School of Pharmaceutical Sciences & Technology

Curriculum for Fellowship Program in

PHARMACEUTICAL PRODUCTION

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Course Title: PHARMACEUTICAL PRODUCTION
Course Type: FELLOWSHIP
Total Credits: 24 Credits (360 Contact Hours; 1 Credit = 15 Hours)
Weekly Commitment: 40 hours per week (full-time) or minimum 10-12 hours per week (research-led program)

Mode: Lectures, Practical /Hands-on, Industry Attachment, Capstone Project Overview

The Fellowship in Pharmaceutical Production is an intensive, short-term postgraduate program designed to equip participants with comprehensive knowledge and practical skills in the manufacturing of pharmaceutical products. This program covers the entire spectrum of pharmaceutical production, from raw material handling to finished product packaging, emphasizing Good Manufacturing Practices (GMP), quality assurance, process validation, and regulatory compliance. The interdisciplinary curriculum integrates pharmaceutical sciences, engineering principles, quality management systems, and current industry standards to prepare professionals for careers in pharmaceutical manufacturing facilities, quality control laboratories, and regulatory affairs departments.

Objectives:

Upon completion of the course, the fellow shall be able to:

- Understand the principles and practices of pharmaceutical manufacturing operations across different dosage forms.
- Apply Good Manufacturing Practices (GMP) and regulatory requirements in pharmaceutical production environments.
- Design and optimize unit operations and manufacturing processes for various pharmaceutical formulations.
- Implement quality control, quality assurance, and process validation protocols.
- Utilize modern equipment and technologies used in pharmaceutical production facilities.
- Analyze and troubleshoot manufacturing problems using systematic approaches.

Course Outcome:

CO1	Explain the fundamentals of pharmaceutical manufacturing, including GMP principles, regulatory frameworks, pharmaceutical engineering basics, facility design requirements, and quality management systems.
CO2	Understand and apply unit operations and manufacturing processes for solid dosage forms, including granulation, compression, coating, encapsulation, and packaging technologies
CO3	Analyze and execute manufacturing processes for liquid and semi-solid dosage forms, including solutions, suspensions, emulsions, ointments, creams, and sterile products manufacturing.
CO4	Interpret and implement advanced manufacturing concepts including process validation, qualification protocols, cleaning validation, analytical method validation, scale-up principles, and emerging technologies in pharmaceutical production.

Teaching & Learning Methods:

The program emphasizes a hands-on, industry-oriented approach. This includes interactive lectures with real-world case studies, mandatory production lab sessions and pilot plant operations, plant visits to pharmaceutical manufacturing facilities, workshops by industry experts and regulatory professionals, daily log book maintenance of all activities (journal reviews, seminars, procedures), and collaborative capstone projects simulating actual production scenarios.

Credit Breakdown:

1. **Core Theory: 10 Credits (150 Lecture Hours)**
2. **Practical/Hands-on: 8 Credits (120 Hours of Laboratory and Industry Attachment)**
3. **Capstone Project: 6 Credits (90 Hours of Research/Documentation)**

SYLLABUS

CORE THEORY - 10 CREDITS (150 LECTURE HOURS)

Module 1: Fundamentals of Pharmaceutical Manufacturing & GMP (30 hours)

- Introduction to pharmaceutical industry structure and drug development lifecycle.
- Good Manufacturing Practices (GMP): principles, documentation, and implementation.
- Regulatory framework: FDA, EMA, WHO-GMP, Schedule M requirements.
- Pharmaceutical plant design: layout, material flow, HVAC systems, and environmental controls.
- Quality management systems: QA, QC, and quality risk management (ICH Q9, Q10).
- Personnel training, hygiene, and safety in pharmaceutical manufacturing.

Module 2: Unit Operations & Solid Dosage Form Production (40 hours)

- Preformulation studies and formulation development principles.
- Size reduction: milling, grinding, and micronization techniques.
- Mixing and blending: theory, equipment, and homogeneity assessment.
- Granulation processes: wet granulation, dry granulation, and fluid bed processing.
- Tablet manufacturing: compression technology, tablet defects, and troubleshooting.
- Coating operations: film coating, sugar coating, and enteric coating systems.
- Capsule filling: hard and soft gelatin capsules, equipment, and process parameters.
- Packaging systems for solid dosage forms: primary and secondary packaging.

Module 3: Liquid, Semi-Solid & Sterile Product Manufacturing (40 hours)

- Manufacturing of oral liquids: solutions, syrups, suspensions, and emulsions.
- Parenteral products: aseptic processing, sterilization methods, and clean room technology.
- Ophthalmic and otic preparations: special requirements and quality considerations.
- Semi-solid dosage forms: ointments, creams, gels, and pastes manufacturing.
- Aerosol and transdermal systems: formulation and filling operations.
- Special considerations for biologics and biotechnology products.

