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

Enabling Pharmaceutical Manufacturing Excellence

# Graduate Certificate in Validation, Compliance and Quality in the Pharmaceutical Industry

This four-course Graduate Certificate in Validation, Compliance and Quality in the Pharmaceutical Industry is designed for individuals who work or aspire to work in validation, compliance or quality functions in industries that are driven by Good Manufacturing Practices (GMP), including pharmaceutical, medical device, biotechnology, cosmetics and personal care product manufacturers. Students learn approaches to process validation, qualification of equipment, utilities, facilities, analytical methods, cleaning validation, etc. Also covered are quality-related concepts and methods, applications to manufacturing equipment, utilities, computerized systems and regulatory compliance issues in the global environment.

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

PME540 Validation in Pharmaceutical Manufacturing
PME560 Quality in Pharmaceutical Manufacturing
PME602 Statistical Methods in Pharmaceutical Manufacturing

### Elective Courses

PME541 Validation of Computerized Systems
PME542 Global Regulation & Compliance in the Pharmaceutical Industry

### Graduation Requirements

12 credits (4 courses)
3 mandatory courses
1 of 2 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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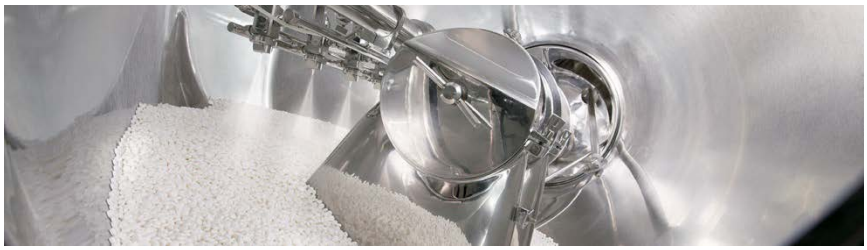

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## PROGRAM OBJECTIVES

The program objectives are to familiarize students with strategies and tools for (i) process validation in the pharmaceutical industry, (ii) quality management in the pharmaceutical industry, (iii) maintaining compliance with global regulatory requirements of Good Manufacturing Practices.

## COURSES

### 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 assess process and mechanical design of pharmaceutical manufacturing facilities, evaluate their compliance with the process needs, and to develop and execute validation documents such as installation, operational and performance qualification protocols and reports.

### PME560 Quality in Pharmaceutical Manufacturing

This graduate course provides a detailed exploration of pharmaceutical quality programs. Topics covered include the quality philosophy that drives the industry from discovery to manufacturing, the systems and tools employed to implement and maintain a sustainable and compliant quality system as well as the application of quality strategies in research and development, commercial production, computer systems and post-marketing pharmacovigilance. Students learn to apply root cause analysis methods, the TRIZ philosophy and lean six sigma principles to real world scenarios. Where appropriate, current case studies are used to illustrate the challenges and issues associated with quality system deployment.

### 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. Approaches to creating representative sampling plans, 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 will be discussed. 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.

### PME541 Validation of Computerized Systems

This graduate course is designed to prepare students to guide the computer system validation process as system business owners and to ensure the maintenance of the systems' validated state throughout their use. Concepts covered include the computer system validation lifecycle, the phases of computer validation, a risk-based model for computer validation, development of user requirements and various testing protocols, regulatory inspections, the computer compliance capability model, the international computer system validation regulated environment and effective compliance strategies. Students complete a capstone project creating selected computer system validation document deliverables for real-world pharmaceutical quality systems.

### PME542 Global Regulation & Compliance in the Pharmaceutical Industry

This graduate course discusses the US and international regulatory environments that govern the pharmaceutical, medical device and biotechnology industries with particular focus on the regulations of the U.S., EU, Japan, China and India. The essential components of Good Laboratory Practices, Good Clinical Practices and Good Manufacturing Practices regulations are covered as well as current regulatory guidance documents and international harmonization efforts. Students will learn the formulation and execution of regulatory strategy, key ethical issues and the potential consequences of ethical lapses. Where appropriate, current case studies are used to illustrate challenges associated with compliance as well as the consequences of noncompliance.