



QUALITY AND PRODUCTIVITY | QP-020

Quality Risk Management for Life Sciences

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Course content

Why Attend

Pharmaceutical, biotechnology and medical device organisations must manage quality risks to protect patients and comply with regulators. Risk-based approaches help focus resources on what matters most for product quality.

This Aractech course explains quality risk management principles and processes aligned with ICH Q9, risk assessment tools such as FMEA, HACCP and risk ranking, risk control and review, integration with the pharmaceutical quality system, and documentation expected by inspectors. Participants conduct risk assessments on realistic cases.

Course Methodology

- Regulatory-focused presentations
- Risk assessment workshops
- Case studies
- Documentation reviews
- Group discussions

Course Objectives

- Explain quality risk management principles and ICH Q9
- Apply risk assessment tools appropriately
- Evaluate and control quality risks
- Integrate QRM into quality systems
- Document risk assessments for inspections
- Review and communicate risks

Course content

Target Audience

- Quality assurance professionals in pharma and biotech
- Manufacturing and validation staff
- Regulatory affairs professionals
- Quality control laboratory managers

Course outline

Detailed course outline

Day-by-day outline for Quality Risk Management for Life Sciences.

Day 1 - QRM Principles

- 09:00-09:39 | Patient safety focus
- 09:39-10:18 | ICH Q9 overview
- 10:18-10:57 | QRM process
- 10:57-11:00 | Subjectivity in risk
- 11:00-11:30 | Coffee break
- 11:30-12:05 | Subjectivity in risk (continued)
- 12:05-12:43 | Regulatory expectations
- 12:43-14:00 | Exercise: Risk question formulation

Day 2 - Risk Assessment Tools

- 09:00-09:39 | Risk ranking and filtering
- 09:39-10:18 | FMEA
- 10:18-10:57 | HACCP
- 10:57-11:00 | Fault tree analysis
- 11:00-11:30 | Coffee break
- 11:30-12:05 | Fault tree analysis (continued)
- 12:05-12:43 | Tool selection
- 12:43-14:00 | Workshop: FMEA for a process

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Day 3 - Risk Control and Review

- 09:00-09:39 | Risk reduction
- 09:39-10:18 | Risk acceptance
- 10:18-10:57 | Review and monitoring
- 10:57-11:00 | Change control links
- 11:00-11:30 | Coffee break
- 11:30-12:05 | Change control links (continued)
- 12:05-12:43 | Deviation management
- 12:43-14:00 | Exercise: Risk control plan

Day 4 - Integration with Quality Systems

- 09:00-09:34 | Quality systems
- 09:34-10:08 | Validation
- 10:08-10:42 | Supplier management
- 10:42-11:00 | Data integrity
- 11:00-11:30 | Coffee break
- 11:30-11:46 | Data integrity (continued)
- 11:46-12:53 | Case study: Inspection finding
- 12:53-14:00 | Exercise: QRM integration

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Day 5 - Documentation and Communication

- 09:00-09:45 | Documenting assessments
- 09:45-10:30 | Inspection readiness
- 10:30-11:00 | Risk communication
- 11:00-11:30 | Coffee break
- 11:30-11:45 | Risk communication (continued)
- 11:45-12:30 | Governance
- 12:30-13:15 | Improvement
- 13:15-14:00 | Capstone: QRM report

Seminar dates

Available seminar dates

Live dates and pricing for Quality Risk Management for Life Sciences generated from the course details page.

Date	Location	Format	Fee
16 - 20 November 2026	Paris	Classroom	€3,825
7 - 11 December 2026	Frankfurt	Classroom	€1,875
11 - 15 January 2027	Amsterdam	Classroom	€2,830
8 - 12 February 2027	Geneva	Classroom	€4,315
8 - 12 March 2027	Istanbul	Classroom	€1,978
12 - 16 April 2027	Cape Town	Classroom	€1,625
10 - 14 May 2027	Barcelona	Classroom	€2,815
14 - 18 June 2027	Paris	Classroom	€3,825
12 - 16 July 2027	Frankfurt	Classroom	€1,875
9 - 13 August 2027	Amsterdam	Classroom	€2,830

Seminar dates

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Date	Location	Format	Fee
13 - 17 September 2027	Geneva	Classroom	€4,315
11 - 15 October 2027	Istanbul	Classroom	€1,978
8 - 12 November 2027	Vienna	Classroom	€3,225
13 - 17 December 2027	Barcelona	Classroom	€2,815
16 - 20 November 2026	Online / Live	Online / Live	€1,815
7 - 11 December 2026	Online / Live	Online / Live	€1,815
11 - 15 January 2027	Online / Live	Online / Live	€1,815
8 - 12 February 2027	Online / Live	Online / Live	€1,815
8 - 12 March 2027	Online / Live	Online / Live	€1,815
12 - 16 April 2027	Online / Live	Online / Live	€1,815

Seminar dates

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Date	Location	Format	Fee
10 - 14 May 2027	Online / Live	Online / Live	€1,815
14 - 18 June 2027	Online / Live	Online / Live	€1,815
12 - 16 July 2027	Online / Live	Online / Live	€1,815
9 - 13 August 2027	Online / Live	Online / Live	€1,815
13 - 17 September 2027	Online / Live	Online / Live	€1,815
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