Module 4: Process Validation, Quality Systems & Advanced Manufacturing (40 hours)

- Process validation: protocol design, execution, and lifecycle approach (ICH Q8, Q9, Q11).
- Equipment qualification: IQ, OQ, PQ protocols and documentation.
- Cleaning validation: principles, methods, and acceptance criteria.
- Analytical method validation: ICH Q2 guidelines and implementation.
- Scale-up and technology transfer from laboratory to commercial production.
- Continuous manufacturing and Process Analytical Technology (PAT).
- Quality by Design (QbD) principles in pharmaceutical manufacturing.
- Emerging trends: 3D printing, personalized medicine, and Industry 4.0 applications.

PRACTICAL/HANDS-ON COMPONENT - 8 CREDITS (120 HOURS)

Practical Module 1: GMP Documentation & Quality Systems (15 hours)

- Preparation of Standard Operating Procedures (SOPs) and Batch Manufacturing Records (BMRs).
- Master Formula Records (MFR) development and documentation practices.
- Deviation handling, CAPA (Corrective and Preventive Action) documentation.
- Change control procedures and implementation.
- Audit preparation and mock regulatory inspections.
- Review of batch records and documentation compliance.

Practical Module 2: Solid Dosage Form Manufacturing (40 hours)

- Raw material receiving, sampling, and testing procedures.
- Hands-on tablet manufacturing: weighing, mixing, granulation, compression, and coating.
- Operation of pharmaceutical equipment: fluid bed dryer, rapid mixer granulator, tablet press.
- Capsule filling operations using manual and automatic machines.
- In-process quality control: weight variation, hardness, friability, disintegration testing.
- Troubleshooting tablet defects: capping, lamination, sticking, picking.
- Packaging operations: blister packaging, strip packaging, and labeling compliance.
- Environmental monitoring in manufacturing areas.

Practical Module 3: Liquid & Sterile Product Manufacturing (35 hours)

- Manufacturing of pharmaceutical solutions, syrups, and suspensions.
- Emulsion preparation and stability testing.
- Aseptic gowning technique and clean room behavior training.
- Sterile product handling and aseptic processing simulation.
- Media fill validation exercises and evaluation.
- Quality control testing: pH measurement, viscosity determination, particulate matter testing.
- Sterility testing procedures and interpretation.
- Manufacturing of semi-solid preparations: ointments and creams.

Practical Module 4: Process Validation & Equipment Operations (30 hours)

- Equipment calibration exercises: balances, thermometers, pressure gauges.
- Installation Qualification (IQ) and Operational Qualification (OQ) execution.
- Process validation protocol development and execution for tablet compression.
- Cleaning validation: sampling techniques, swab and rinse methods.
- Performance Qualification (PQ) for manufacturing equipment.
- Operation and troubleshooting of pharmaceutical manufacturing equipment.
- Process capability studies and statistical process control.
- Root cause analysis exercises for manufacturing deviations.

PROJECT - 6 CREDITS (90 HOURS)

The Project is a mandatory component providing real-world application of pharmaceutical production concepts. Fellows will work individually or in small teams on an industry-relevant project under faculty supervision.

Project Scope:

Projects typically involve one or more of the following:

- Development of a complete manufacturing process for a selected pharmaceutical dosage form.
- Process optimization studies for existing manufacturing processes.
- Validation protocol development and execution (process validation, cleaning validation, or method validation).
- Scale-up studies from laboratory to pilot or commercial scale.
- Quality by Design (QbD) application in formulation and process development.
- Comparative study of manufacturing processes or equipment.
- Investigation and resolution of a manufacturing problem with CAPA implementation.

Project Deliverables:

- **Project Proposal** (Week 1-2): Problem statement, objectives, methodology, and timeline.
- **Literature Review** (Week 3-4): Comprehensive review of relevant manufacturing practices and regulatory requirements.
- **Experimental Work/Data Collection** (Week 5-16): Execution of manufacturing trials, validation studies, or process optimization.
- **Data Analysis and Interpretation** (Week 17-20): Statistical analysis, comparison with specifications, and conclusions.
- **Final Report** (Week 22-23): Comprehensive technical report including:
  - Introduction and background
  - Materials and methods
  - Results and discussion
  - Manufacturing records and quality data
  - Regulatory compliance assessment
  - Conclusions and recommendations

Project Presentation (Week 24): Oral presentation with Q&A session before faculty panel.

Project Assessment Criteria:

- Scientific rigor and methodology (30%)
- Quality of documentation and compliance with GMP (25%)
- Data analysis and interpretation (20%)
- Innovation and problem-solving approach (15%)
- Presentation and communication skills (10%)

FELLOWSHIP REQUIREMENTS

Log Book/Work Diary:

Fellows MUST maintain a daily log book documenting all activities including:

- Lectures attended and key learnings

- Practical sessions and procedures performed
- Journal reviews and literature studied
- Seminars and workshops attended
- Manufacturing operations observed or performed
- Quality control tests conducted
- Project work progress
- Reflection on learning experiences

The log book must be certified by the assigned supervisor/mentor on a monthly basis throughout the fellowship duration.

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