Manufacturing, Validation, Compliance and Quality Assurance
Master of Science in Pharmaceutical Manufacturing

The Master of Science in Pharmaceutical Manufacturing is a 30 credit degree program designed for recent engineering, science or pharmacy graduates seeking credentials for entry into manufacturing industries that are driven by Good Manufacturing Practices (GMP), including pharmaceutical, biotechnology, cosmetics and personal care product manufacturers. It also attracts engineers, scientists and other specialists who are already working in GMP-regulated manufacturing industries and who are interested in becoming transformational leaders in their organizations. The students gain a thorough understanding of pharmaceutical technologies and modern manufacturing facilities in the context of global regulatory requirements. The program concentrates primarily on the areas related to commercial manufacturing, such as GMP, manufacturing technologies, facilities design, validation, compliance and quality assurance.

Graduates gain the skills necessary for solving challenging problems, utilizing emerging pharmaceutical technologies effectively to reach business goals and leading innovation across organizations. The courses are taught by a mix of full-time and part-time faculty with distinguished professional records in the pharmaceutical industry. The program offers a unique blend of small class sizes, intense collaboration and professional networking opportunities. Graduates will develop and practice communication, interpersonal and team collaboration skills, which will enable them to function effectively in regulated manufacturing environments.

CURRICULUM

Mandatory Foundation Courses

PME530 Introduction to Pharmaceutical Manufacturing
PME535 Good Manufacturing Practices in Pharmaceutical Facilities Design
PME540 Validation in Pharmaceutical Manufacturing
PME560 Quality in Pharmaceutical Manufacturing
PME602 Statistical Methods in Pharmaceutical Manufacturing

Primary Elective Courses

PME541 Validation of Computerized Systems
PME542 Global Regulation & Compliance in the Pharmaceutical Industry
PME626 Manufacturing of Biopharmaceutical Products
PME628 Manufacturing & Packaging of Pharmaceutical Oral Solid Dosage Products
PME629 Manufacturing of Sterile Pharmaceuticals

Graduation Requirements

30 credits
5 foundation courses
5 elective courses
- At least two 600-level PME technology courses
- 1 elective course may be substituted by a project
- 2 elective courses may be substituted by a Master’s Thesis
Cumulative GPA of 3.0 or better

For more information, please contact:

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PROGRAM OBJECTIVES

The program aims to teach students strategies, methods and techniques to (i) enable consistent production of high quality products through a thorough understanding of pharmaceutical materials, manufacturing processes and equipment, (ii) maintain compliance with the regulatory requirements on GMP, (iii) analyze the design and operations of pharmaceutical facilities and establish ways to increase quality and to reduce costs and time to market, and (iv) take leadership roles in the GMP-regulated manufacturing industries.

FOUNDATION COURSES

PME530 Introduction to Pharmaceutical Manufacturing

This graduate course approaches pharmaceutical manufacturing from the need to balance 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. It provides an overview of process technologies and equipment used in manufacturing of various drug dosage forms and active pharmaceutical ingredients as well as regulatory issues and facility engineering.

PME535 Good Manufacturing Practices in Pharmaceutical Facilities Design

This graduate course familiarizes students with current GMP compliance in the design of pharmaceutical and biopharmaceutical facilities, including issues related to process, material and people flow. It also covers the special requirements of the pharmaceutical industry related to architecture and engineering, including process, utilities, electrical and computer systems. Specialized requirements for heating, ventilation and air conditioning (HVAC), automation and process safety are also covered. Students will develop and review drawings and documents used in facilities design and learn how to defend products against contamination.

PME540 Validation in Pharmaceutical Manufacturing

This graduate course discusses validation of pharmaceutical manufacturing processes as an essential requirement with respect to compliance with current Good Manufacturing Practices (cGMP). It covers validation concepts for process, equipment, facility, cleaning, sterilization, filtration, analytical methods and computer systems. The latest FDA guidance documents related to validation are reviewed and discussed. Students learn to develop documents such as Validation Master Plan, IQ, OQ and PPQ protocols and reports.

PME560 Quality in Pharmaceutical Manufacturing

This graduate course provides a detailed exploration of quality programs with specific application to the particular requirements of the pharmaceutical industry, using case studies to illustrate the challenges and issues associated with quality system deployment. Students will develop an understanding of the quality philosophy that drives the industry 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.

PME602 Statistical Methods in Pharmaceutical Manufacturing

This graduate course focuses on the application of statistical reasoning in pharmaceutical manufacturing, particularly in production, quality assurance, quality control, validation and analytical laboratories. It covers regression and correlation, analysis of variance, gage repeatability and reproducibility, statistical process control, process capability analysis and design of experiments. 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.

GRADUATE CERTIFICATES

Pharmaceutical Manufacturing Validation, Compliance & Quality in the Pharmaceutical Industry