PME 530 Introduction to Pharmaceutical Manufacturing

Pharmaceutical manufacturing is vital to the success of the technical operations of a pharmaceutical company. This course is approached from the need to balance company economic considerations with the regulatory compliance requirements of safety, effectiveness, identity, strength, quality, and purity of the products manufactured for distribution and sale by the company. Overview of chemical and biotech process technology and equipment; dosage forms and finishing systems; facility engineering; health, safety, and environment concepts; and regulatory issues.

Cross-listed with: ME 530, CHE 530.

PME 531 Process Safety Management

This course reviews the 12 elements of the Process Safety Management (PSM) model created by the Center for Chemical Process Safety of the American Institute of Chemical Engineers. PSM systems were developed as an expectation/demand of the public, customers, in-plant personnel, stockholders, and regulatory agencies because reliance on chemical process technologies were not enough to control, reduce, and prevent hazardous materials incidents. PSM systems are comprehensive sets of policies, procedures, and practices designed to ensure that barriers to major incidents are in place, in use, and effective. The objectives of this course are to: define PSM and why it is important, describe each of the 12 elements and their applicability, identify process safety responsibilities, give real examples and practical applications to help better understand each element, share experiences and lessons learned of all participants, and assess the quality and identify enhancements to a student’s site PSM program.

Cross-listed with: CHE 531.

PME 535 Good Manufacturing Practice in Pharmaceutical Facilities Design

Current Good Manufacturing Practice compliance issues in design of pharmaceutical and biopharmaceutical facilities; issues related to process flow, material flow and people flow, and A&E mechanical, industrial, HVAC, automation, electrical, and computer; bio-safety levels; developing effective written procedures so that proper documentation can be provided, and then documenting through validation that processes with a high degree of assurance do what they are intended to do; levels I, II, and III policies; clinical phases I, II, and III, and their effect on plant design; defending products against contamination; and building quality into products.

Cross-listed with: ME 535, CHE 535.
PME 540 Validation in Pharmaceutical Manufacturing

Validation of a pharmaceutical manufacturing process is an essential requirement with respect to compliance with Good Manufacturing Practices (GMP). Course covers: validation concepts for process, equipment, facility, cleaning, sterilization, filtration, analytical methods and computer systems; validation Master Plans, IQ, OQ, and PPQ protocols; and validation for medical devices.

Cross-listed with: ME 540, CHE 540.

PME 541 Validation of Computerized Systems

Computers and computerized systems are ubiquitous in pharmaceutical manufacturing. Validation of these systems is essential to assure public safety and compliance with appropriate regulatory issues regarding validation: GMP, GCP, 21CFR Part 11, etc. This course covers validation concepts for various classes of computerized systems and applications used in the pharmaceutical industry; importance of requirements engineering in validation; test protocols and design; organizational maturity considerations.

Cross-listed with: ME 541. Prerequisites: PME 540 or ME 540 or CHE 540.

PME 542 Global Regulation and Compliance in the Pharmaceutical Industry

This course explores the economic theory of regulation in general, and the US and international regulatory environments that govern the pharmaceutical and biotechnology industries with particular focus on the US Food and Drug Administration, the European Agency for the Evaluation of Medical Products and the Japanese Ministry of Health, Labor and Welfare. The essential components of Good Laboratory Practices, Good Clinical Practices, and Good Manufacturing Practices regulations will be covered. Students will develop an understanding of the formulation and execution of regulatory strategy and key ethical issues in medical research and production. Where appropriate, case studies will be used to illustrate the challenges and issues associated with compliance as well as the consequences of noncompliance. Ethical issues and the potential consequences of ethical lapses will also be explored. Current events will be used to illustrate key ethical principles and serve as a basis for discussion.

PME 555 Lean Six Sigma

Course explores the current application of Lean Six Sigma in Manufacturing. Topics covered include: Lean Six Sigma Concepts and Techniques, Project and Team Dynamics, Tools of Lean Six Sigma and their Application, and Designing Manufacturing Processes for Lean Six Sigma. Emphasis is on DMAIC, including Define, Measure, Analyze, Improve, and Control methodology, with the students’ skill set developed through case studies and project work on actual manufacturing processes using statistical software (Minitab). At the conclusion of this course, students will understand the concepts and principles of Lean Six Sigma, be competent with Minitab software and be able to apply these techniques to manufacturing processes.
PME 560 Quality in Pharmaceutical Manufacturing

This course provides a detailed exploration of quality programs with specific application to the particular requirements of the pharmaceutical industry. Students will develop an understanding of the quality philosophy which drives the industry from discovery through manufacturing, and of the systems and tools that are employed to implement and maintain a sustainable and successful quality system. Application of quality strategies in research and development, commercial production, computer systems, post-marketing, and other areas will be included. Where appropriate, case studies will be used to illustrate the challenges and issues associated with quality system deployment.

PME 580 Medical Device Design and Technology

Early history of medical devices and procedures. Minimally invasive and open procedures, techniques and devices, including mechanical and electrosurgical devices. Manufacturing methods for catheters, balloons, plastic and metal components. Design of metal device components including material selection and strength and deformation adequacy using material properties and classical mechanics. Selection of insulation materials for and testing of electrosurgical devices. Selection of medical plastics and design elements. Balloon and catheter burst strength. The Poiseuille flow equation and its use for fluid flow through catheters and vessels. Rapid prototyping techniques, advantages and limitations. Understanding of biocompatibility testing and accelerated age testing using the Arrhenius equation. Device sterilization methods and testing. Developing a project plan from brainstorming to product release for a new device.

