Post-Master's Certificate: Advanced Regulatory Affairs and Quality Assurance

SCHOOL OF PHARMACY

About the Certificate

The post-master's certificate in Advanced Regulatory Affairs and Quality Assurance is designed to allow individuals holding a master's degree in Regulatory Affairs and Quality Assurance (RAQA) to pursue advanced coursework from a broad array of topics and receive formal recognition for their work. The certificate program is also open to those holding an advanced degree in the sciences who have worked extensively in the pharmaceutical industry and seek a cadre of advanced courses in RA or QA to be compliant with Food and Drug Administration regulations on training records.

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 completing the program to earn the post-master's certificate must hold a master's degree in Regulatory Affairs and Quality Assurance from Temple University or a peer institution. An advanced degree in the sciences is also accepted.

Applicants who did not earn their master's degree from Temple University's School of Pharmacy must formally apply to the certificate program. They must provide proof of their advanced degree, including a transcript and documentation of the titles and descriptions of previous RA/QA courses taken. A summary of their industry experience in the form of a CV or resume is also required.

Bachelor's Degree in Discipline/Related Discipline: Applicants completing the program to earn a graduate certificate 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: 12-15, depending on the institution from which and/or the subject in which the master's degree was earned[1]

Required Courses:

Code	Title	Credit Hours
Select four or five from the following approved courses:		12-15
PS 5501	Development of Sterile Products	
PS 8005	Pharmaceutical Biotechnology	
PS 8111	Introduction to Toxicology	
PS 8403	Advanced Pharmacogenomics	
QARA 5000	Special Topics in Regulatory Affairs and Quality Assurance	
QARA 5401	Fundamentals of Pharmacology and Pharmacokinetics	
QARA 5408	Pharmacoeconomics	
QARA 5451	Statistical Quality Control	
QARA 5458	Global Biopharmaceutical Industry	
QARA 5469	Pharmaceutical Laboratory Quality Systems and Operations	
QARA 5471	Biotechnology: Bioprocess Basics	
QARA 5472	Pharmaceutical Marketing	

QARA 5473	Generic Drug Regulation (ANDAs)
QARA 5474	Process Validation
QARA 5476	Good Laboratory Practices
QARA 5477	Good Manufacturing Practices
QARA 5478	High Purity Water Systems
QARA 5479	Advanced Good Manufacturing Practices - Defining "c"
QARA 5491	Pre-Approval Inspections
QARA 5492	Production of Sterile Parenterals
QARA 5493	Sterilization Processes
QARA 5494	Quality Audit
QARA 5495	Investigational New Drug/New Drug Application Submissions
QARA 5496	Regulation of Medical Devices: Compliance
QARA 5497	Statistics for Clinical Trials
QARA 5498	Computerized System Validation
QARA 5499	Drug Dosage Forms
QARA 5502	Regulation of Medical Devices: Submissions
QARA 5505	Global Regulation of Medical Devices
QARA 5506	Environmental Law and Regulation (EPA)
QARA 5508	Good Pharmacovigilance Operations
QARA 5511	Advanced Audit Workshop of Quality Systems
QARA 5512	Microbiological Concepts in Pharmaceutical Manufacturing
QARA 5513	Active Pharmaceutical Ingredients (APIs)
QARA 5515	Biologics/Biosimilars: A Regulatory Overview
QARA 5516	Cleaning Validation
QARA 5532	Global Labeling Regulation: Principles and Practices
QARA 5533	Requirements for Product Labeling and Advertising
QARA 5534	Regulatory Aspects of Biomedical/Technical Communication
QARA 5535	Advanced Topics in Labeling Development
QARA 5536	Good Clinical Practices
QARA 5537	Clinical Trial Management
QARA 5538	Clinical Drug Safety and Pharmacovigilance
QARA 5539	Global Clinical Drug Development
QARA 5541	Pharmaceutical Packaging: Technology and Regulation
QARA 5543	Good Distribution Practices
QARA 5544	Regulatory Intelligence
QARA 5545	Post Approval Changes (PAC)
QARA 5546	Global Pharmaceutical Excipient Regulation
QARA 5547	Project Management for Clinical Trials
QARA 5571	Post-Marketing Safety Surveillance
QARA 5572	Vaccines: Regulatory Affairs and Quality Assurance Issues
QARA 5573	Pharmacoepidemiology
QARA 5574	Pharmaceutical Quality Management Systems
QARA 5575	Regulatory Sciences: Managing the Guidelines to Quality
QARA 5576	Global CMC Issues and Regulatory Dossier
QARA 5577	Global CMC Regulatory Compliance for Biopharmaceuticals and Other Biologics
QARA 5578	Benefit Risk Management and Safety Signaling of Healthcare Products
QARA 5579	Regulatory and Legal Basis of Pharmacovigilance
QARA 5591	Global Regulatory Affairs
QARA 5594	Regulation of Dietary Supplements and Functional Foods
QARA 5595	Food Law
QARA 5596	Food Labeling and Regulatory Affairs
QARA 5599	Clinical Aspects of Pharmaceutical Medicine

QARA 5601	Industry Interactions with FDA/Health Authorities
QARA 5602	
QARA 5605	Advanced Topics in Food and Drug Law
QARA 5611	Regulation of Advertising and Promotions
QARA 5612	Bioethics for Pharmaceutical Professionals
QARA 5615	Project Management for Pharmaceutical Professionals
QARA 5618	Clinical Data Management (CDM)
QARA 5622	Unit Operations
QARA 5625	Process Analytical Technology (PAT)
QARA 5627	Statistical Design of Experiments (DOE)
QARA 5629	Process Monitoring
QARA 5655	Analytical Chemistry in Pharmaceutical Laboratories
QARA 8002	Pharmaceutical Analysis
QARA 8003	Preformulation - Small Molecules
QARA 8004	Solid Dosage Forms: Small Molecules
QARA 8006	Physical Pharmacy I
QARA 8007	Applied Biopharmaceutics
Total Credit Hours	**12-15**

[1] Students who earned their MS in Regulatory Affairs and Quality Assurance from Temple University's School of Pharmacy are permitted to select any four 3-credit courses not previously completed as part of their MS curriculum. Those who earned a master's degree in Regulatory Affairs and Quality Assurance from a peer institution, as well as those holding an advanced degree in the sciences, are required to take five 3-credit courses.

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/advanced-regulatory-affairs-quality-assurance-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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Regulatory Affairs and Quality Assurance Graduate Program
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Department Contacts:

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