

Temple University School of Pharmacy Regulatory Affairs and Quality Assurance Graduate Program 425 Commerce Drive, Suite 175 • Fort Washington, PA 19034 Phone: 267-468-8560 • Fax: 267-468-8565 Email: qara@temple.edu • Web: pharmacy.temple.edu/raqa



<u>Fall 2025 – Registration Form for Online Courses</u> <u>REGISTER EARLY</u> to guarantee your spot in a course. PLEASE PRINT CLEARLY. Email completed form to <u>QARAREG@temple.edu</u>.

Continuing Students: 9-digit TUid		TUmail	
All Students: Name			
Home Address			(Check, if address change)
City	State	Zip	
Are you a Pennsylvania Resident? Yes 1	No If yes, fo	r how long? _	
Personal Phone (REQUIRED)	Work	Phone	Ext
Home Email	Work F	Email	
Name of Employer			
Title	Department		
Employer Street Address	M	ailstop (C	Check, if address change)
City	State	Zip	
Year received Undergraduate Degree Is this your first RA and QA course at Temp Yes Did you include the selection in the proof of the	le? state residency for	m? (We cannot	Master's Major process your registration without it).
IEW STUDENTS must: _1) watch the online course tutorial in Expectat _ 2) Include the Temple U State Residency form _ 3) Include a copy of your resume and photoco _ 4) Include a color photo of yourself lew students who earned all degrees abroad mu	ions of Online Stude	ents. List the ke	y word at the end and include it on page 3 uate transcripts
DrugsBasic Pharmaceutical DevelopmentI	No APRSGCI mentMedical Decadeling, Advertising uring (Biotechnology	PR Expected vicesGlobal g & Promotions gy)Validation	Pharmacovigilance Food RA and QA Generic Pharmaceutical Manufacturing Sterile Process Sciences Biologics & Biosimilars: Regulatory
Applicants' Signature:	DA D		te:
RAQA Tuition for each 3-Credit Course: University Services Fee (based on credits):			Non-Resident: \$4,743.00 \$378.00 9+ credits: \$528.00

On the pages that follow, please check which online course you wish to register for and make sure you complete and include the Proctoring pages.

Proctoring Procedures

STUDENT AGREES TO THESE PROCEDURES:

- 1. I agree to take the exam on the designated exam date. If I need to take the exam on a different date due to a **documented emergency**, I understand that I will be charged a non-refundable fee for the makeup. I agree to take the makeup exam within 1 week (no exceptions). If I do not, the grade for the exam is an automatic 0.
- 2. I will show photo ID at the start of the exam and observe appropriate conduct throughout the test.
- 3. During the exam, I will observe appropriate test procedures, which include staying in the room. Unless otherwise specified by written instructions on the exam, I will not use books, notes, cell phones, pagers, additional laptops, computers or electronic devices or the Internet (except for using the Proctorio online system).
- 4. I will abide by Temple University's code of academic honesty. Submitting false information on this form or not following RAQA policies for proctored exams is subject to disciplinary action.
- 5. I will not copy RAQA exams or any portion of RAQA exams or discuss the content of any aspect of them with students, work colleagues, or friends either verbally or through electronic means or social media (including, but not limited to email, X, Facebook, pagers, etc.) before, during, or after the exam.
- 6. I understand that I must have administrative rights for my computer to use Proctorio.
- 7. I have reviewed the Drop/Add policy for RAQA courses and understand that weeknight courses must be dropped before the third scheduled class meeting and weekend courses must be dropped before the second scheduled class meeting, **otherwise I am still financially responsible for tuition**. The Drop/Add policy is available at: https://pharmacy.temple.edu/raqa/applying/student-policies-and-services/dropadd-policy

Student Name (print)	Date
Student Daytime Phone Number	
Student Email	
Student Signature	
Course Title and Semester	
Course Instructor	

This page must be submitted with the Registration Form for Online Courses. We cannot process a registration without this page.

Before indicating your course	choice, please check one of the re	equired statements:
I have not previously taken a	Temple RAQA online course.	
		anged my computer or location that I'll the self-test of online courses before
You must check and sign the fo signatures.	ollowing statements. We will not	process registrations without
	online course, I acknowledge I have statement about proctored exam.	e read and will abide by Expectations
taking the class), I agree to comple link for the Self-Test is in that docu	te the self-test of Zoom as stipulated	computer or location where I will be in <i>Expectations of Online Students</i> . (The
cannot take the exam for a course make the exam due to a documente	d to take proctored exams on a specific on the designated date, I will select ed emergency, I agree to pay a \$25.00 per exam change. The third time the	exam change fee. For subsequent
participate in RAQA Zoom cours	(microphone) and a webcam for my ses to ensure that all students have an one headsets or webcams will be dro	enjoyable online learning experience.
I agree to keep my webcam or	n during all course meetings and use	the microphone for discussions.
	n Dave Brickett (<u>dbrick@temple.edu</u>) ekday between August 5 and Septemb	
	nline proctoring, I understand that I m Proctorio. (Many work computers ha	
		RAQA Office. If I do not have a TUmail s before the class starts, my registration
I understand that I must check	TUmail to receive the link for the firs	t and all subsequent class meetings.
Signature	Name	Date

