



School of Pharmaceutical Sciences & Technology

Curriculum for
Fellowship Program in

Pharmaceutical Operation Management



Malla Reddy Vishwavidyapeeth

(Deemed to be University)

Suraram, Hyderabad Telangana 500055

Email : info@mrvv.edu.in, Phone : [950 777 9999](tel:9507779999)



Course Title: Fellowship in Pharmaceutical operations Management

Course Type: FELLOWSHIP

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

Mode: Lectures, Practicals/Hands-on, Project

Overview

Fellowship programs in Pharmaceutical Operations Management typically emphasize industry-relevant skills in manufacturing, quality assurance, supply chain, and regulatory compliance. Core topics cover GMP/GLP standards, process validation, logistics, pharmacoconomics, and lean operations. Students engage in simulations for batch production and audits, with assessments via quizzes, assignments, and a final capstone report

Objectives:

- Develop expertise in pharmaceutical manufacturing processes, quality systems, and regulatory compliance.
- Enable optimization of supply chains, scale-up operations, and project management in pharma settings.
- Foster problem-solving skills through simulations, industry tools, and real-world projects for leadership roles

Course Outcome:

CO No.	Course Outcome
C01	Analyze pharmaceutical production cycles, organizational structures, and strategic marketing frameworks (4Ps, PLC) to design optimized workflows and project plans using CPM/PERT technique.
C02	Implement quality assurance systems, including cGMP/GLP compliance, SPC tools, process validation, and audit protocols (CAPA, PDCA), ensuring adherence to ISO/FDA/ICH standards for product reliability and safety.
C03	Apply advanced pharmaceutical technologies like QbD, PAT, solubility enhancement, and controlled release formulations to scale-up processes from lab to commercial production while meeting regulatory validation requirements.
C04	Optimize supply chain logistics through ERP/SAP integration, cold chain strategies, vendor management, and risk mitigation, incorporating sustainable practices and track-and-trace compliance.
C05	Utilize statistical process control (SPC charts, DOE, Cp/Cpk), Lean Six Sigma, and OEE metrics to enhance production operations, reduce variability, and manage GMP change controls for continuous improvement.



Teaching & Learning Methods:

Fellowship in Pharmaceutical Operations Management syllabus adopt a comprehensive, blended learning framework designed for working pharma professionals, integrating digital tools, industry simulations, and experiential projects

Syllabus

Theory - 10 Credits (150 Lecture Hours)

Module 1: Pharmaceutical Administration and Management (45 hours)

- Management of Operations: Product definition, production cycles, types of production practices, and productivity measurement.
- Organizational Design: Pharma company structure, mission/vision statements, departmental roles.
- Strategic Management: Market segmentation, product positioning, 4Ps of marketing, product life cycle.
- Project Planning: Network analysis techniques (CPM, PERT) for time-bound production deadlines.
- Additional Modules: R&D team management, inventory software, product costing, break-even analysis.

Module 2: Quality Assurance and Regulatory Affairs (45 hours)

- Quality Control & Assurance Basics: Definition and characteristics of quality per ISO 9000:2000 standards. Statistical process control (SPC), acceptance sampling, and reliability testing
- cGMP elements: Personnel hygiene/training, premises/equipment validation, raw materials/components testing, production/process controls, packaging/labeling, laboratory controls, and documentation. GLP for non-clinical safety studies, including study plans, data integrity, and facility standards. Concepts of *de novo* drug design and fragment-based lead discovery.
- Regulatory Affairs & Validation: Pharmaceutical process validation, Drug approval processes. Clinical research protocols, ethics committees, and adverse event reporting.
- Compliance Audits: Types of audits, preparation checklists, non-conformance management, CAPA implementation. Risk-based auditing, mock inspections, and continuous improvement via PDCA cycles.

Module 3: Advanced Pharmaceutical Technology (30 hours):

- Physicochemical principles: Solubility enhancement, polymorphism, bulk characterization.
- Advanced dosage forms: Controlled release systems, biotech formulations, sterile products.



- Scale-up and process optimization: QbD (Quality by Design), PAT (Process Analytical Technology)
- Regulatory tech aspects: Validation of new technologies per ICH/FDA guidelines.

Module 4: Supply Chain Management (15 hours):

- Cold chain management, vendor qualification, ERP systems (SAP), risk mitigation for APIs/excipients.
- Reverse logistics, track-and-trace (DSCSA compliance), and sustainable supply chains.

Module 5: Statistical Process Control and Production Operations (15 hours):

- SPC charts (X-bar, R, CUSUM), capability indices (Cp/Cpk), DOE for optimization.
- Lean Six Sigma, OEE calculation, batch records, change control in GMP environments.

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

Module 1: Pharmaceutical Administration and Management

- **Product Definition & Production Cycles:** Simulate batch scheduling using MS Project; hands-on CPM/PERT network diagramming for 3-drug production timelines .
- **Organizational Design:** Role-play pharma org charts in Lucidchart; design departmental workflows and mission/vision alignment exercises.
- **Strategic Management & Project Planning:** 4Ps marketing simulation game; break-even analysis spreadsheets for generic launches; inventory software (e.g., Tally ERP demo) for costing.

Module 2: Quality Assurance and Regulatory Affairs

- **CGMP/GLP Practicals:** Virtual cleanroom tours; personnel hygiene protocols checklist creation; mock equipment validation using IQ/OQ/PQ templates.
- **SPC & Audits:** Minitab software for control charts (X-bar/R), acceptance sampling plans, and CAPA form filling from simulated non-conformances.
- **Validation & Compliance:** Process validation protocol drafting; mock FDA/EMA audit preparation with TrackWise software; PDCA cycle application to lab deviations.

Module 3: Advanced Pharmaceutical Technology

- **Physicochemical Labs:** Virtual solubility enhancement experiments (pH-solubility profiles, polymorph screening via DSC simulations).
- **Dosage Form Design:** DesignSpace software for QbD; controlled release matrix formulation using Simcyp; sterile product fill-finish simulations.



- **Scale-up:** PAT tool demos (NIR spectroscopy); tech transfer documents from lab to pilot scale.

Module 4: Supply Chain Management

- **ERP & Logistics:** SAP S/4HANA sandbox for demand forecasting, vendor qualification scorecards, cold chain mapping (Thermo Fisher sim).
- **Risk & Sustainability:** Reverse logistics modeling; DSCSA track-and-trace exercises; API supply disruption scenario planning.

Module 5: Statistical Process Control and Production Operations

- **SPC Tools:** Minitab/JMP for CUSUM charts, DOE (factorial designs), Cp/Cpk computation on batch data.
- **Lean Operations:** OEE calculator Excel tool; value stream mapping for GMP lines; change control simulations.

Project: six Credits (90 Self Study/Research Hours)

It serves as the capstone experiential element, requiring participants to apply theory and practical skills to a real-world pharmaceutical operations challenge at their workplace or sponsor organization, fostering innovation and leadership

Objective

- Integrate Modules 1-5 knowledge to identify, analyze, and resolve an operations bottleneck.
- Demonstrate higher-order skills: problem formulation, data-driven solutions using SPC/QbD/Lean, regulatory compliance, and strategic recommendations.

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