School of Pharmaceutical Sciences & Technology

Curriculum for
Fellowship Program in

Pharmaceutical Project Management

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Course Title: Pharmaceutical Project management
Course Type: FELLOWSHIP
Duration: 360 Hours (can be structured as 24 Credits)
Mode: Lectures, Practicals/Hands-on, Project

Overview

Pharmaceutical Project Management syllabi typically cover essential skills for managing drug development, regulatory compliance, and commercialization projects in the pharma industry. These programs blend general project management principles with industry-specific topics like GMP standards and risk assessment. They emphasize practical tools such as PERT/CPM for timelines and stakeholder coordination.

Objectives:

- Understand the pharmaceutical industry ecosystem
  Grasp key stages of drug development, regulatory compliance, and industry workflows.
- Apply project management principles in pharma contexts
  Use standard frameworks like PMBOK or PRINCE2 tailored to pharmaceutical projects.
- Plan and execute pharmaceutical projects effectively
  Develop full project plans including scope, schedule, budget, risk, and quality strategies.
- Manage regulatory and compliance challenges
  Interpret and incorporate global regulatory requirements (FDA, EMA, CDSCO) into project plans.
- Lead cross-functional teams and communications
  Coordinate and communicate with diverse stakeholders such as R&D, regulatory affairs, quality, and manufacturing.
- Use project management tools and techniques
  employ modern PM software and tools for scheduling, reporting, and performance tracking.
- Assess and mitigate project risks
  Identify potential risks in pharma projects and implement mitigation strategies.
- Demonstrate professional leadership and decision-making skills
  Lead project teams, resolve conflicts, and make data-informed decisions.
- Integrate quality management into project life cycles
  Ensure projects meet quality standards and regulatory expectations.

Course Outcome:

CO No	Course Outcome
CO1	Demonstrate a comprehensive understanding of the pharmaceutical industry ecosystem, including drug discovery, development stages, regulatory pathways, and commercialization processes.
CO2	Apply standard project management frameworks and tools (PMBOK, PRINCE2, Gantt charts, PERT/CPM, WBS) to plan and manage pharmaceutical projects effectively.
CO3	Develop and manage project budgets, schedules, and resources while applying financial control techniques and earned value management in pharmaceutical projects.
CO4	Analyze regulatory, quality, and risk management requirements and integrate global compliance standards (FDA, EMA, CDSCO, GMP) into pharmaceutical project planning and execution.
CO5	Exhibit leadership, communication, and decision-making skills to manage cross-functional teams, stakeholders, and change processes in complex pharmaceutical project environments.

Teaching & Learning Methods:

Teaching and learning methods for Pharmaceutical Project Management syllabi emphasize interactive, industry-relevant approaches to build practical skills in drug development timelines, regulatory compliance, and team coordination.

Syllabus

Theory - 10 Credits (150 Lecture Hours)

Module 1: Pharmaceutical Industry Fundamentals (15 hours)

- Overview of the global pharmaceutical value chain and ecosystem
- Drug discovery and development phases (from R&D to market launch)
- Unique challenges in pharma project environments (long timelines, regulatory needs)
- Lifecycle of pharmaceutical projects

Module 2: Project Management Frameworks& Planning (30 hours)

- Definitions, terminologies, and lifecycle of projects
- Traditional vs. agile project management methods
- Pharma-specific adaptations of PMBOK/PRINCE2
- Introduction to tools such as Gantt charts, CPM, PERT, WBS

- Scope definition and project chartering
- Work Breakdown Structure (WBS) and activity sequencing
- Resource allocation and scheduling
- Time estimation and project feasibilities

Module 3: Budgeting & Financial Management (15 hours):

- Cost estimation and budgeting principles
- Funding models in pharmaceutical projects
- Financial risks and cost control methods

Module 4: Regulatory Environment & Compliance & Risk Management (30 hours):

- Understanding global regulatory agencies (FDA, EMA, CDSCO etc.)
- Regulatory timelines and their impact on project planning
- Compliance documentation and audits
- Good Manufacturing Practices (GMP) and quality standards
- Identifying, assessing, and mitigating project risks
- Risk registers and contingency planning
- Regulatory and clinical trial risk considerations

Module 5: Quality Management & Control (15 hours):

- Quality assurance techniques
- Process validation standards
- Quality risk management in regulated environments

Module 6: Stakeholder, Communication Management& Leadership (30 hours):

- Managing cross-functional teams (R&D, Regulatory, Marketing)
- Communication plans and stakeholder matrices
- Reporting project progress and managing expectations
- Leadership styles in project environments
- Conflict resolution and motivational strategies
- Cross-cultural communication for global project teams

Module 7: Advanced Topics & Applications (15 hours)

- Portfolio management and prioritization
- Change management and continuous improvement
- Use of digital tools (PM software, dashboards, data analytics)
- Case studies from real pharma R&D or manufacturing projects

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

1. Orientation to Pharmaceutical Projects and Life Cycle Mapping
2. Preparation of Project Charter and Scope Statement
3. Work Breakdown Structure (WBS) and Activity Sequencing
4. Project Scheduling using Gantt Chart and CPM
5. Resource Allocation and Responsibility Matrix (RACI)
6. Cost Estimation and Budget Preparation
7. Earned Value Management (EVM) Analysis
8. Risk Identification and Risk Register Preparation
9. Quality Management Plan and Validation Strategy
10. Regulatory Timeline Planning (FDA/EMA/CDSCO)
11. Stakeholder Register and Communication Plan
12. Change Control and Documentation Management

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

- Generic drug product launch planning
- Clinical trial phase scheduling
- Regulatory submission planning
- API plant setup project
- Quality remediation project

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