All rights reserved. This document or portions of this document may not be reproduced or copied without written permission of the Regulatory Affairs and Quality Assurance Graduate Program of the Temple University School of Pharmacy. 5000. FDA Inspection Readiness (990) crn: 58832 (1.5 credits) (Tuesdays) 5459 Drug Development (990) crn: 17910 (Wednesdays) TENATIVE

5459. Drug Development (990) crii: 1/910 (wednesdays) TENATIVE
5459. Drug Development (991) crn: 7407 (Mondays)
5459. Drug Development (992) crn: 28608 (Saturdays)
5471. Biotechnology: Bioprocess Basics (990) crn: 58817 (Tuesdays) Undergraduate introductory Chemistry and /or Biochemistry courses. Submit resume with registration.
5474. Process Validation (990) crn: 54364 (Mondays)
5476. Good Laboratory Practices (990) crn: 58818 (Wednesdays)
5477. Good Manufacturing Practices (990) crn: 9357 (Mondays)
5477. Good Manufacturing Practices (991) crn: 34740 (Thursdays)
5492. Production of Sterile Products (990) crn: 58819 (Wednesdays)Strong science background. Submit resume with registration.
5494. Quality Audit (990) crn: 25897 (Tuesdays) I have completedGLPs (5476),GMPs (5477),Advanced GMPs (5479), orGCPs (5536) in(list semester and year).
5495. IND/NDA Submissions (990) crn: 46250 (Thursdays) I have completedDrug Development (5459) orFood and Drug Law (5592) in(lissemester and year).
5495. IND/NDA Submissions (991) crn: 58820 (Saturdays)I have completedDrug Development (5459) orFood and Drug Law (5592) in(lissemester and year).
_5496. Regulation of Medical Devices: Compliance (990) crn: 51969 (Tuesdays)
5497. Statistics for Clinical Trials (990) crn: 58838 (Tuesdays)
5502. Regulation of Medical Devices: Submissions (990) crn: 58821 (Thursdays)
5504. Patient-Focused Regulation Policy for Medical Products (990) crn: 56884 (Thursdays) I have completed Drug Development (5459) and Food and Drug Law (5592) in(list semester and year). Suggested prerequisites:Regulation of Medical Devices Submissions (5502), IND/NDA Submissions (5495)
5508. Good Pharmacovigilance Operations (990) crn: 51972 (Wednesdays)
5512. Microbiological Concepts in Pharmaceutical Manufacturing (990) crn: 58822 (Thursdays) Strong science background. Attach resume with registration form.

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5513. Active Pharmaceutical Ingredients (990) crn: 58827 (Mondays) I have completed Drug Development (5459) in (list semester and year).	
5514. Regulatory eSubmissions (990) crn: 58828 (Wednesdays)	
I have completed Drug Development (5459) or IND/NDA Submissions (5495),	
(list semester and year). Please include your resume with registration.	
5515. Biologics/Biosimilars: A Regulatory Overview (990) crn: 28574 (Wednesdays)	
I have completed Drug Development (5459). Science background required students should inclu	ıde
resume with registration.	
5536. Good Clinical Practices (990) crn: 9358 (Tuesdays)	
5536. Good Clinical Practices (991) crn: 56678 (Saturdays)	
5537. Clinical Trial Management (990) crn: 49401 (Wednesdays)	
I have completed Good Clinical Practices (5536), (list year and semester). Student	S
with clinical experience may ask to take the course but must include their resume with registration.	
5543. Good Distribution Practices (990) crn: 56677 (Wednesdays)	
I have completed GMPs (5477), (list year and semester).	
5546. Global Pharmaceutical Excipient Regulation (990) crn: 46254 (Wednesdays)	
5547. Project Management for Clinical Trials (990) crn: 58829 (Mondays)	
5548. Risk Management for Pharmaceutical and Medical Devices (990) crn: 42737 (Mondays)	
5571. Post-Marketing Safety Surveillance (990) crn: 58830 (Mondays)	
5572. Vaccines: RA and QA Issues (990) crn: 39783 (Wednesdays)	
I have completed Drug Development (5459) (list year and semester). Students at	re
also expected to have a college-level background in general biology and chemistry and some knowl	
of general microbiology and /or immunology.	
5574. Pharmaceutical Quality Management Systems (990) crn: 46256 (Mondays)	
I have completed Drug Development (5459) (list year and semester).	
5578. Risk Management and Safey Signaling of Healthcare Products (990) crn: 58831 (Thursday	vs)
5591. Global Regulatory Affairs (990) crn: 23442	
5592. Food and Drug Law (990) crn: 7202 (Wednesdays)	
5592. Food and Drug Law (991) crn: 23754 (Tuesdays)	
5595. Food Law (990) crn: 54379 (Thursdays)	
5612. Bioethics for Pharmaceutical Professionals (990) crn: 42739 (Thursdays)	
8002. Pharmaceutical Analysis (990) crn: 46377 (Mondays)	

	Strong science background. This consists of a minimum of 2 years of general chemistry, including on organic and one analytical chemistry course. RAQA students must submit their resume for permission to register.
8	003. Preformulation – Small Molecules (990) crn: 54371 (Tuesdays)
	$\underline{\hspace{0.5cm}}$ Strong science background is required. \widehat{RAQA} students must include resume with registration form.
8	005. Pharmaceutical Biotechnology (990) crn: 58834 (Thursdays)
	Strong science background required. This consists of a minimum of 2 years of general chemistry,
	including one organic and one analytical chemistry course. RAQA students must submit their resume for permission to register.