



# 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 2024 - Registration Form for Online Courses

**REGISTER EARLY to Guarantee Your Spot in a Course. PLEASE PRINT CLEARLY.**  
Email completed form to [QARAREG@temple.edu](mailto:QARAREG@temple.edu) or Fax to 267.468.8565.

**Continuing Students:** 9-digit TUID \_\_\_\_\_ TUmial \_\_\_\_\_

**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. Jot down 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](mailto: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 \$3,558.00 Non-Resident: \$4,425.00

**University Services Fee (based on credits):** 1 – 4.9 credits: \$111.00 5 – 8.9 credits: \$184.00 9 + credits: \$244.00

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 agree to pay a \$15.00 fee for each exam using RPNOW. The fee is paid to RPNOW via credit card at the start of the exam.
3. I will show photo ID at the start of the exam and observe appropriate conduct throughout the test.
4. 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, a cell phone, pagers, electronic devices, laptops or computers or the Internet (except for using the RPNOW online system).
5. 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>
6. 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, Twitter, Facebook, pagers, etc.) before, during, or after the exam.
7. **If my course uses RPNOW, I understand that I must have administrative rights for my computer** (which means I can download programs to the computer).
8. 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 Summer 2024:**

**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 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.

\_\_\_\_ **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 enjoy a great 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 April 1, 2024 and May 23, 2024.

\_\_\_\_ 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 RPNOW online proctoring, I understand that I must have administrative rights to the computer I use, so I can download RPNOW. (Many work computers have firewalls which block external programs from being used.)

\_\_\_\_ Once I obtain a TUMail account, I will forward the address to the RAQA Office. If I do not have a TUMail 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 TUMail to receive the link for the first and all subsequent class meetings.**

Signature \_\_\_\_\_ Name \_\_\_\_\_ Date \_\_\_\_\_

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**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 to download the brochures about each conference.**

\_\_\_ *I understand that I must pay a \$15.00 fee to RPNOW for online proctoring. I wish to register for:*

- 1) \_\_\_ **Validation University – April 23 - 25, San Diego, CA, section 007 crn: 11575**
- 2) \_\_\_ **Analytical Method Development – June 4 – 5, Philadelphia, PA, section 008, crn: 12423**
- 3) \_\_\_ **Cleanroom Contamination/Environmental Monitoring – Aug 6-8, section 009, crn: 12567**

**NEW COURSE:**

\_\_\_ **5650. Patient Focused Regulatory Policy for Medical Products (990) crn: 13922 (Thursdays)**

\_\_\_ *I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.*

\_\_\_ *I have completed Drug Development (5459) in \_\_\_\_\_ (list semester and year) as well as Food and Drug Law (5592) \_\_\_\_\_ (list semester and year).*

\_\_\_ **5401. Fundamentals of Pharmacology and Pharmacokinetics (990) crn: 13329 (Wednesdays)**

\_\_\_ *I have a background in science.*

\_\_\_ *I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.*

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

\_\_\_ *I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.*

\_\_\_ **5459. Drug Development (991) crn: 6040 (Wednesdays)**

\_\_\_ *I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.*

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

\_\_\_ *I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.*

\_\_\_ **5476. Good Laboratory Practices (990) crn: 13938 (Wednesdays)**

\_\_\_ *I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.*

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

\_\_\_ *I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.*

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

\_\_\_ *I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.*

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

\_\_\_ **5479. Advanced GMPs-Defining “c” (990) crn: 7676 (Mondays)**

\_\_\_ *I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.*

\_\_\_ *I have completed GMPs (5477) in \_\_\_\_\_ (list semester and year)*

OR \_\_\_ *I have included a copy of my resume indicating my GMP experience.*

\_\_\_ **5494. Quality Audit (991) crn: 4137 (Tuesdays)**

\_\_\_ *I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.*

\_\_\_ *I have 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 (Thursdays)**

\_\_\_ *I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.*

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

\_\_\_ **5495. IND/NDA Submissions (991) crn: 13939 (Saturdays)**

\_\_\_ *I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.*

\_\_\_ *I completed \_\_\_Drug Development (5459) or \_\_\_Food and Drug Law (5592) in \_\_\_\_\_ (list semester and year).*

*Continued on next page....*

- \_\_\_\_\_ **5501. Development of Sterile Products (990) crn: 13916 (Thursdays)**  
 \_\_\_\_\_ I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.  
 \_\_\_\_\_ I have a science background, which includes 2 years of general chemistry, including one organic and one analytical course..
- \_\_\_\_\_ **5502. Regulation of Medical Devices: Submissions (990) crn: 13332 (Thursdays)**  
 \_\_\_\_\_ I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.
- \_\_\_\_\_ **5513. Active Pharmaceutical Ingredients (990) crn: 13917 (Thursdays)**  
 \_\_\_\_\_ I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.  
 \_\_\_\_\_ I completed Drug Development (5459) in \_\_\_\_\_ (list semester and year).
- \_\_\_\_\_ **5514. Regulatory eSubmissions (990) crn: 13918 (Wednesdays)**  
 \_\_\_\_\_ I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.  
 \_\_\_\_\_ I have completed \_\_\_\_\_ Drug Development (5459) in \_\_\_\_\_ (list semester and year).
- \_\_\_\_\_ **5536. Good Clinical Practices (990) crn: 3423 (Mondays)**  
 \_\_\_\_\_ I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.
- \_\_\_\_\_ **5537. Clinical Trial Management (990) crn: 5872 (Tuesdays)**  
 \_\_\_\_\_ I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.  
 \_\_\_\_\_ I completed GCP (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)**  
 \_\_\_\_\_ I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.  
 \_\_\_\_\_ I have completed GCPs (RAQA 5536 or P383) in \_\_\_\_\_ list semester and year OR  
 \_\_\_\_\_ I have industry GCP experience and have attached my resume.
- \_\_\_\_\_ **5547. Project Management for Clinical Trials (990) crn: 11572 (Mondays)**  
 \_\_\_\_\_ I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.
- \_\_\_\_\_ **5576. Global CMC Issues and Regulatory Dossiers (990) crn: 13920 (Mondays)**  
 \_\_\_\_\_ I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.
- \_\_\_\_\_ **5591. Global Regulatory Affairs (990) crn: 1733 (Tuesdays)**  
 \_\_\_\_\_ I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.
- \_\_\_\_\_ **5592. Food and Drug Law (990) crn: 1734 (Sundays)**  
 \_\_\_\_\_ I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.
- \_\_\_\_\_ **5596. Food Labeling and Regulatory Affairs (990) crn: 13921 (Mondays)**  
 \_\_\_\_\_ I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.
- \_\_\_\_\_ **5650. Patient Focused Regulatory Policy for Medical Products (990) crn: 13922 (Thursdays)**  
 \_\_\_\_\_ I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.  
 \_\_\_\_\_ I have completed Drug Development (5459) in \_\_\_\_\_ (list semester and year) as well as Food and Drug Law (5592) \_\_\_\_\_ (list semester and year).

**SECOND SUMMER SEMESTER**

**NEW COURSE:**

- \_\_\_\_\_ **5000. Critical Case Study Analysis of Mainstream Pharmaceutical Literatures (111) crn: 13923 (Tuesdays).**