

Graduate Certificate: Pharmaceutical Manufacturing: Process Development and Analysis

SCHOOL OF PHARMACY

About the Certificate

The graduate certificate in Pharmaceutical Manufacturing: Process Development and Analysis is designed to enhance students' understanding of the science and regulations involved in pharmaceutical manufacturing processes. Through coursework, students learn how to set standards for increasing product quality, improve plant efficiency, lower production costs, and meet current domestic and global compliance requirements. The curriculum also reflects the culture of meeting continuous manufacturing quality, such as the Food and Drug Administration's Quality Metric Guidance document and its focus on data integrity, change control, quality risk management, Installation Qualifications (IQ), Operational Qualifications (OQ), and Performance Qualifications (PQ).

Time Limit for Certificate Completion: 3 years

Campus Location: Fort Washington

Full-Time/Part-Time Status: The certificate may be completed on a part-time basis. NOTE: International students may not be eligible to apply for a student visa based on admission to the certificate program. Please contact the School of Pharmacy's program coordinator for more information.

Non-Matriculated Student Policy: Non-matriculated students may take up to 9 credits of coursework before applying to the certificate program.

Admission Requirements and Deadlines

Application Deadline:

Fall and Spring admissions are on a rolling basis. Interested students should contact the School of Pharmacy for permission to enroll in coursework.

APPLY HERE to the post-baccalaureate certificate program.

Bachelor's Degree in Discipline/Related Discipline: Applicants must hold a BS degree in Biochemistry, Biology, Chemistry, Engineering, Pharmacy, Physics or related discipline. They must also have a basic knowledge of pharmaceutical manufacturing processes.

Certificate Requirements

Number of Credits Required to Complete the Certificate: 12

Required Courses:

Code	Title	Credit Hours
Core Courses ¹		
QARA 5622	Unit Operations	3
QARA 5627	Statistical Design of Experiments (DOE)	3
QARA 5629	Process Monitoring	3
Elective		3
Select one from the following:		
QARA 5512	Microbiological Concepts in Pharmaceutical Manufacturing	
QARA 5548	Risk Management of Pharmaceutical and Medical Devices	
QARA 5625	Process Analytical Technology (PAT)	
Total Credit Hours		12

¹ It is recommended that students take the core courses in the following order, if possible: QARA 5622 first, QARA 5629 second, and QARA 5627 third. The elective is taken last.

GPA Required to be Awarded the Certificate: 3.0 minimum

Contacts

Certificate Program Web Address:

<https://pharmacy.temple.edu/raqa/certificate-programs/pre-masters-certificates/pharmaceutical-manufacturing-process-development-and-analysis-certificate>

Department Information:

Regulatory Affairs and Quality Assurance Graduate Program
425 Commerce Drive, Suite 175
Fort Washington, PA 19034-2728
qara@temple.edu
267-468-8560

Mailing Address for Application Materials:

Temple University
Regulatory Affairs and Quality Assurance Graduate Program
425 Commerce Drive, Suite 175
Fort Washington, PA 19034-2728

Department Contacts:

Admissions:

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