Pharmaceutical Risk Management (GxP Focus) Training Course

Professional Development Training Course Outline

Category	Risk Management	**Duration**	5 Days
Base Fee	$1,500 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

The Pharmaceutical and Biotechnology sectors operate under a stringent global regulatory framework, collectively known as Good "x" Practice (GxP). This framework encompasses vital disciplines like Good Manufacturing Practice (GMP), Good Clinical Practice (GCP), and Good Laboratory Practice (GLP), all designed to ensure patient safety, product quality, and data integrity. Navigating this complex, ever-evolving landscape requires a systematic, proactive approach to identifying, assessing, controlling, and reviewing risks. Quality Risk Management (QRM), particularly as defined by ICH Q9, is the indispensable methodology for making evidence-based, risk-proportionate decisions across the entire product lifecycle, from R&D through distribution. A deficiency in risk control is a primary cause of regulatory non-compliance, resulting in FDA 483s, warning letters, and costly product recalls. Therefore, advanced, role-specific training in GxP Risk Management is not merely a compliance task; it's a strategic imperative for operational excellence and maintaining global regulatory compliance.

Pharmaceutical Risk Management (GxP Focus) Training Course is specifically engineered to bridge the gap between regulatory theory and practical implementation of QRM within a GxP-compliant environment. Participants will master a risk-based approach to critical processes, including change control, deviation management, CAPA development, and validation. We emphasize modern trends like Data Integrity, digital transformation in quality systems, and supply chain risk mitigation. Through interactive workshops and real-world case studies, delegates will gain the confidence and practical tools to conduct robust risk assessments, establish proportionate controls, and build an audit-ready Quality Management System (QMS). By embedding a strong risk culture, this training transforms compliance from a reactive burden into a competitive advantage, ensuring the consistent supply of safe and effective medicines globally.

Programme Curriculum

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Course Duration

5 days

Course Objectives

1. Master the ICH Q9 Quality Risk Management framework and its GxP application.
2. Apply a risk-based approach to design and optimize a robust Quality Management System (QMS).
3. Conduct systematic Risk Assessments using industry-standard tools.
4. Ensure Data Integrity and compliance with ALCOA+ principles in all GxP records.
5. Develop risk-proportionate strategies for Computer System Validation (CSV) and GAMP 5.
6. Integrate risk principles into Change Control and Deviation Management processes.
7. Identify and mitigate critical risks across the global Pharmaceutical Supply Chain
8. Formulate effective, risk-informed Corrective and Preventive Actions (CAPA) plans.
9. Interpret and respond effectively to recent Regulatory Trends related to QRM findings.
10. Implement proactive risk control measures in Good Manufacturing Practice (GMP) operations
11. Strengthen Audit Readiness and Inspection preparedness through robust QRM documentation.
12. Evaluate and manage Third-Party Risk Management (suppliers, CMOs) in a GxP context.
13. Foster a company-wide Quality Culture centered on proactive risk identification and communication.

Target Audience

1. Quality Assurance (QA) Professionals and Quality Control (QC) Personnel
2. Regulatory Affairs Specialists and Compliance Managers
3. R&D Scientists and Process Development Engineers
4. Manufacturing and Production Supervisors
5. Validation Engineers (Process, Cleaning, Computer System Validation)

6. Auditors (Internal and External/Supplier Auditors)
7. Senior Management responsible for GxP Oversight and Resource Allocation
8. Supply Chain and Distribution (GDP) Managers

Course Modules

Module 1: Foundational QRM Principles and GxP Framework

- Overview of the GxP Ecosystem
- ICH Q9 Quality Risk Management (QRM) Model.
- The role of QRM in the entire Product Lifecycle
- Defining Risk Appetite and establishing a QRM policy.
- Case Study: Analyzing a real-world FDA Warning Letter to trace the root cause back to a failure in a foundational QRM process.

Module 2: Risk Assessment Tools and Techniques

- Systematic Risk Identification methods
- Qualitative, Quantitative, and Semi-Quantitative Risk Analysis.
- In-depth application of Failure Mode and Effects Analysis for manufacturing processes.
- Introduction to Hazard Analysis and Critical Control Points for contamination control.
- Case Study: Performing an FMEA on a Sterile Manufacturing Process to prioritize critical control points.

Module 3: Risk Control, Review, and Communication

- Determining risk acceptability and prioritization.
- Risk Control strategies.
- Developing Risk Acceptance Criteria and setting effective Control Measures.
- Establishing a periodic Risk Review and monitoring system.
- Case Study: Evaluating the residual risk following the implementation of new environmental monitoring controls in a QC laboratory.

Module 4: QRM in Quality Management Systems (QMS)

- Applying QRM to Deviation, OOS, and OOT Management for risk-based investigation depth.
- Integrating risk into CAPA effectiveness checks.
- Using QRM to rationalize the scope and depth of Change Control procedures.
- The relationship between QRM, SOPs, and Good Documentation Practices
- Case Study: Designing a risk-based CAPA plan after a significant deviation involving a critical raw material to prevent recurrence.

Module 5: Data Integrity and Computer System Validation (CSV)

- Data Integrity as a GxP Risk
- Applying the ALCOA+ Principles as risk control measures.
- Risk-Based CSV: Scoping validation activities
- Validation for Cloud-Based and Digitally Transformed GxP systems.
- Case Study: Assessing the data integrity risk of an unvalidated spreadsheet used for batch release calculations and proposing appropriate CSV/control measures.

Module 6: Risk in Manufacturing and Facility Operations (GMP/GEP)

- QRM application to Equipment Qualification and Calibration programs.
- Risk-based approach to Cleaning Validation and establishing acceptable limits.
- Managing the risks of Cross-Contamination in multi-product facilities.
- Facilities and Equipment Good Engineering Practice from a QRM perspective.
- Case Study: Utilizing QRM to justify a reduced revalidation frequency for a utility system based on robust performance monitoring data.

Module 7: Supply Chain and Distribution Risk Management (GDP)

- Identifying and assessing risks posed by Third-Party Suppliers and vendors.
- Managing Cold Chain and Temperature Excursion Risks in distribution
- Strategies for preventing Counterfeiting and ensuring product traceability.
- Developing a Business Continuity Plan based on supply chain risk assessment.
- Case Study: Performing a risk assessment on a logistics partner to mitigate the risk of temperature excursion for a biologic product during transit.

Module 8: Audit Readiness and Quality Culture

- Preparing QRM documentation for Regulatory Inspections
- Role of QRM in Internal Audit program design and non-conformance trending.
- Techniques for articulating QRM decisions effectively during an audit.
- Strategies for fostering a Proactive Risk Culture within the organization.
- Case Study: Simulating an Inspector Interview where participants must defend a risk acceptance decision made during a critical process change.

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	27 Nov 2026	Online	$1,000
23 Nov 2026	27 Nov 2026	Physical	$1,500
23 Nov 2026	27 Nov 2026	Physical	$3,000
23 Nov 2026	27 Nov 2026	Physical	$3,000
23 Nov 2026	27 Nov 2026	Physical	$6,000
23 Nov 2026	27 Nov 2026	Physical	$4,500
23 Nov 2026	27 Nov 2026	Physical	$6,000
23 Nov 2026	27 Nov 2026	Physical	$6,000

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