PRACTITIONER TRAINING · GOOD PRACTICE (GXP)

ICH Q9 Quality Risk Management

Self-paced online training (video) · 13 modules · about 3 hours of video, plus practice exercises · about 6 hours in total · English, with captions

Apply quality risk management across the pharmaceutical product life cycle following ICH Q9(R1), from hazard identification and risk assessment to control, communication, review and risk-based decisions.

WHO IT IS FOR

Quality assurance and quality control staff, production, engineering and validation staff, regulatory affairs specialists, QRM facilitators and managers in pharmaceutical, biotech and API manufacturing companies.

WHAT YOU WILL LEARN

- Explain the principles of quality risk management and the QRM process
- Identify hazards and assess risks with an appropriate level of formality
- Reduce subjectivity in risk assessments and their outputs
- Select and apply tools such as FMEA, FTA, HACCP and risk ranking
- Make and document risk-based decisions, including product availability risks
- Integrate QRM into deviations, change control, CAPA and the quality system

MODULES (13)

1. Welcome: why quality risk management matters
2. ICH Q9(R1) at a glance
3. Starting well: roles and initiating QRM
4. Risk assessment, step by step
5. Risk control, communication and review
6. How much formality?
7. Subjectivity and risk-based decisions
8. Product availability and shortage risks
9. Tools 1: basic methods, FMEA and FMECA
10. Tools 2: FTA, HACCP and risk ranking
11. QRM in deviations, investigations and CAPA
12. QRM in change, validation, suppliers, facilities
13. Putting it together and the final exam

PRICE

US$99 per learner

Per learner, by team size

1–10 learners	**US$99**
11–50 learners	**US$79**
51–200 learners	**US$69**

Excluding taxes.

DURATION

About 6 hours in total (3 hours of video)

MODULES

13

FORMAT

Self-paced online training (video)

LANGUAGE

English, with captions

ACCESS

12 months

CERTIFICATE

Sterling Academy Certificate of Completion

Scan for the course page, prices and enrolment