Quality Assurance in Pharmaceutical Manufacturing Training Course

Professional Development Training Course Outline

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

Course Introduction

The pharmaceutical industry operates within one of the most highly regulated environments globally, where product quality, patient safety, regulatory compliance, and data integrity are critical success factors. Quality Assurance (QA) in Pharmaceutical Manufacturing plays a pivotal role in ensuring that pharmaceutical products consistently meet predefined quality standards throughout the product lifecycle. With increasing regulatory scrutiny from agencies such as FDA, EMA, WHO, MHRA, and PIC/S, organizations require highly skilled professionals capable of implementing robust Quality Management Systems (QMS), Good Manufacturing Practices (GMP), risk-based quality approaches, and continuous improvement initiatives. Quality Assurance in Pharmaceutical Manufacturing Training Course equips participants with the latest industry knowledge, practical tools, and regulatory expectations to strengthen quality culture and operational excellence.

The course focuses on emerging pharmaceutical quality trends including Quality by Design (QbD), Pharmaceutical Quality Systems (PQS), Data Integrity Compliance, Computer System Validation (CSV), Annex 1 Sterile Manufacturing Requirements, Risk Management, CAPA Effectiveness, and Regulatory Inspection Readiness. Through real-world case studies, industry best practices, and practical applications, participants will gain expertise in quality assurance frameworks that drive compliance, manufacturing efficiency, product reliability, and patient-centric outcomes. The program is designed to help pharmaceutical professionals navigate evolving regulatory landscapes while enhancing organizational competitiveness and sustainable quality performance.

Programme Curriculum

Quality Assurance in Pharmaceutical Manufacturing Training Course

Introduction

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Course Duration

5 days

Course Objectives

By the end of this training, participants will be able to:

1. Understand advanced Good Manufacturing Practices (cGMP) requirements.
2. Implement robust Pharmaceutical Quality Management Systems (QMS).
3. Apply Quality Risk Management (QRM) principles based on ICH Q9.
4. Develop effective CAPA Management and Root Cause Analysis strategies.
5. Strengthen Data Integrity and ALCOA+ Compliance practices.
6. Implement Quality by Design (QbD) methodologies in manufacturing.
7. Manage Regulatory Inspection Readiness and audit preparedness.
8. Enhance Deviation Management and Investigation Excellence.
9. Ensure compliance with Annex 1 Sterile Manufacturing Requirements.
10. Apply Computer System Validation (CSV) and digital quality controls.
11. Establish effective Supplier Quality Management programs.
12. Improve Continuous Process Verification (CPV) and process performance monitoring.
13. **Drive Operational Excellence and Quality Culture Transformation initiatives.**

Target Audience

1. Quality Assurance Managers and Executives
2. Quality Control Analysts and Supervisors
3. Pharmaceutical Manufacturing Managers
4. Validation and Qualification Engineers
5. Regulatory Affairs Professionals
6. Production Supervisors and Team Leaders
7. Compliance and Audit Specialists
8. Pharmaceutical Industry Consultants and Trainers

Course Modules

Module 1: Pharmaceutical Quality Systems (PQS) and Regulatory Frameworks

- Overview of Pharmaceutical Quality Systems
- ICH Q10 Quality System Requirements
- FDA, EMA, WHO and PIC/S Expectations
- Quality Governance and Leadership
- Building a Sustainable Quality Culture
- **Case Study:** FDA Warning Letter Analysis and Quality System Remediation.

Module 2: Current Good Manufacturing Practices (cGMP)

- cGMP Principles and Requirements
- Documentation and Record Control
- Personnel Training and Qualification
- Facility and Equipment Compliance
- GMP Inspection Readiness
- **Case Study:** Manufacturing Compliance Failures and Corrective Actions.

Module 3: Quality Risk Management (QRM)

- ICH Q9 Risk Management Framework
- Risk Identification and Assessment
- FMEA and Risk Ranking Tools
- Risk Control and Mitigation Strategies
- Risk Review and Monitoring
- **Case Study:** Risk-Based Decision Making in Sterile Manufacturing.

Module 4: Deviation, CAPA and Root Cause Analysis

- Deviation Management Systems
- Investigation Techniques
- Root Cause Analysis Tools
- CAPA Lifecycle Management
- CAPA Effectiveness Verification

Case Study: Recurring Batch Failure Investigation and CAPA Implementation.

Module 5: Data Integrity and Documentation Compliance

- ALCOA+ Principles
- Electronic Records and Signatures
- Data Governance Frameworks
- Audit Trail Review Requirements
- Data Integrity Inspection Expectations
- **Case Study:** Data Integrity Breach and Regulatory Consequences.

Module 6: Validation, Qualification and Quality by Design (QbD)

- Process Validation Lifecycle
- Equipment Qualification (IQ/OQ/PQ)

- Cleaning Validation Strategies
- Quality by Design Concepts
- Continued Process Verification
- **Case Study:** Process Validation Failure and Product Recall Prevention.

Module 7: Supplier Quality Management and Auditing

- Supplier Qualification Programs
- Vendor Risk Assessment
- Quality Agreements Management
- Internal and External Audits
- Audit Observation Management
- **Case Study:** Raw Material Supplier Quality Deficiency Investigation.

Module 8: Inspection Readiness and Continuous Improvement

- Regulatory Inspection Preparation
- Mock Audits and Gap Assessments
- Quality Metrics and KPI Monitoring
- Lean Quality and Operational Excellence
- Continuous Improvement Programs
- **Case Study:** Successful Regulatory Inspection Readiness Program.

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
28 Sep 2026	02 Oct 2026	Online	$1,000
28 Sep 2026	02 Oct 2026	Physical	$1,500
28 Sep 2026	02 Oct 2026	Physical	$0
28 Sep 2026	02 Oct 2026	Physical	$0
28 Sep 2026	02 Oct 2026	Physical	$0
28 Sep 2026	02 Oct 2026	Physical	$0
28 Sep 2026	02 Oct 2026	Physical	$0
28 Sep 2026	02 Oct 2026	Physical	$0

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

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