Cross-listed with: ME 580.

PME 600 Engineering Economics and Cost Analysis

This course presents advanced techniques and analysis designed to permit managers to estimate and use cost information in decision making. Topics include: historical overview of the management accounting process, statistical cost estimation, cost allocation, and uses of cost information in evaluating decisions about pricing, quality, manufacturing processes (e.g., JIT, CIM), investments in new technologies, investment centers, the selection process for capital investments, both tangible and intangible, and how this process is structured and constrained by the time value of money, the source of funds, market demand, and competitive position.

Cross-listed with: EM 600.

PME 602 Statistical Methods in Pharmaceutical Manufacturing

This course is focused on the application of statistics and statistical reasoning in pharmaceutical manufacturing, particularly in production, quality assurance, quality control, validation and analytical
laboratories. Basic statistical definitions and concepts are described. Students will learn various
measures of central tendency and spread of data, how to present data graphically and be introduced to
the probability distributions most commonly encountered in pharmaceutical manufacturing.
Approaches to choosing samples for analysis, statistical inference, sample size and power will be
discussed. The course also covers regression and correlation, analysis of variance, gage repeatability and
reproducibility, statistical process control, process capability analysis and design of experiments as
applied to pharmaceutical manufacturing. Students will learn to apply statistical software to analyze
common problems that arise in pharmaceutical manufacturing operations, including evaluation of
dosage form weight and content uniformity, potency, dissolution, bio-equivalency and other product
quality attributes.

Cross-listed with: ME 602.

PME 609 Introduction to Project Management

This course deals with the problems of managing a project, which is defined as a temporary organization
of human and nonhuman resources, within a permanent organization, for the purpose of achieving a
specific objective; both operational and conceptual issues will be considered. Operational issues include
definition, planning, implementation, control and evaluation of the project. Conceptual issues include
project management vs. hierarchical management, matrix organization, project authority, motivation
and morale. Cases will be used to illustrate problems in project management and how to resolve them.

PME 626 Manufacturing of Biopharmaceutical Products

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.

Cross-listed with: ME 626. Prerequisites: PME 530 or ME 530 or CHE 530.

PME 628 Manufacturing and Packaging of Pharmaceutical Oral Solid Dosage Products

The course covers oral solid dosage (OSD) manufacturing and packaging in the pharmaceutical industry.
Production unit operations include blending, granulation, size reduction, drying, compressing, and
coating for tablets, as well as capsule filling. Packaging aspects reviewed include requirements for
primary and secondary containers and labeling, package testing. The course emphasizes design, scale-
up, trouble-shooting, validation, and operation of typical OSD manufacturing and packaging facilities,
including equipment, material flow, utilities, and quality assurance. Topics related to cGMP, process
validation, manufacturing and packaging documentation, QA and QC in OSD manufacturing will be
presented. The term project required for this course involves conceptual design of a contract manufacturing and packaging facility for OSD products, including equipment selection, development of the process flow diagrams, room layouts and other design elements, as well as preparation of Standard Operating Procedures for various unit operations.

Cross-listed with: ME 628. Prerequisites: PME 530 or ME 530 or CHE 530.

PME 629 Manufacturing of Sterile Pharmaceuticals

This course is focused on the special characteristics and types of sterile dosage forms and the technologies for their manufacturing. Topics such as environmental and contamination controls, facility design, water and air quality, personnel and other requirements for sterile manufacturing are covered. Sterilization methods for the equipment, components, intermediate and finished products are reviewed. Terminal sterilization and aseptic processing technologies including blow-fill-seal and barrier isolation systems are discussed. The course also includes topics such as Good Manufacturing Practices (GMP) regulations and guidance on aseptic manufacturing, quality assurance and control, stability, storage and distribution applicable to sterile dosage forms manufacturing.

Cross-listed with: ME 629. Prerequisites: PME 530 or ME 530 or CHE 530.

PME 647 Environmental Systems (HVAC) in Healthcare Manufacturing

Proven techniques and creative tools presented for design, development, and delivery of Environmental Systems necessary for the control and monitoring of classified spaces to manufacture drugs, medical devices, and research labs with potent or biologic compounds. Obtain knowledge of pharmaceutical environmental requirements, understanding of theories and principles of operation for Heating, Ventilating, and Air Conditioning (HVAC) equipment and system configurations to satisfy regulatory acceptance criteria, gaining practical knowledge of environmental system design and implementation including validation that supports drug production. Course also includes Building Automation Systems conceptual design and application for controlling and monitoring a regulated production environment. Exploring new trends and technologies of HVAC systems and design for sterile and aseptic manufacturing, barrier and isolation technologies, containment of potent compounds, specific extraction, flammable solvent handling, and using HVAC system as secondary protection of products and operators.

Cross-listed with: ME 647, CHE 647.

PME 660 Medical Devices Manufacturing

Technical tools and knowledge required to operate and manage in medical devices manufacturing environment. Current requirements in medical devices regulations, quality systems, and design elements related to manufacturing steps to assure patients health and safety. Requirements concerning selection and supply of raw materials and components for manufacturing; design and qualification of facilities, equipment, and process systems; testing, controls and inspection for compliance. Combination
products, validation, external contractors, and case studies. Focus on understanding the principles and methods required in a medical devices manufacturing environment in compliance with GMP regulations. Cross-listed with: ME 660.