Post-Master's Certificate: Biopharmaceutical Manufacturing and Regulatory Affairs

SCHOOL OF PHARMACY

About the Certificate

The post-master's certificate in Biopharmaceutical Manufacturing and Regulatory Affairs is intended to enable Regulatory Affairs and Quality Assurance (RAQA) specialists to receive formal recognition for studying the highly specialized, rapidly growing field of pharmaceutical biotechnology, which includes the manufacturing techniques and applicable regulations used in the development and production of biotechnology products. The first biopharmaceutical product, namely, recombinant human insulin, was approved in 1982. Since then, products derived through biotechnology have provided advances in medicine that include therapeutic monoclonal antibodies, cancer vaccines, cytokines, antisense technology, interference RNA, and growth factors. The regulatory framework required for the approval of biotechnology-derived products (or biologics) is lengthy, rigorous and highly complicated. This certificate delves into the complex regulations governing the development, manufacturing and distribution of such products.

Through completion of the certificate, students understand the following:

- the pharmaceutical science behind the discovery of biotechnology products, including biologics, biosimilars and biopharmaceuticals;
- the requirements for sourcing and testing materials used in the production of biotechnology products;
- the technologies and unique considerations associated with the manufacturing and distribution of biotechnology products;
- the applicable regulations involved with biotechnology products; and
- the processes used to sterilize biotechnology products, 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: 15

Required Courses:

Code	Title	Credit Hours
Core Courses		
QARA 5471	Biotechnology: Bioprocess Basics	3
QARA 5475		3
QARA 5515	Biologics/Biosimilars: A Regulatory Overview	3
QARA 5577	Global CMC Regulatory Compliance for Biopharmaceuticals and Other Biologics	3
Elective		**3**
Select one from the following:		

QARA 5492	Production of Sterile Parenterals
QARA 5493	Sterilization Processes
QARA 5501	Development of Sterile Products
QARA 5512	Microbiological Concepts in Pharmaceutical Manufacturing
QARA 5572	Vaccines: Regulatory Affairs and Quality Assurance Issues
Total Credit Hours	**15**

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/pre-masters-certificates-raqa/biopharmaceutical-manufacturing-regulatory-affairs-certificatepre-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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Regulatory Affairs and Quality Assurance Graduate Program
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Department Contacts:

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