Graduate Certificate: Sterile Process Manufacturing

SCHOOL OF PHARMACY

About the Certificate

The graduate and post-master's certificate in Sterile Process Manufacturing is intended to enable Regulatory Affairs and Quality Assurance (RAQA) students to receive formal recognition for studying the techniques and applicable regulations used in the development and manufacture of sterile products. Sterile products include a wide range of commonly used products, such as intradermal (ID), intramuscular (IM), intravenous (IV), and subcutaneous (SC) products, vaccines, and products administered directly into different parts of the body, such as arteries (intra-arterial), bones (intrasternal), heart (intracardiac), or the spinal canal (intrathecal). Sterile products must be manufactured using aseptic (or free from contamination) methods wherein the drug substance, excipients, and vehicle (e.g., saline or water for injection) are combined in a container, such as a syringe. Generally, the final dosage form cannot be sterilized at the end of the manufacturing process, since the drug substance would become degraded. Therefore, sterility must be ensured during the manufacturing process by utilizing sterile filtration, microbial controls, and facility design, all of which must follow regulatory guidelines.

Through completion of the certificate, whether post-baccalaureate or post-master's, students understand the following:

- routes and types of administration of sterile products;
- regulations, processes, and unique considerations involved with sterile parenteral products;
- manufacturing and facility requirements for the design and production of sterile products;
- validation and compliance specifications for sterile products; and
- methods used for sterilization, including regulatory requirements for thermal, gaseous, radiation, filtration, and aseptic processing.

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.

Master's Degree in Discipline/Related Discipline: Applicants completing the program to earn a post-master's certificate must hold a master's degree in a Pharmacy-related field.

Bachelor's Degree in Discipline/Related Discipline: Applicants completing the program to earn a post-baccalaureate certificate must hold a B.S. degree in Biochemistry, Biology, Chemistry, Physics, or a health-related discipline.

Certificate Requirements

Number of Credits Required to Complete the Certificate: 12

Required Courses:

<table>
<thead>
<tr>
<th>Code</th>
<th>Title</th>
<th>Credit Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>QARA 5492</td>
<td>Production of Sterile Parenterals</td>
<td>3</td>
</tr>
<tr>
<td>or QARA 5493</td>
<td>Sterilization Processes</td>
<td></td>
</tr>
<tr>
<td>QARA 5512</td>
<td>Microbiological Concepts in Pharmaceutical Manufacturing</td>
<td>3</td>
</tr>
<tr>
<td>Electives</td>
<td>Select two from the following:</td>
<td>6</td>
</tr>
<tr>
<td>QARA 5492</td>
<td>Production of Sterile Parenterals</td>
<td></td>
</tr>
<tr>
<td>QARA 5493</td>
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<table>
<thead>
<tr>
<th>Course Code</th>
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<tbody>
<tr>
<td>QARA 5501</td>
<td>Development of Sterile Products</td>
</tr>
<tr>
<td>QARA 5572</td>
<td>Vaccines: Regulatory Affairs and Quality Assurance Issues</td>
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</tbody>
</table>

Total Credit Hours 12

1 Course may be selected as an elective only if not taken as a core course above.

GPA Required to be Awarded the Certificate: 3.0 minimum

Contacts

Certificate Program Web Address:
https://www.temple.edu/pharmacy_qara/certificates.htm

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, M.S.
Program Coordinator
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267-468-8560