



CHARLES V. SCHAEFER, JR. SCHOOL OF ENGINEERING & SCIENCE

Pharmaceutical Manufacturing – From Fundamentals to Expertise

Graduate Certificate in Pharmaceutical Manufacturing

This four-course Graduate Certificate in Pharmaceutical Manufacturing is 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 provides an introductory overview of the pharmaceutical industry, touching on all basic manufacturing processes, facility design issues, validation, compliance and quality assurance concepts and pharmaceutical technologies.

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 Courses

PME530 Introduction to Pharmaceutical Manufacturing
PME535 Good Manufacturing Practices in Pharmaceutical Facilities Design
PME540 Validation in Pharmaceutical Manufacturing

Elective Courses

PME626 Manufacturing of Biopharmaceutical Products
PME628 Manufacturing & Packaging of Pharmaceutical Oral Solid Dosage Products
PME629 Manufacturing of Sterile Pharmaceuticals

Graduation Requirements

12 credits (4 courses)
3 mandatory courses
1 of 3 elective courses
Cumulative GPA of 3.0 or better

STUDY OPTIONS

Gain a rigorous, applicable education no matter how you choose to study. Courses are delivered:

- On-campus, one class per week for 15 weeks
- Online via our award-winning WebCampus

ADMISSION REQUIREMENTS

- 4-year undergraduate degree in engineering, science or pharmacy
- Official college transcripts
- Competitive GRE scores
- Competitive TOEFL / IELTS scores (for international students whose native language is not English)
- Two letters of recommendation

Apply today at:

www.stevens.edu/sit/graduate/

For more information, please contact:

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PROGRAM OBJECTIVES

The program objectives are to familiarize students with (i) common pharmaceutical products, manufacturing processes and equipment, (ii) the concepts of compliance with the regulatory requirements on Good Manufacturing Practices, (iii) process validation in the pharmaceutical industry, and (iv) design and operations of pharmaceutical facilities.

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. 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.

PME626 Manufacturing of Biopharmaceutical Products

This graduate 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.

PME628 Manufacturing & Packaging of Pharmaceutical Oral Solid Dosage Products

This graduate course introduces students to 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 and package testing. The course emphasizes design, scale-up, trouble-shooting, validation and operation of typical OSD manufacturing and packaging facilities.

PME629 Manufacturing of Sterile Pharmaceuticals

This graduate course is focused on the special characteristics and types of sterile dosage forms and the technologies for their manufacturing. Topics covered include environmental and contamination controls, facility design, water and air quality, aseptic techniques, sterilization methods, GMP regulation and guidance on aseptic manufacturing, quality assurance and control, stability, storage and distribution applicable to sterile dosage forms manufacturing.