Good Manufacturing Practices (GMP) in Pharmaceuticals Training Course

Professional Development Training Course Outline

Category	Quality Assurance and ISO standards	**Duration**	5 Days
Base Fee	$1,100 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

Good Manufacturing Practices (GMP) in Pharmaceuticals Training Course represent the backbone of quality assurance in the pharmaceutical industry. This training course provides an in-depth understanding of globally recognized GMP standards, regulatory compliance, and best practices that ensure the production of safe, effective, and high-quality pharmaceutical products. With the increasing demand for pharmaceutical products worldwide, adherence to GMP regulations is critical for building trust, meeting international standards, and maintaining competitive advantage.

The course is designed to empower participants with the knowledge and practical skills necessary to implement, maintain, and audit GMP systems effectively. It combines case studies, industry insights, and hands-on learning to enhance compliance with FDA, WHO, EMA, and other global regulatory requirements. Participants will explore real-life GMP challenges and solutions while gaining practical strategies to ensure regulatory readiness and operational excellence.

Programme Curriculum

Good Manufacturing Practices (GMP) in Pharmaceuticals Training Course

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Course Objectives

1. Understand the fundamentals of Good Manufacturing Practices in pharmaceuticals.
2. Learn global GMP regulatory frameworks including FDA, WHO, and EMA guidelines.
3. Enhance knowledge of pharmaceutical quality assurance systems.
4. Identify key GMP requirements for facilities, equipment, and documentation.
5. Improve compliance with pharmaceutical production and packaging standards.
6. Develop skills for implementing quality risk management in GMP systems.
7. Apply practical techniques for handling deviations and corrective actions.
8. Gain insights into effective GMP auditing and self-inspections.
9. Strengthen knowledge of GMP in sterile and non-sterile manufacturing.
10. Examine case studies on GMP compliance failures and success strategies.
11. Explore GMP data integrity, validation, and digital documentation practices.
12. Learn best practices for training and competency management under GMP.
13. Build expertise in continuous improvement and GMP-driven operational excellence.

Organizational Benefits

- Strengthened compliance with international GMP standards
- Enhanced reputation for quality and safety in the pharmaceutical market
- Reduced risks of regulatory violations and costly recalls
- Improved efficiency of manufacturing operations
- Increased employee awareness of compliance responsibilities
- Stronger pharmaceutical quality management systems
- Better preparedness for regulatory audits and inspections
- Improved customer trust and market competitiveness
- Effective risk management across the manufacturing process
- Long-term operational sustainability and profitability

Target Audiences

- Quality Assurance professionals
- Regulatory Affairs personnel
- Pharmaceutical production managers
- GMP auditors and inspectors
- Research and Development teams
- Validation and compliance officers
- Pharmaceutical engineers and supervisors
- Training and development managers

Course Duration: 5 days

Course Modules

Module 1: Introduction to Good Manufacturing Practices

- History and evolution of GMP standards
- Importance of GMP in pharmaceuticals
- Key principles of GMP compliance
- International GMP regulatory frameworks
- Current global trends in GMP
- Case study: GMP failures and lessons learned

Module 2: Regulatory Guidelines and Compliance

- FDA GMP requirements
- WHO GMP standards
- EMA GMP frameworks
- Key similarities and differences in global regulations
- Role of national regulatory bodies
- Case study: Regulatory inspection outcomes

Module 3: Pharmaceutical Quality Systems

- Components of a quality system
- Documentation and record-keeping standards
- Quality risk management in GMP
- Change control processes
- Training and competence in quality systems
- Case study: Successful implementation of a quality management system

Module 4: Facilities and Equipment Compliance

- GMP requirements for pharmaceutical facilities
- Equipment qualification and calibration
- Environmental monitoring standards
- Cleanroom design and compliance
- Preventive maintenance strategies
- Case study: Facility compliance audit

Module 5: Production and Packaging Standards

- GMP in pharmaceutical manufacturing
- Validation of manufacturing processes
- Packaging compliance requirements
- Handling of raw materials and intermediates
- Cross-contamination prevention strategies
- Case study: Packaging error investigation

Module 6: Laboratory Controls and Documentation

- GMP in laboratory testing and analysis
- Data integrity and accuracy requirements
- Documentation and electronic record compliance
- Handling out-of-specification results
- Validation of analytical methods
- Case study: Data integrity failure in testing

Module 7: GMP in Sterile Manufacturing

- Aseptic processing requirements
- Sterile area operations and personnel practices
- Cleanroom classification standards
- Microbial contamination control
- Sterilization validation procedures
- Case study: Sterility assurance audit

Module 8: Auditing and Continuous Improvement

- Principles of GMP auditing
- Self-inspection and third-party audits
- Corrective and preventive actions (CAPA)
- Monitoring and evaluating compliance trends
- Continuous improvement strategies in GMP
- Case study: Continuous improvement in pharmaceutical GMP systems

Training Methodology

- Interactive lectures and expert presentations
- Case study analysis and group discussions
- Practical exercises and simulations
- Regulatory guideline interpretation sessions
- Knowledge checks and assessments

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.org or call *+254724527104*

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
03 Aug 2026	07 Aug 2026	Online	$1,100
10 Aug 2026	14 Aug 2026	Online	$1,100
17 Aug 2026	21 Aug 2026	Online	$1,100
24 Aug 2026	28 Aug 2026	Online	$1,100
31 Aug 2026	04 Sep 2026	Online	$1,100
07 Sep 2026	11 Sep 2026	Online	$1,100
14 Sep 2026	18 Sep 2026	Online	$1,100
21 Sep 2026	25 Sep 2026	Online	$1,100

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