Post-Master's Certificate: Biologics and Biosimilars Manufacturing

SCHOOL OF PHARMACY

About the Certificate

Given the rapidly expanded development of biopharmaceuticals in the past decade, an immediate need exists for professionals with knowledge of and credentials in key manufacturing quality issues governing biologics and biosimilar drugs. The post-master's certificate in Biologics and Biosimilars Manufacturing requires the completion of coursework focusing on how biologics and biosimilars are manufactured, looking specifically at regulatory compliance elements, fundamentals of Quality by Design (QbD) and Statistical Process Control (SPC). Chemistry, Manufacturing and Controls (CMC) strategies, including materials sourcing and testing requirements, are also studied. Discussions include the technologies used in manufacturing and the unique considerations that arise when dealing with such technologies as cell and gene therapies, therapeutic monoclonal antibodies, vaccines, cytokines, antisense technology, interference RNA and growth factors.

Time Limit for Certificate Completion: 4 years, with courses meeting for a minimum of 36 class contact hours over 10 or 12 consecutive weeks

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 Biology, Chemistry, Engineering, Pharmacy, Physics or related field.

Certificate Requirements

Number of Credits Required to Complete the Certificate: 15

Required Courses:

Code	Title	Credit Hours
Core Courses		
PS 8005	Pharmaceutical Biotechnology	3
QARA 5471	Biotechnology: Bioprocess Basics [1]	3
QARA 5515	Biologics/Biosimilars: A Regulatory Overview [1]	3
QARA 5577	Global CMC Regulatory Compliance for Biopharmaceuticals and Other Biologics	3
Elective		
Select one from the following:		3
PS 5501	Development of Sterile Products	
QARA 5000	Special Topics in Regulatory Affairs and Quality Assurance [2]	
QARA 5451	Statistical Quality Control	
QARA 5468	Validation of Facilities, Utilities and Equipment (FUE)	
QARA 5474	Process Validation	
QARA 5479	Advanced Good Manufacturing Practices - Defining "c"	
QARA 5492	Production of Sterile Parenterals	
QARA 5493	Sterilization Processes	

QARA 5512	Microbiological Concepts in Pharmaceutical Manufacturing	
QARA 5516	Cleaning Validation	
QARA 5572	Vaccines: Regulatory Affairs and Quality Assurance Issues	
QARA 5625	Process Analytical Technology (PAT)	
QARA 5627	Statistical Design of Experiments (DOE)	
QARA 5629	Process Monitoring	
Total Credit Hours		**15**

1

With prior written approval of the RAQA Office, students with demonstrated experience in biotechnology or biologics/biosimilar regulatory aspects may substitute an elective for QARA 5471 or QARA 5515.

2

Before taking QARA 5000 Special Topics in Regulatory Affairs and Quality Assurance as an elective, students must receive prior written approval from the RAQA Office to ensure that the course content focuses specifically on biologics and biosimilars.

GPA Required to be Awarded the Certificate: 3.0 minimum

Contacts

Certificate Program Web Address:

https://pharmacy.temple.edu/raqa/certificate-programs/post-masters-certificates/biologics-and-biosimilars-manufacturing

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:

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