



School of Pharmacy

TEMPLE UNIVERSITY

**Regulatory Affairs and Quality Assurance
Graduate Program**

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

Spring 2025 - Registration Form for Online Courses

REGISTER EARLY to guarantee your spot in a course. PLEASE PRINT CLEARLY.

Email completed form to QARAREG@temple.edu or Fax to 267.468.8565.

Continuing Students: 9-digit TUID _____ TUmail _____

All Students: Name _____

Home Address _____ (Check, if address change) []

City _____ State _____ Zip _____

Are you a Pennsylvania Resident? Yes ___ No ___ If yes, for how long? _____

Personal Phone (REQUIRED) _____ Work Phone _____ Ext _____

Home Email _____ Work Email _____

Name of Employer _____

Title _____ Department _____

Employer Street Address _____ Mailstop _____ (Check, if address change) []

City _____ State _____ Zip _____

Year received Undergraduate Degree _____ Major _____ Year received Master's _____ Major _____

Is this your first RA and QA course at Temple?

___ Yes Did you include the state residency form? **(We cannot process your registration without it).**

___ No If no, how many courses have you completed so far: _____

NEW STUDENTS must:

1) watch the online course tutorial in Expectations of Online Students. List the key word at the end and include it on page 3.

2) Include the Temple U State Residency form

3) Include a copy of your resume and photocopies of all undergraduate and graduate transcripts

4) Include a color photo of yourself OR email the photo to garareg@temple.edu. Make sure you include your name.

New students who earned all degrees abroad must include photocopies of TOEFL/ IELTS score ___ and WES/ECE report ___

Are you: ___ Non-Matriculated ___ Matriculated (which means accepted into the MS degree program)

Do you plan to pursue the MS Degree? ___ Yes ___ No

Which degree do you plan to pursue: ___ RAQA ___ PRS ___ GCPR ___ ABMRA Expected year to graduate: _____

Which certificate do you intend to pursue?

___ Drug Development ___ Clinical Trial Management ___ Medical Devices ___ Global Pharmacovigilance

___ Food RA and QA ___ Generic Drugs ___ Basic Pharmaceutical Development ___ Labeling, Advertising & Promotions

___ Pharmaceutical Manufacturing ___ Sterile Process Manufacturing ___ Biopharmaceutical Manufacturing (Biotechnology)

___ Validation Sciences ___ Biologics & Biosimilars: Regulatory Aspects ___ Biologics & Biosimilars: Manufacturing

___ Post Master's Certificate (indicate which one : _____)

Applicant's Signature: _____ **Date:** _____

RAQA Tuition for each 3-Credit Course: PA Resident \$3,672.00 Non-Resident: \$4,566.00

University Services Fee (based on credits): 1 – 4.9 credits: \$186.00 5 – 8.9 credits: \$364.00 9 + credits: \$508.00

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. See: <https://pharmacy.temple.edu/raqa/student-policies-and-services/academic-honesty>
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 _____ 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.

Online Courses Spring 2025:

Before indicating your course choice, please check one of the required statements:

____ I have not previously taken a Temple RAQA online course.

____ I completed a Temple RAQA online course previously and have not changed my computer or location that I'll be using this coming semester. (If I have changed either, I will complete the self-test of online courses before registering).

You must check and sign the following statements. We will not process registrations without signatures.

____ By registering for any RAQA online course, **I acknowledge I have read and will abide by *Expectations of Online Students*, including the statement about proctored exams.**

____ If this is my first Temple U Online course (or if I have changed my computer or location where I will be taking the class), I agree to complete the self-test of Zoom as stipulated in *Expectations of Online Students*. (The link for the Self-Test is in that document). **The key word given at the end is: _____ (REQUIRED).**

____ I understand that I am required to take proctored exams on a specified date. **If I know in advance that I cannot take the exam for a course on the designated date, I will select another course.** If I am unable to make the exam due to a documented emergency, I agree to pay a \$25.00 exam change fee. For subsequent exams, the fee increases to \$50.00 per exam change. The third and subsequent times the charge is \$100.00.

____ **I have purchased a headset with a microphone and a webcam for my computer, which are required to participate in RAQA Zoom courses** to ensure that all students have an enjoyable online learning experience. Students who do not have microphone headsets or webcams will be dropped and not allowed to register in future semesters.

____ I agree to test my headset with Dave Brickett (dbrick@temple.edu) or Mike Doukas (mdoukas@temple.edu) on a weekday between December 3 – 20, 2024, or between January 6 – 20, 2025.

____ I agree to purchase a webcam for my computer (if one is not already built in) to participate in Online Courses.

____ If my courses use Proctorio online proctoring, I understand that I must have administrative rights to the computer I use, so I can download Proctorio. (Many work computers have firewalls which block external programs from being used.)

____ Once I obtain a TUmial account, I will forward the address to the RAQA Office. If I do not have a TUmial account or a headset with microphone or have not tested Zoom two days before the class starts, my registration may be cancelled.

I understand that I must check TUmial to receive the link for the first and all subsequent class meetings.

Signature _____ Name _____ Date _____

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COURSE SELECTION for SPRING 2025

Check the course(s) for which you wish to register (maximum of two):

_____ 5000. KENX Conference (1.5 credits earned for each conference attended). Call office for details. Also visit the KENX website (KENX.org/conferences/) to download the brochures about each conference. To be announced.

