

Graduate Certificate: Biologics and Biosimilars: Regulatory Aspects

SCHOOL OF PHARMACY

Learn more about the graduate certificate in Biologics and Biosimilars: Regulatory Aspects.

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 U.S. and global regulations governing biologics and biosimilar drugs. The graduate certificate in Biologics and Biosimilars: Regulatory Aspects explores the regulatory, strategic, technical and scientific issues that are unique to biologics and biosimilar drug manufacturers.

Discussions include the clinical, manufacturing, regulatory and strategic issues that challenge the global commercialization pathways of biological products, as well as current technical and scientific issues involved in developing biological products in major regions of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Questions such as how biologics and biosimilars differ from chemically synthesized drugs and the unique analytical methods used to characterize biologics, as opposed to small molecule testing, are covered. Topics include Quality by Design (QbD) principles relating to development, manufacturing and testing of biologics. Three required courses review the drug development process, biologic and biosimilar regulations, as well as global Chemistry, Manufacturing and Controls (CMC) issues for biologics. Depending on career focus, students may select electives in sterile products (such as vaccines), pharmacovigilance issues, clinical issues or regulatory eSubmissions.

The Biologics and Biosimilars: Regulatory Aspects certificate may be pursued on its own or as part of the Regulatory Affairs and Quality Assurance MS.

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 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 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		
QARA 5459	Drug Development	3
QARA 5515	Biologics/Biosimilars: A Regulatory Overview	3
QARA 5577	Global CMC Regulatory Compliance for Biopharmaceuticals and Other Biologics	3
Electives		
Select two from the following:		6
PS 5492	Production of Sterile Products	
QARA 5514	Regulatory eSubmissions	
QARA 5538	Clinical Drug Safety and Pharmacovigilance	
QARA 5571	Post-Marketing Safety Surveillance	

QARA 5572	Vaccines: Regulatory Affairs and Quality Assurance Issues
QARA 5650	Special Topics in Regulatory Affairs and Quality Assurance ¹
Total Credit Hours	

15

¹ Before taking QARA 5650 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://www.temple.edu/academics/degree-programs/biologics-and-biosimilars-regulatory-aspects-certificate-graduate-ph-bbra-grad>

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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