

Graduate Certificate: Generic Drugs

SCHOOL OF PHARMACY

About the Certificate

The graduate certificate in Generic Drugs studies the topics that are unique to generic drug manufacturers. Courses focus on the regulatory issues that are critical for generic industry professionals to understand if they are to ensure that their companies create safe and effective bioequivalent drugs. Coursework delves into the global business environment of generic therapeutic products and pertinent domestic and global regulations. Starting with an overview of the drug development process for innovator products, the required courses compare and explore the Abbreviated New Drug Application (ANDAs) used for generics. Elective courses enable students to explore various manufacturing and regulatory issues, including current trends in the global marketplace regarding APIs and excipients. The certificate allows students to sharpen their knowledge of this industry niche without committing to a master's degree.

The Generic Drugs certificate provides the tools and information to understand how generic drugs are regulated locally, nationally and globally. Students become familiar with:

- domestic and global regulations for generic products,
- the highly competitive environment of generic products,
- manufacturing issues of global products, and
- current regulatory filing and quality assurance issues affecting generic products.

Time Limit for Certificate Completion: 4 years

Campus Location: Online and 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 Biology, Chemistry, Engineering, Pharmacy, Physics or related fields.

Certificate Requirements

Number of Credits Required to Complete the Certificate: 12

Required Courses:

Code	Title	Credit Hours
Core Courses		
QARA 5459	Drug Development	3
QARA 5473	Generic Drug Regulation (ANDAs)	3
Electives		
Select two from the following:		6
PS 8004	Solid Dosage Forms - Small Molecules	
QARA 5458	Global Biopharmaceutical Industry	
QARA 5477	Good Manufacturing Practices	
QARA 5513	Active Pharmaceutical Ingredients (APIs)	
QARA 5543	Good Distribution Practices	
QARA 5546	Global Pharmaceutical Excipient Regulation	
QARA 5576	Global CMC Issues and Regulatory Dossier	

QARA 5650 Special Topics in Regulatory Affairs and Quality Assurance

QARA 5655 Analytical Chemistry in Pharmaceutical Laboratories

Total Credit Hours

12

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/generic-drugs>

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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