

# Graduate Certificate: Medical Device

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SCHOOL OF PHARMACY

## About the Certificate

The U.S. Food and Drug Administration (FDA) regulation of medical devices has the same objective as its regulation of drugs: protecting public health by ensuring a balance of risk vs. benefit for marketed products. Some high-risk medical devices, such as sutures, contact lenses and antibiotic sensitivity disks, were regulated as drugs before legislation was passed in 1976 extending the FDA's regulatory authority over devices. Because medical devices are highly variable in complexity and technology, a more flexible approach to regulation has evolved to meet this variability than has evolved for drugs.

The graduate certificate in Medical Device focuses on the domestic and global regulations governing the medical device field. Many pharmaceutical companies have separate device divisions or entire subsidiaries that focus on marketing medical and diagnostic devices, such as diagnostic instruments and kits, surgical sponges, and drug delivery devices, which range from syringes to transdermal patches. Regulatory affairs professionals pursuing this certificate deepen their understanding of the device field by exploring the similarities and differences in pharmaceutical and device regulations. The certificate reviews key aspects of the medical device industry: regulation, compliance and submissions in the domestic and global realms. Instructors are experts from the medical device sector who conduct highly interactive classes with hands-on workshops, enabling students to apply their knowledge immediately to the workplace.

**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 bachelor's degree from an accredited institution. While no specific major is required, most applicants should have a background in biological sciences, engineering, healthcare, natural sciences or related disciplines.

## Certificate Requirements

*Number of Credits Required to Complete the Certificate: 15*

*Required Courses:*

Code	Title	Credit Hours
<b>Core Courses</b>		
QARA 5496	Regulation of Medical Devices: Compliance	3
QARA 5502	Regulation of Medical Devices: Submissions	3
QARA 5505	Global Regulation of Medical Devices	3
QARA 5592	Food and Drug Law	3
<b>Elective</b>		
Select one from the following:		3
QARA 5474	Process Validation	
QARA 5494	Quality Audit	
QARA 5498	Computerized System Validation	
QARA 5499	Drug Dosage Forms	
QARA 5541	Pharmaceutical Packaging: Technology and Regulation	
QARA 5548	Risk Management of Pharmaceutical and Medical Devices	

**Total Credit Hours**

**15**

**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/medical-devices>

### **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:*  
Wendy Lebing, MALD, MS  
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