

Quality Risk Management Fundamentals

Get hands-on with Quality Risk Management

Gain insight into Quality Risk Management (ICH Q9), understand its core principles, and learn how to apply them in practice.

About the course

Quality Risk Management (QRM) has become a key element across the life sciences industry. Regulatory authorities such as the EMA and the Danish Medicines Agency (DKMA) now expect risk management to be integrated into all major decisions – from product development and process design to batch release and continuous improvement.

This course provides a fundamental understanding of the principles behind QRM and demonstrates how to apply its methods within your own organisation. The training is based on the ICH Q9 guideline and its practical relevance to GMP activities. You will gain insight into both the classical and the modern approaches to risk management.

Through case studies, you will gain hands-on experience in risk assessment and learn how to select the appropriate level of formality – from structured models such as FMECA to more informal approaches used in everyday decision-making.

We focus on the fundamental concepts and traditional methods while building on the modern understanding of QRM, with particular emphasis on the revised ICH Q9 guideline and the latest regulatory expectations – including a presentation from the Danish Medicines Agency (DKMA).

Throughout the course, there will be plenty of opportunities to exchange experiences and discuss practical challenges with other participants.

The course provides a solid understanding of how QRM supports the pharmaceutical quality system and helps you prioritise resources where the risks are greatest.

The course spans two days with an overnight stay, which provides time and space for reflection, immersion, and networking across participants—and thereby significantly enhances your overall learning outcomes.

Sign-up

Course

Quality Risk Management Fundamentals

Format

2 days, overnight stay included

Price this year

17.500 kr. excl. VAT

Choose date and sign up

Hillerød 17. aug – 18. aug. 2026

Target group

This course is designed for academics, laboratory technicians, engineers, and new employees in the life sciences industry who are involved in risk assessments or risk-based decision-making.

No prior knowledge of the subject is required. The course provides a solid foundation for getting started with QRM.

What you gain

Your benefit

- You gain a practical understanding of the principles of Quality Risk Management and ICH Q9.
- You learn how to perform and document risk assessments using both formal and informal methods.
- You can apply QRM as a basis for risk-based decision-making in your daily GMP work.

Your company's benefit

- Your employee can actively apply QRM within the company's quality system and in day-to-day decision-making.
- Your employee helps strengthen compliance and document risk-based decisions for regulatory authorities.
- Your employee is equipped to use risk management as a strategic tool for prioritisation and continuous improvement.

Course program

The course duration is 2 days. Accommodation is included.

- Introduction to Quality Risk Management and regulatory requirements
- Principles and terminology in ICH Q9
- The risk management process flow – the six steps
- Differences between guidelines and standards
- Formality – selecting the appropriate method and tools
- Risk analysis using FMECA (case work)
- Informal approaches and “risk-based decision making”
- Regulatory perspective: expectations from DKMA
- Risk management from development to batch release