_____ Please contact me when the KENX Spring Conference schedule is available.

_____ 5459. Drug Development (990) crn: 42713 (Thursdays)

_____ 5459. Drug Development (991) crn: 28687 (Wednesdays)

_____ 5459. Drug Development (992) crn: 51026 (Saturdays)

_____ 5477. Good Manufacturing Practices (990) crn: 3439 (Thursdays)

_____ 5477. Good Manufacturing Practices (991) crn: 55325 (Tuesdays)

_____ 5493. Sterilization Processes (990) crn: 53063 (Mondays)

___ I included my resume to confirm my science background.

_____ 5494. Quality Audit (990) crn: 31574 (Tuesdays)

___ I completed ___ GLPs (5476) or ___ GMPs (5477) or ___ GCPs (5536) or ___ Advanced GMPs (5479) in _____ (list semester and year).

_____ 5495. IND/NDA Submissions (990) crn: 20675 (Mondays)

___ I completed ___ Drug Development (5459) or ___ Food & Drug Law (5592) in _____ (list semester and year).

_____ 5495. IND/NDA Submissions (991) crn: 31567 (Saturdays)

___ I completed ___ Drug Development (5459) or ___ Food & Drug Law (5592) in _____ (list semester and year).

_____ 5501. Development of Sterile Products (990) crn: 55322 (Wednesdays)

___ I included my resume, which indicates my science background (2 years of general chemistry, including one organic and one analytical course).

_____ 5503. Design Controls for Medical Devices and Combination Products (990) crn: 48475 (Tuesdays)

_____ 5505. Global Medical Device Regulation (990) crn: 51059 (Mondays)

_____ 5508. Good Pharmacovigilance Operations (990) crn: 53066 (Wednesdays)

_____ 5509. Pediatric and Orphan Drug Regulation (990) crn: 55323 (Thursdays)

_____ 5512. Microbiological Concepts in Pharmaceutical Manufacturing (990) crn: 55321 (Thursdays)

___ I attached a copy of my resume to indicate my science background.

_____ 5514. Regulatory eSubmissions (990) crn: 42720 (Wednesdays)

___ I completed ___ Drug Development (5459) in _____ (list semester and year) and ___ IND/NDA Submissions (5495) in _____ (list semester and year).

___ I did not complete 5459 and 5495 but have attached my resume for special approval to register.

_____ 5536. Good Clinical Practices (990) crn: 51052 (Mondays)

Continued on next page....

- _____ **5537. Clinical Trial Management (990) crn: 20667 (Wednesdays)**
 _____ I completed GCPs (5536 or P383) in _____ (list semester and year) OR _____ I have attached my resume which indicates industry GCP experience.
- _____ **5544. Regulatory Intelligence (990) crn: 51035 (Sundays)**
 _____ I completed Drug Development (5459) on _____ (list semester and year) **and** _____ Food & Drug Law (5592) in _____ (list semester and year).
- _____ **5572. Vaccines: RA and QA Issues (990) crn: 45613 (Thursdays)**
 _____ I completed _____ Drug Development (5459) in _____ (list semester and year).
 _____ I have included my resume which indicates my science background.
- _____ **5573. Pharmacoepidemiology (990) crn: 51062 (Mondays)**
- _____ **5574. Quality Management Systems (990) crn: 51029 (Mondays)**
 _____ I completed _____ Drug Development (5459) in _____ (list semester and year).
- _____ **5575. Regulatory Sciences: Managing the Guidelines for Quality (990) crn: 53069 (Tuesdays)**
 _____ I have included my resume which indicates my science background.
- _____ **5577. Global CMC – Biopharmaceuticals and Other Biologics (990) crn: 55328 (Tuesdays)**
- _____ **5578. Risk Management and Safety Signaling of Healthcare Products (990) crn: 53070 (Thursdays)**
 _____ I completed either _____ Clinical Drug Safety and Pharmacovigilance (5538) OR _____ Post Marketing Safety Surveillance (5571) in _____ (list semester and year).
- _____ **5591. Global Regulatory Affairs (990) crn: 20671 (Mondays)**
 _____ I completed _____ Drug Development (5459) OR _____ Food and Drug Law (5592) in _____ (semester and year).
- _____ **5592. Food and Drug Law (990) crn: 9424 (Wednesdays)**
- _____ **5592. Food and Drug Law (991) crn: 25838 (Tuesdays)**
- _____ **5594. Regulation of Dietary Supplements and Functional Food (990) 42729 (Wednesdays)**
- _____ **5597. Food Good Manufacturing Practices (990) crn: 51045 (Mondays)**
- _____ **5611. Regulation of Advertising and Promotions (990) crn: 51038 (Tuesdays)**
- _____ **5612. Bioethics for Pharmaceutical Professionals (990) crn: 28699 (Thursdays).**
- _____ **5615. Project Management for Pharmaceutical Professionals (990) crn: 31575 (Mondays)**
 _____ I have completed at least four courses in the RAQA graduate program by Spring 2025.
- _____ **5650. Critical Analysis of Media Coverage of the Pharmaceutical Industry (990) crn: 45587 (Tuesdays)**
- _____ **5650. Regulation of Artificial Intelligence & Machine Learning (AI/ML) Medical Devices (991) crn: 55327 (ONLINE) (Tuesdays)**
 _____ I completed _____ Drug Development (5459) OR _____ Food & Drug Law (5592) in _____ (list semester and year).

Pharmaceutical Science Courses: Science Background Required
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- _____ **8004. Solid Dosage Forms – Small Molecules (990) crn: 55324 (Wednesdays)**
 _____ I included my resume, which indicates my science background (2 years of general chemistry, including one organic and one analytical course).
- _____ **8005. Pharmaceutical Biotechnology (990) crn: 51044 (Thursdays)**
 _____ I included my resume, which indicates my science background (2 years of general chemistry, including one organic and one analytical course).