pharmakon

Quality Risk Management Fundamentals

Get hands-on with Quality Risk Management

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

Quality Risk Management (QRM) has become a key element across the life science industry. Regulatory authorities such as EMA and 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 gives you a fundamental understanding of the principles behind QRM and shows you how to apply its methods in 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 work, you will get hands-on experience with risk assessment and learn how to select the right level of formality – from structured models such as FMECA to more informal approaches used in everyday decision-making.

We focus on the basic concepts and traditional methods, and build on the modern understanding of QRM with special emphasis on the revised ICH Q9 and the latest expectations from the authorities – 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 highest.

The course language is English.
If all participants are Danish-speaking, the course will be conducted in Danish with English slides.

At this course you will meet:
Hanna Kviat Antonsen, Senior Quality Manager, Ascendis Pharma A/S
Michael Schousboe, Senior QMS Specialist, Novo Nordisk A/S
Henning Boje Andersen, Professor Emeritus, Technical University of Denmark (DTU)

Underviser fra Lægemiddelstyrelsen

Course facts

FORMAT
2 days

PRICE THIS YEAR
17.500 DKK excl. VAT, overnight stay included

Sign-up dates

Hillerød

17. aug. — **18. aug.**
2026

Do you have questions about this course?

Kontakt
Kursuskoordinator
Andreas Goldschadt
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Target group

This course is aimed at academics, laboratory technicians, engineers, and new employees in the life science industry who work with 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.

Your benefits

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

Your company's benefits

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

Course agenda

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

The course language is English.

Sign up online at
www.pharmakon.dk