

# Master of Science in Pharmaceutical Manufacturing Engineering

## Program Description

The Department of Chemical and Energy Engineering (C&EE) at PAF-IAST offers Master of Science (MS) program in the “Pharmaceutical Manufacturing Engineering” in collaboration with department of Biomedical Sciences (PAF-IAST). Pharmaceutical Manufacturing Engineering is an important area for pharmaceutical drugs manufacturing industries and several international universities are offering this program. PAF-IAST is the first Institute in Pakistan to offer this professional postgraduate program.

In pharmaceutical manufacturing industries, a pharmacist does research, develops and tests new medicines and treatments, ensuring their safety and quality. While engineers design and operate pharmaceutical manufacturing processes to achieve the production goal. However, designing an efficient and economical process requires the knowledge of process engineering along with pharmacokinetics, drug delivery and validation. Our MS program combines these subjects in a single curriculum. Thus, students not only learn about the nature of drugs but also acquire the engineering knowledge to design/select the most suitable and efficient process for particular drug production. Being an interdisciplinary degree program, students will be able to solve challenging problems in pharmaceutical manufacturing, utilize emerging pharmaceutical technologies effectively to reach business goals of industries and lead innovation across relevant organizations. The MS program is aimed to prepare students for professional advancement in this dynamic and rapidly evolving field. Experienced faculty members of the department will train students to apply the knowledge of mathematics, science, and engineering to pharmaceutical processes. Students will work in multidisciplinary teams to design systems or processes and solve problems faced by pharmaceutical manufacturing industry.

The Institute has signed MoUs with nearby Hattar Industrial State which has several pharmaceutical manufacturing industries. Students and faculty members will be regularly engaged with these industries. Students will have the opportunity to learn and gain hands-on experience and to help the industry in improving the production performance and minimize the cost. MoUs are not limited to Hattar Industrial State only and will be expanded to country-wide industries gradually.

## Associated Careers

Graduates of this program will find career opportunities in pharma, biotech, biopharmaceuticals, cosmetics, nutritionals and medical devices manufacturing in Pakistan and around the world as well.

## Semester-wise Course Break-up and Detailed Course Outlines

Duration to obtain a degree of *Master of Science in Pharmaceutical Manufacturing Engineering* is 2 years (4 semesters). Students have to register and pass 5 compulsory courses (15 CHs), 3 elective courses (9 CHs) and Research Thesis (6 CHs), all equals to 30 CHs. Academic Writing and Research Methodology and Weekly Seminars are non-credit compulsory courses.

### Semester-wise Course Break-up

<i>1<sup>st</sup> Semester</i>		
Course Code	Course title	Credit Hours
PHM-844	Pharmaceutical Engineering	3
CHE-811	Unit Operations	3
XXX-###	Elective 01	3

<i>2<sup>nd</sup> Semester</i>		
Course Code	Course Title	Credit Hours
PHM-841	Pharmaceutical Characterizations	3
PHM-843	Validation and Regulatory Issues in the Pharmaceutical Industry	3
XXX-###	Elective 02	3

<i>3<sup>rd</sup> Semester</i>		
Course Code	Course Title	Credit Hours
SS-821	Research Methodology*	2

XXX-###	Elective 03	3
XXX-###	Elective 04	3

*\*This course is non-credit compulsory course.*

<b>4<sup>th</sup> Semester</b>		
<b>Course Code</b>	<b>Course Title</b>	<b>Credit Hours</b>
PHM-899	Thesis	6
<b>Total Credit Hours:</b>		<b>30</b>

<b>Electives</b>			
<b>S.No</b>	<b>Course Code</b>	<b>Course Title</b>	<b>Credit Hours</b>
1	PHM-846	Pharmaceutical Facility Design	3
2	CHE-813	Pharmaceutical Packaging Technology	3
3	PHM-842	Pharmacokinetics and Drug Delivery	3
4	CHE-825	Advanced Reaction Engineering	3
5	CHE-824	Process Simulation and Integration	3
6	CHE-826	Advanced Transport Phenomena	3
7	CHE-814	Advanced Separation Processes	3
8	CHE-812	Micromechanics of Particulate Technology	3
9	CHE-821	Process Technology	3
10	BME-801	Biomedical Engineering	3
11	PHM-845	Biopharmaceutical Engineering	3
12	MATH-801	Engineering Mathematics	3
13	CHE-815	Advanced Thermodynamics	3
14	CH-811	Industrial Biochemistry	3
15	CH-812	Pharmaceutical Chemistry	3

## Detailed Course Outlines

### **PHM-844 Pharmaceutical Engineering**

This course provides an overview of the pharmaceutical industry, including basic information about drug discovery and development, FDA requirements and approval processes, drug dosage forms, and the role of key operational units in drug manufacturing processes. This course enables the students to: understand the role of the pharmaceutical industry in the global market and its implications; learn the fundamentals of the drug development cycle and the investment required to bring a drug to market; learn the most important drug manufacturing processes and the key elements of dosage formulation.

