Graduate Certificate: Medical Device

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:

<table>
<thead>
<tr>
<th>Code</th>
<th>Title</th>
<th>Credit Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>QARA 5496</td>
<td>Regulation of Medical Devices: Compliance</td>
<td>3</td>
</tr>
<tr>
<td>QARA 5502</td>
<td>Regulation of Medical Devices: Submissions</td>
<td>3</td>
</tr>
<tr>
<td>QARA 5505</td>
<td>Global Regulation of Medical Devices</td>
<td>3</td>
</tr>
<tr>
<td>QARA 5592</td>
<td>Food and Drug Law</td>
<td>3</td>
</tr>
</tbody>
</table>

Elective
Select one from the following:

<table>
<thead>
<tr>
<th>Code</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>QARA 5474</td>
<td>Process Validation</td>
</tr>
<tr>
<td>QARA 5494</td>
<td>Quality Audit</td>
</tr>
<tr>
<td>QARA 5498</td>
<td>Computerized System Validation</td>
</tr>
<tr>
<td>QARA 5499</td>
<td>Drug Dosage Forms</td>
</tr>
<tr>
<td>QARA 5541</td>
<td>Pharmaceutical Packaging: Technology and Regulation</td>
</tr>
<tr>
<td>QARA 5548</td>
<td>Risk Management of Pharmaceutical and Medical Devices</td>
</tr>
</tbody>
</table>

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
Assistant Dean
qara@temple.edu
267-468-8560