Risk-Based Quality Management in Manufacturing Training Course

Professional Development Training Course Outline

Category	Manufacturing	**Duration**	10 Days
Base Fee	$3,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

Risk-Based Quality Management (RBQM) in manufacturing is a modern, proactive approach that integrates quality assurance with structured risk assessment to ensure consistent product quality, regulatory compliance, and operational efficiency. In today's highly competitive and regulated industrial environment, organizations must shift from reactive quality control to predictive, data-driven decision-making frameworks. This training course equips professionals with advanced skills in GMP compliance, ISO 9001:2015 risk-based thinking, quality risk assessment (QRA), CAPA systems, and continuous improvement methodologies to strengthen manufacturing excellence.

Risk-Based Quality Management in Manufacturing Training Course is designed to help participants master ICH Q9 Quality Risk Management, Six Sigma integration, Lean Manufacturing principles, digital quality systems, and real-time risk monitoring tools. By embedding risk-based thinking into every stage of production, organizations can minimize deviations, reduce defects, optimize cost of quality, and enhance customer satisfaction. The course blends theory, global standards, and real-world applications to prepare professionals for Industry 4.0 manufacturing environments.

Programme Curriculum

Risk-Based Quality Management in Manufacturing Training Course

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Course Duration

10 days

Course Objectives

1. Understand principles of Risk-Based Quality Management (RBQM) in manufacturing
2. Apply ICH Q9 Quality Risk Management framework effectively
3. Implement ISO 9001:2015 risk-based thinking requirements
4. Conduct Failure Mode and Effects Analysis (FMEA) for process control
5. Develop robust Corrective and Preventive Action (CAPA) systems
6. Improve compliance with GMP and regulatory quality standards
7. Use statistical process control (SPC) for defect prevention
8. Integrate Lean Six Sigma methodologies into quality systems
9. Build effective risk assessment and mitigation strategies
10. Enhance deviation management and root cause analysis (RCA) skills
11. Apply digital quality management systems (QMS) tools
12. Strengthen audit readiness and inspection preparedness
13. Drive continuous improvement and operational excellence culture

Target Audience

- Quality Assurance Managers
- Quality Control Analysts
- Manufacturing & Production Supervisors
- Process Engineers
- Regulatory Affairs Specialists
- Compliance Officers
- Lean Six Sigma Practitioners
- Pharmaceutical, FMCG, Automotive & Food Industry Professionals

Course Modules

Module 1: Introduction to Risk-Based Quality Management

- Concept of RBQM in manufacturing
- Evolution from traditional QC to risk-based systems
- Key global standards (ICH Q9, ISO 9001)
- Risk-based thinking principles
- Importance in modern manufacturing
- **Case Study:** Pharmaceutical company reducing batch failures using RBQM

Module 2: Regulatory Frameworks & Compliance

- GMP guidelines overview
- ISO 9001:2015 requirements
- FDA & EMA expectations
- Audit compliance strategies
- Documentation standards
- **Case Study:** Food industry compliance audit failure recovery

Module 3: Quality Risk Management (ICH Q9)

- Risk identification techniques
- Risk analysis methods
- Risk evaluation matrix
- Risk control strategies
- Risk review lifecycle
- **Case Study:** Medical device risk assessment improvement

Module 4: Failure Mode and Effects Analysis (FMEA)

- FMEA methodology
- Severity, occurrence, detection scoring
- Risk Priority Number (RPN)
- Process vs design FMEA
- Implementation steps
- **Case Study:** Automotive assembly line defect reduction

Module 5: CAPA Systems

- Corrective vs preventive actions
- Root cause analysis tools
- CAPA lifecycle management
- Documentation best practices
- Effectiveness verification
- **Case Study:** Cosmetic manufacturing contamination control

Module 6: Statistical Process Control (SPC)

- Control charts and variability
- Process capability analysis
- Data interpretation techniques
- Out-of-control process detection
- Quality trend analysis
- **Case Study:** Electronics manufacturing yield improvement

Module 7: Lean Manufacturing Integration

- Lean principles in quality systems
- Waste reduction strategies
- Value stream mapping
- Kaizen implementation
- Continuous flow optimization

- **Case Study:** FMCG production efficiency enhancement

Module 8: Six Sigma in Risk Management

- DMAIC methodology
- Defect reduction strategies
- Sigma level improvement
- Process capability enhancement
- Data-driven decision-making
- **Case Study:** Textile industry defect minimization

Module 9: Deviation Management

- Types of deviations
- Investigation workflows
- Documentation systems
- Escalation procedures
- Preventive measures
- **Case Study:** Pharmaceutical batch deviation handling

Module 10: Root Cause Analysis (RCA)

- 5 Whys technique
- Fishbone diagram (Ishikawa)
- Data collection methods
- Problem-solving frameworks
- Verification of causes
- **Case Study:** Machinery breakdown in production plant

Module 11: Digital Quality Management Systems

- eQMS platforms
- Automation in quality control
- Data integrity principles
- Cloud-based QMS solutions
- Real-time monitoring tools
- **Case Study:** Smart factory digital transformation

Module 12: Audit & Inspection Readiness

- Internal audit planning
- External inspection preparation
- Audit trail documentation
- Non-conformance handling
- Compliance reporting
- **Case Study:** Regulatory inspection success in pharma plant

Module 13: Supplier Quality Management

- Supplier qualification process
- Risk-based supplier evaluation
- Material quality assurance

- Vendor audits
- Supply chain risk control
- **Case Study:** Automotive supplier defect elimination

Module 14: Continuous Improvement Systems

- PDCA cycle implementation
- Quality improvement culture
- Performance metrics tracking
- Employee involvement strategies
- Innovation in quality systems
- **Case Study:** Manufacturing plant productivity boost

Module 15: Advanced Risk Analytics & Industry 4.0

- Predictive quality analytics
- AI in quality management
- IoT-enabled monitoring
- Big data in manufacturing
- Smart factory integration
- **Case Study:** AI-driven defect prediction in production line

Training Methodology

This course employs a participatory and hands-on approach to ensure practical learning, including:

- Interactive lectures and presentations.
- Group discussions and brainstorming sessions.
- Hands-on exercises using real-world datasets.
- Role-playing and scenario-based simulations.
- Analysis of case studies to bridge theory and practice.
- Peer-to-peer learning and networking.
- Expert-led Q&A sessions.
- Continuous feedback and personalized guidance.

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.org or call *+254769199797*

Certification

Upon successful completion of this training, participants will be issued with a globally- recognized certificate.

Tailor-Made Course

We also offer tailor-made courses based on your needs.

Key Notes

a. The participant must be conversant with English.

b. Upon completion of training the participant will be issued with an Authorized Training Certificate

c. Course duration is flexible and the contents can be modified to fit any number of days.

d. The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.

e. One-year post-training support Consultation and Coaching provided after the course.

f. Payment should be done at least a week before commence of the training, to Fineskill Training Center account, as indicated in the invoice so as to enable us prepare better for you.

Upcoming Scheduled Sessions

Start Date	End Date	Location	Price
23 Nov 2026	04 Dec 2026	Online	$2,000
23 Nov 2026	04 Dec 2026	Physical	$3,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$9,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$12,000

Ready to enroll or request a customized program? Book online or contact us:

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