### **CHE-811 Unit Operations**

This course examines methodologies, both applied and fundamental, to analyze and scale up manufacturing pharmaceutical processes involving liquid and dispersed-phase systems, such as liquid and multiphase mixing, sterilization and sanitation, lyophilization, filtration, centrifugation and others. The emphasis is primarily on the engineering aspects of the pharmaceutical processes examined in the course.

### **PHM-841 Pharmaceutical Characterizations**

The material and powder characterization including nano- and micro-structural characterization of solid dosage forms.

### **PHM-843 Validation and Regulatory Issues in the Pharmaceutical Industry**

This course is focused on the development of a working knowledge of the Federal Code of Regulations and its impact on the pharmaceutical and allied industries. The history of the Federal Government's regulation of the pharmaceutical industry is studied. Also covered is the industry's response and the methodologies it uses to comply with these regulations.

### **SS-821 Research Methodology**

Basics of technical writing process, Technical writing techniques and applications, Definition and basics of research, research purpose, Design of research methods, Identification of research problem, literature review, Selection of data collection techniques, selection of representative sample, writing of research proposals, Data collection and analysis techniques, Limitations and significance of research techniques, Quantitative and qualitative research procedures, Writing of research reports, Presentation skills, oral presentations

### **PHM-846 Pharmaceutical Facility Design**

This course provides instruction in design of state-of-the art pharmaceutical facilities for both manufacturing and R&D, by identifying key functional requirements and design concepts necessary to pharmaceutical processes. Interdisciplinary training will be provided in appropriate areas of facility design.

### **CHE-813 Pharmaceutical Packaging Technology**

This course focuses on developing a working knowledge of the machinery and unit operations used in transferring a drug substance in the bulk final form to a finished product ready for sale to the consuming public. Packaging of both liquid and solid forms in various types of delivery containers such as vials/ampoules, blister packs, individual packets, bottles, pouches and syringes is examined. The cleaning, sterilization and scaling/capping required for each dosage form is discussed, as well as freeze-drying, tableting capsule filling, and form/fill/seal, and proper labelling of final drug forms.

### **PHM-842 Pharmacokinetics and Drug Delivery**

The course covers the basic principles of pharmacokinetics, including drug transport, parenteral and enteral routes of drug administration, and factors affecting drug absorption, distribution, metabolism, and excretion. Mathematical pharmacokinetic models and drug delivery processes are also presented and quantitatively studied.

### **CHE-825 Advanced Reaction Engineering**

Kinetics of heat and mass transfer processes, Kinetics of complex reactions (reaction networks), Molecular transfer processes, Knowledge of reaction mechanisms, Elements of optimum design for various reactor types, multiple reactions, and temperature effects. Yield and selectivity optimization with emphasis on small-scale pharmaceutical production. Introduction to non-ideal reactor design. Study of various models for catalytic and non-catalytic solid-fluid reactions.

### **CHE-824 Process Simulation and Integration**

**Process Simulation:** Physicochemical property calculations in (bio)chemical process engineering, Modeling and simulation of complete process plant systems, Energy integration and optimization across plants and larger plant sections, Pinch analysis of plants in process engineering, Optimization of energy concepts, Design of heat-exchanger concepts, Detailed planning of heat exchangers, 3D-modelling of apparatus and machines in plant design, Detailed design of piping systems, Detailed planning of plants (incl. constructive considerations), Fundamentals of plant engineering and construction, Design, construction, implementation, and operation of technical systems, Selected examples of apparatus and component construction

**Numerical Simulations:** Basic concepts of fluid flows, Conservation equations (Navier-Stokes), Spatial and temporal discretization: finite volume method, lattice types, convergence, Boundary conditions, Methods of stationary and non-stationary flow, Numerical solution methods for equation systems, Turbulent flows and modelling, Boundary conditions, Boundary layers and idealized solutions, Thermal problems, Further simulation models (Lattice Boltzmann methods, particle simulation), Development of solution strategies, Data types, vectors, and matrices in MATLAB, Vector and matrix operations, Loops and branches, Scripts and functions, Data

importing and exporting, communication with other common software, Graphical user interface, Numerical analysis by MATLAB

### **CHE-826 Advanced Transport Phenomena**

A unified treatment of molecular and turbulent momentum, energy, and mass transport. Emphasis is on the mathematical description of physical mechanisms in momentum and energy transport.

