



# School of Pharmaceutical Sciences & Technology

Curriculum for  
Fellowship Program in

**Good Manufacturing Practice (GMP) &  
Good Laboratory Practice (GLP)**



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**Course Title:** GOOD MANUFACTURING PRACTICES & GOOD LABORATORY PRACTICES

**Course Type:** FELLOWSHIP

**Duration:** 360 Hours (can be structured as 24 Credits)

**Mode:** Lectures, Practicals/Hands-on, Project

### Overview

This course provides comprehensive knowledge of pharmaceutical quality systems with a strong focus on Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP). It integrates regulatory expectations (FDA, EMA, WHO, OECD), quality philosophies (TQM, QbD, Six Sigma), and practical industry applications such as documentation, audits, data integrity, and post-market surveillance. The course prepares students to understand, implement, and comply with global quality and regulatory standards in pharmaceutical manufacturing and testing environments.

### Objectives:

The objectives of this course are to enable students to:

1. Understand the principles and importance of Quality Assurance and Quality Control in the pharmaceutical industry.
2. Explain GMP and GLP regulatory frameworks and their application in manufacturing and laboratory operations.
3. Apply quality management concepts such as TQM, QbD, and Six Sigma to pharmaceutical processes.
4. Develop competence in facility design, equipment qualification, and documentation practices.
5. Interpret data integrity requirements, including ALCOA+ principles and electronic records compliance.
6. Gain practical knowledge of audits, deviations, RCA, CAPA, and post-market regulatory surveillance.

### Course Outcome:

Upon successful completion of the course, the student will be able to:

- **CO1:** Differentiate between Quality Assurance and Quality Control and explain their roles in pharmaceutical quality systems.
- **CO2:** Interpret and apply GMP regulations, including facility design, sanitation, and equipment qualification.
- **CO3:** Explain GLP principles, roles of Study Director and QAU, and SOP management.
- **CO4:** Demonstrate understanding of documentation systems, batch records, deviations, and material management under cGMP.
- **CO5:** Apply data integrity principles (ALCOA+) and regulatory requirements for electronic records (21 CFR Part 11).



- **C06:** Analyze audit findings and implement RCA and CAPA systems to ensure regulatory compliance and continuous improvement.

### Teaching & Learning Methods:

The course will be delivered using a combination of the following teaching methodologies:

- **Didactic lectures** using PowerPoint presentations and regulatory guidance documents
- **Case study discussions** based on FDA warning letters and inspection observations
- **Flow charts and real-time examples** for GMP/GLP processes
- **Demonstration of documents** such as SOPs, BPRs, deviation reports, and CAPA formats
- **Interactive sessions** for QbD, Six Sigma, and risk-based approaches
- **Guest lectures / industry talks** from quality and regulatory professionals (where applicable)

Students will engage in the following learning activities:

- **Self-study** of regulatory guidelines (FDA, OECD, WHO, EMA)
- **Group discussions and presentations** on GMP/GLP compliance topics
- **Preparation of mock SOPs, batch records, and audit checklists**
- **Problem-based learning** using deviation and CAPA scenarios
- **Assignments and quizzes** to reinforce regulatory concepts
- **Viva and written assessments** focusing on practical regulatory understanding

### Syllabus

#### Theory - 10 Credits (150 Lecture Hours)

##### Module 1: Foundations of Quality Systems (30 Hours)

- Introduction to Quality Assurance (QA) vs. Quality Control (QC).
- Philosophy of TQM, Quality by Design (QbD), and Six Sigma in Pharma.
- The 10 Golden Rules of GMP.

##### Module 2: Good Manufacturing Practices (GMP) – Part 11 & Annex 1 (40 Hours)

- Facility design: Cleanroom classifications, HVAC systems, and water systems (PW/WFI).
- Equipment qualification: DQ, IQ, OQ, PQ.
- Sanitation, hygiene, and cross-contamination prevention.

##### Module 3: Good Laboratory Practices (GLP) & Data Integrity (40 Hours)

- OECD Principles of GLP; Roles of the Study Director and Quality Assurance Unit (QAU).
- Standard Operating Procedures (SOP) writing and management.
- ALCOA+ principles for data integrity and electronic records (21 CFR Part 11).



**Module 4: Documentation & Material Management (20 Hours)**

- Batch Release: Batch Production Records (BPR) and Batch Deviations.
- Vendor qualification and raw material sampling plans (c.GMP requirements).

**Module 5: Audits, Variations, and Post-Market Surveillance (20 Hours)**

- Internal vs. External Audits (FDA, EMA, WHO inspections).
- Root Cause Analysis (RCA) and CAPA (Corrective and Preventive Action) systems.

**Practical/Hands-on Component: 8 Credits (120 Lab Hours)**

**Lab 1: Cleanroom Protocols & Gowning**

- a) Simulated gowning procedures for Grade A/B areas and aseptic hand washing.
- b) Environmental monitoring: Air sampling and surface swabbing.

**Lab 2: Equipment Calibration & Validation**

- a) Hands-on calibration of analytical instruments (HPLC, UV-Vis, Dissolution testers).
- b) Executing an IQ/OQ protocol for a laboratory centrifuge or incubator.

**Lab 3: Documentation & SOP Drafting (30 Hours)**

- a) Workshop: Writing a compliant SOP for an analytical method.
- b) Filling out Batch Manufacturing Records (BMR) and correcting documentation errors per GLP.

**Lab 4: Laboratory Safety & Chemical Management (20 Hours)**

- a) Handling hazardous chemicals, MSDS interpretation, and spill control.
- b) Logbook maintenance and sample chain-of-custody tracking.

**Lab 5: Audit Simulation & CAPA Workshop (20 Hours)**

- a) Mock audit of a lab facility to identify "Observations" or "Non-conformities."
- b) Drafting a CAPA plan based on a mock deviation report.

**Project: 6 Credits (90 Self Study/Research Hours)**

The project requires the fellow to select a specific focus area (either GMP or GLP) and complete an independent study or audit. Examples include:

- a) **Validation Master Plan (VMP):** Creating a complete VMP for a new pharmaceutical manufacturing line.
- b) **Gap Analysis:** Conducting a comprehensive GLP gap analysis for a Research & Development lab.
- c) **Stability Study Design:** Developing a 2026-compliant stability testing protocol for a new drug substance.
- d) **Computerized System Validation (CSV):** Validating a Laboratory Information Management System (LIMS) according to GAMP 5.

**References:**

1. Current Good Manufacturing Practice (CGMP) regulations. Silver Spring (MD): U.S. Food and Drug Administration; 2023. Available from: FDA website.



2. OECD principles of good laboratory practice (GLP). Paris: OECD Publishing; 1998. Updated 2023.
3. *Pharmaceutical quality assurance*. 2nd ed. Pune: Nirali Prakashan; 2012.
4. *ISPE good practice guides: quality systems and facilities*. Tampa (FL): ISPE; 2017.
5. Nagori BP, Nagori SK. Handbook of Good Laboratory Practice (GLP) in Pharmaceutical Industry.
6. World Health Organization (WHO). WHO Handbook: Good Laboratory Practice (GLP) (Special Programme for Research and Training in Tropical Diseases). Geneva: WHO; 2000.
7. Weinberg S. Good Laboratory Practice Regulations. 4th ed.
8. Good manufacturing practice for pharmaceuticals, 6<sup>th</sup> Edition, JOSEPH D.NALLY.
9. Good manufacturing practice for pharmaceuticals 7<sup>th</sup> Edition by GRAHAM P.BUNN.

