


Quality Risk Management (QRM) (e-Learning)

 **Delivery:** e-Learning

 **Duration:** 3 hours

 **Cost:** £100 (+ VAT)

Course overview

This highly interactive eLearning course is aligned to the latest science and risk based principles and regulatory guidances in the EU and US. It will go into detail on the steps involved in carrying out a risk exercise, from the initiation stage to completion and review. It also covers the intent and outline content of the ICH's recent draft ICH Q8(R1) that was sent out for industry comment at the end 2021 and is due for final publication later in Q3 2022.

If you wish to try before you buy, book free trial version.

Who should attend?

This course is suitable for people in development, manufacturing, engineering or validation who may have no, or limited quality risk management experience or for those with experience but who wish to be updated with the latest application, particularly regarding science and risk based principles.

Course programme

This course includes the following topics/sessions:

- Regulatory background - EU, US, ICH
- ICH Q8/11 – product and process understanding
- ICH Q9 – principles and tools
- Setting up and running an FMEA
- Pulling it all together
- Review of latest draft of ICH Q9(R1)

Learning outcomes

By the end of the course you will be able to:

- Understand the regulatory drivers for QRM, with particular emphasis on European and US requirements and expectations
- Understand how ICH Q9 underpins ICH Q8, Q10 and Q11 for activities in development, manufacturing, engineering and process validation
- Understand the principles of QRM, the ICH Q9 framework and the importance of common language and approaches, and the differences between QRM and risk analysis
- Understand how to set up and run a risk management exercise, including team selection, risk assessment, analysis, control, review and communication
- Recognise the importance of product Critical Quality Attributes, Critical Process Parameters and Control Strategy in regard to science and risk-based principles
- Appreciate how to use FMEA, risk ranking, cause effect matrix and other related Risk Analysis techniques, such as process flow diagrams, 'fishbone', 'brainstorming' etc.
- Gain knowledge on background and detail of the latest ICH Q9 published draft

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