



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

Summer 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 qarareg@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 credits: \$116.00 5-8 credits: \$193.00 9+ credits: \$256.00

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.*

**Online Courses Summer 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 time the charge is \$100.00. After that, the fee becomes \$125.00.

\_\_\_ **I have purchased a headset (with 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 keep my webcam on during all course meetings and use the microphone for discussions.

\_\_\_ I agree to test my headset with Dave Brickett (dbrick@temple.edu) or Jessie Chen (Jessie.chen@temple.edu) on a weekday between April 15 and May 17, 2025.

\_\_\_ 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 \_\_\_\_\_

## COURSE SELECTION for SUMMER 2025

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

\_\_\_ 5000. FDA Inspection Readiness (111) crn: 13923 1.5 credits (Tuesdays)

\_\_\_ 5000. Critical Case Study: Analysis of Mainstream Pharmaceutical Literature (112) crn: 14468 (1.5 credits) (Thursdays)

\_\_\_ 5459. Drug Development (990) crn: 2539 (Wednesdays)

\_\_\_ 5459. Drug Development (991) crn: 6040 (WEEKEND COURSE - Sundays)

\_\_\_ 5472. Pharmaceutical Marketing (990) crn: 13919 (Wednesdays)

\_\_\_ 5477. Good Manufacturing Practices (990) crn: 4136 (Mondays)

\_\_\_ 5478. High Purity Water Systems (990) crn: 12414 (Tuesdays)

\_\_\_ I have previously completed a college-level chemistry course.

\_\_\_ 5479. Advanced Good Manufacturing Practices – Defining ‘c’ (990) crn: 7676 (Wednesdays)

\_\_\_ I completed Good Manufacturing Practices (5477) in \_\_\_\_\_ (list semester and year) OR \_\_\_ I have attached my resume which indicates at least 5 years of GMP experience.

\_\_\_ 5494. Quality Audit (990) crn: 4137 (Wednesdays)

\_\_\_ 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: 13915 (WEEKEND COURSE - Saturdays)

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

\_\_\_ 5496. Regulation of Medical Devices: Compliance (990) crn: 14469 (Thursdays)

\_\_\_ 5514. Regulatory eSubmissions (990) crn: 13918 (Tuesdays)

\_\_\_ I completed \_\_\_ Drug Development (5459) in \_\_\_\_\_ (list semester and year) OR \_\_\_ 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.

\_\_\_ 5515. Biologics/Biosimilars: A Regulatory Overview (990) crn: 14470 (Wednesdays)

\_\_\_ I have attached a copy of my resume which indicates an undergraduate or graduate degree in science.

\_\_\_ I completed Drug Development (5459) in \_\_\_\_\_ (list semester and year).

\_\_\_ 5536. Good Clinical Practices (990) crn: 3423 (Mondays)

\_\_\_ 5537. Clinical Trial Management (990) crn: 5872 (Tuesdays)

\_\_\_ I completed GCPs (5536 or P383) in \_\_\_\_\_ (list semester and year) OR \_\_\_ I have attached my resume which indicates industry GCP experience.

\_\_\_ 5538. Clinical Drug Safety and Pharmacovigilance (990) crn: 13333 (Thursdays)

\_\_\_ 5543. Good Distribution Practices (990) crn: 14471 (Wednesdays)

\_\_\_ I completed Good Manufacturing Practices (5477) in \_\_\_\_\_ (list semester and year) OR \_\_\_ I have attached my resume which indicates several years of industry GMP experience. ).

\_\_\_ 5545. Post-Approval Changes (PAC) (990) crn: 14472 (Mondays)

\_\_\_ 5591. Global Regulatory Affairs (990) crn: 1733 (Thursdays)

\_\_\_ I completed \_\_\_ Drug Development (5459) OR \_\_\_ Food and Drug Law (5592) in \_\_\_\_\_ (list semester and year).

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\_\_\_\_\_ 5592. Food and Drug Law (990) crn: 1734 (Tuesdays)

\_\_\_\_\_ 5596. Food Labeling and Regulatory Affairs (990) crn: 13921 (Thursdays)

\_\_\_\_\_ 5612. Bioethics for Pharmaceutical Professionals (990) crn: 14473 (WEEKENDS - SATURDAYS)

\_\_\_\_\_ 5650. Investigations in Industry (Internal, Quality and Criminal) (990) crn: 13922 (Mondays)  
\_\_\_\_\_ I completed Good Manufacturing Practices (5477) in \_\_\_\_\_ (list semester and year).

**ON-CAMPUS Course with ONLINE Sessions: If you are interested in the course below but can't attend on-campus sessions, please email [QARAREG@temple.edu](mailto:QARAREG@temple.edu):**

\_\_\_\_\_ 5650 Pharmaceutical Regulatory Leadership (101) crn: 13914 (Wednesdays)  
\_\_\_\_\_ I have completed \_\_\_\_\_ Drug Development (5459) in \_\_\_\_\_ (list semester and year OR \_\_\_\_\_ Food and Drug Law (5592) in \_\_\_\_\_ (list semester and year).