Quality Risk Management
How to Apply ICH Q9 in Practice

Delivery: Classroom, Inhouse, e-Learning **Duration:** 1 day **Cost:** £560 (+ VAT)

Course overview

This one day course provides the delegate with understanding of the principles of and practical application of Quality Risk Management (QRM). The course is focused on ICH Q9 (QRM) requirements and its use in development, manufacturing, engineering, validation or other functions. It also covers its links to ICH Q8 (Pharmaceutical Development), Q10 (Quality Systems) and Q11 (Drug Substance Development) and ICH Q12 (Lifecycle)

The 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 will also cover the intent and outline content of the ICH's recent draft ICH Q8(R1) that was sent out for industry comment end 2021 and is due for final publication later in 2022. If this final version is published by the time of the course, the course will fully take this into account.

Classroom courses - Please note, the advertised venue may need to be changed, if the required number of delegates is not met. In this situation, the course will be converted to an Online Virtual course and all delegates notified accordingly. The decision regarding the venue will be made at least 4 weeks before the course is due to run.

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 will cover the following:

- 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
- Exercise - your action plan

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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Tel: +44 (0)118 918 4000 Email: trainingsales@rssl.com www.rssl.com
RSSL Training, Reading Science Centre, Whiteknights, Reading, Berkshire RG6 6LA