### **CHE-814 Advanced Separation Processes**

The course covers the basic and advanced principles of separation with or without chemical reaction in phase equilibrium-based, external field-driven and membrane-based separation processes.

### **CHE-812 Micromechanics of Particulate Technology**

Presents methodologies for analyzing the macroscopic properties of particulate systems. Includes characterization and processing of particulate systems at the microlevel, predicting macroscopic properties from microlevel models, and analysis of particulate manufacturing processes involving solids processing, such as solids characterization, blending, milling, granulation, tableting, etc. Course includes laboratory demonstrations and a class project involving use of surface modification.

### **CHE-821 Process Technology**

**Chemical process engineering:** Introduction to the basic physicochemical principles of the description of reaction engineering processes with a focus on chemical equilibrium and reaction kinetics, Basic types and operating modes of reactors, Evaluation criteria for reactors, Calculation of conversion, yield, and selectivity in complex reactions, Introduction to kinetics, Kinetics of homogeneous reactions, Principles of heterogeneous catalysis, Analysis of reaction kinetics data, Residence time distribution in ideal reactors

**Thermal process engineering:** Phase equilibrium, Vaporization (p-x diagram), Distillation (t-x diagram/McCabe-Thiele), Rectification, Absorption, Extraction

**Mechanical process engineering:** Characterization of particles and particle systems in mechanical process engineering, Particle measurement technology, Basic principles of separation, classification, and sorting processes, Gas-particle separation processes, Solid-liquid separation processes, Mixing processes, Agitation

### **BME-801 Biomedical Engineering**

Overview of the biomedical engineering field with applications relevant to the healthcare industry such as medical instrumentation and devices. Introduction to the nervous

system, propagation of the action potential, muscle contraction and introduction to the cardiovascular system. Discussion of ethical issues in biomedicine

### **PHM-845 Biopharmaceutical Engineering**

This course is focused on topics related to the technology, design and operations of modern biopharmaceutical facilities. It covers process, utilities and facility design issues and encompasses all major manufacturing areas, such as fermentation, harvest, primary and final purification, media and buffer preparation, equipment cleaning and sterilization, critical process utilities, unit operations including cell culture, centrifugation, conventional and tangential flow filtration, chromatography, solution preparation, and bulk filling. The application of current Good Manufacturing Practices and Bioprocessing Equipment Standards will be discussed.

### **MATH-801 Engineering Mathematics**

Review of limits, continuity, partial differentiation, Leibnitz's rule; implicit functions and Jacobians; gradients, divergence, curl, line and surface integrals; theorems of Stokes, Gauss and Green; complex numbers, elementary functions, analytic functions, complex integration, power series, residue theorem, evaluation of real definite integrals; systems of linear equations, rank, eigenvalues and eigenvectors.

### **CHE-815 Advanced Thermodynamics**

Principles of thermodynamics developed quantitatively to include thermodynamic functions and their application to chemical engineering processes.

### **CH-811 Industrial Biochemistry**

Introduction to industrial biochemistry, Types of industries, Introduction to fermentation and its applications, Selection of industrially important organism for food, pharmaceutical, fertilizer, textile, tanneries, paper and other related industries, Brief introduction to microbial metabolites. Production of enzymes, antibiotics, acetic acid and ethanol by microbial fermentation, Manipulation of fermentation for enhanced production of targeted metabolite, Plant extraction and purification of extracted components, Manufacturing of glucose from rice, corn, potato and wheat for their industrial applications, Quality assurance and value addition.

### **CH-812 Pharmaceutical Chemistry**

Introduction to pharmaceutical chemistry, classification and nomenclature of organic pharmaceutical compounds. hyperconjugation, steric effects inductive effect and mesomeric effect, Nucleophilic and electrophilic substitution reaction in aromatic system, Theory of resonance, Orientation in electrophilic substitution reactions on benzene ring, Organic reactions: Baeyer-Villiger oxidation; Diels Alder reaction; Grignard's reaction, metal hydride reduction and Wolf Krishna reduction, Friedel Craft's reaction, Perkin

reaction, Cannizzaro reaction, Carbonium ion rearrangements; Pinacol-pinacolone, Wagner-Merwein, Wolf, Hofmann and Beckmann rearrangements, Carbanions; condensation reaction (Aldol condensation; Favorskii rearrangement; Wittig reaction), Stereoisomerism, optical isomerism, geometrical isomerism, tautomerism of carbonyl compounds, resolution of racemic mixture and conformational analysis, Free radicals: Introduction, structure and stability, General methods of preparations, properties, identification test and pharmaceutical applications of the following classes and their analogs: alcohols, phenols, ethers, aldehydes, ketones, carboxylic acids, esters, amines