

Post-Master's Certificate: Medical Device

SCHOOL OF PHARMACY

About the Certificate

The post-master's certificate in Medical Device is designed for those who hold an MS in Regulatory Affairs and Quality Assurance and want to keep current with industry issues and meet regulatory requirements for training. The certificate program is also open to professionals with other master's or doctoral degrees.

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.

Coursework for the Medical Device post-master's certificate 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 post-master's 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-master's certificate program.

Master's Degree in Discipline/Related Discipline: Applicants must hold a master's degree in a Pharmacy-related field, including but not limited to an MS in Regulatory Affairs and Quality Assurance. Graduates of Temple University's RAQA program take certificate coursework to keep current with industry issues and meet regulatory requirements for training. Applicants with an advanced science degree from an accredited institution of higher learning other than Temple University must have worked in the pharmaceutical industry for a minimum of three years.

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 discipline.

Certificate Requirements

Number of Credits Required to Complete the Certificate: 15

Required Courses:

Code	Title	Credit Hours
Core Courses		
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 ¹	3
Elective		
Select one from the following:		3

QARA 5474	Process Validation
QARA 5494	Quality Audit
QARA 5498	Computerized System Validation
QARA 5503	Design Controls for Medical Devices and Combination Products
QARA 5511	Advanced Audit Workshop of Quality Systems
QARA 5541	Pharmaceutical Packaging: Technology and Regulation
QARA 5548	Risk Management of Pharmaceutical and Medical Devices

Total Credit Hours**15**

¹ Graduates of Temple's MS in Regulatory Affairs and Quality Assurance program will have completed QARA 5592 as part of their master's degree. Those credits are brought forward to count for the Medical Device post-master's certificate. These students are then required to take QARA 5496 Regulation of Medical Devices: Compliance, QARA 5502 Regulation of Medical Devices: Submissions, QARA 5505 Global Regulation of Medical Devices, and one elective to complete the post-master's certificate in Medical Device. Any student who previously completed QARA 5496, QARA 5502 and/or QARA 5505 as part of their MS degree program must select an elective to replace any previously completed course(s) in fulfilling the required 15 credits for the post-master's certificate.

GPA Required to be Awarded the Certificate: 3.0 minimum

Contacts

Certificate Program Web Address:

<https://pharmacy.temple.edu/academics/regulatory-affairs-quality-assurance-ms-programs-non-thesis-certificates/about/certificate-programs-raqa/post-masters-certificates-raqa/medical-devices-certificate-post-masters-raqa>

Department Information:

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 425 Commerce Drive, Suite 175
 Fort Washington, PA 19034-2728
 qara@temple.edu
 267-468-8560

Mailing Address for Application Materials:

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 Regulatory Affairs and Quality Assurance Graduate Program
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Department Contacts:

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