for Risk Management
- The basic requirements of ICH Q9
- Relationship to other systems – Deviations and Change Control
- Identifying possible hazards
- Estimating the associated risk – removing subjectivity
- Review and reduction of risk
- Risk Management Techniques Hazards - FMECA, HAZOP and Preliminary Hazard Analysis
- How to apply Risk Management to all aspects of Quality and Service Provision
- Risk assessment practical exercises

## Who should participate?

Engineers, Scientists, Managers, Production Personal, Quality Professionals and other personnel in the Pharmaceutical industry who need to gain a solid foundation in the principles and practices of Quality Risk Management.

## What will I learn?

Participants will achieve the following learning outcomes from the programme;

- State the basic requirements of ICH Q9.
- Identify and quantify risks.
- Decide on the acceptability of those risks.
- Re-evaluate risks following corrective action.
- Use techniques such as FMECA, HAZOP and Preliminary Hazard Analysis.
- Apply risk assessment to Deviations and Change Controls.
- Comply with company risk management procedures and complete associated documentation correctly.

## How do we train and support you?

### **In-House Courses**

Course tutor will contact your organisation in advance to discuss the programme in detail. In-house courses can be customised to meet your organisation's specific requirements.

### **Course Manual**

Delegates will receive a comprehensive course manual with relevant course materials.

## Tutors



**Gerry Burke**  
[View Profile](#)



**John Lafferty**  
[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](https://www.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.



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