

# Graduate Certificate: Sterile Process Manufacturing

## SCHOOL OF PHARMACY

Learn more about the graduate certificate in Sterile Process Manufacturing.

## About the Certificate

The graduate 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 items, such as intradermal (ID), intramuscular (IM), intravenous (IV), and subcutaneous (SC), as well as 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 (i.e., 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, 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:** 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 Biochemistry, Biology, Chemistry, Physics or a health-related discipline.

## Certificate Requirements

*Number of Credits Required to Complete the Certificate: 12*

*Required Courses:*

Code	Title	Credit Hours
<b>Core Courses</b>		
QARA 5492 or QARA 5493	Production of Sterile Parenterals Sterilization Processes	3
QARA 5512	Microbiological Concepts in Pharmaceutical Manufacturing	3
<b>Electives</b>		<b>6</b>

Select two from the following:

QARA 5492	Production of Sterile Parenterals <sup>1</sup>
QARA 5493	Sterilization Processes <sup>1</sup>

QARA 5501	Development of Sterile Products
QARA 5572	Vaccines: Regulatory Affairs and Quality Assurance Issues
<b>Total Credit Hours</b>	

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://pharmacy.temple.edu/raqa/certificate-programs/pre-masters-certificates/sterile-process-manufacturing>

### Department Information:

Regulatory Affairs and Quality Assurance Graduate Program  
 425 Commerce Drive, Suite 175  
 Fort Washington, PA 19034-2728  
[qara@temple.edu](mailto: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](mailto:qara@temple.edu)  
 267-468-8560