Post-Master's Certificate: Sterile Process Manufacturing

SCHOOL OF PHARMACY

About the Certificate

The 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 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 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.

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
Core Courses		
QARA 5492	Production of Sterile Parenterals	3
or QARA 5493	Sterilization Processes	
QARA 5512	Microbiological Concepts in Pharmaceutical Manufacturing	3
Electives		**6**
Select two from the following:		
QARA 5492	Production of Sterile Parenterals [1]	

QARA 5493	Sterilization Processes [1]	
QARA 5501	Development of Sterile Products	
QARA 5572	Vaccines: Regulatory Affairs and Quality Assurance Issues	
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://pharmacy.temple.edu/academics/regulatory-affairs-quality-assurance-ms-programs-non-thesis-certificates/about-programs/certificate-programs-raqa/post-masters-certificates-raqa/sterile-process-manufacturing-certificate-post-masters-raqa

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:

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Department Contacts:

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