



# 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 2022 - Registration Form for Online Courses

**REGISTER EARLY TO GUARANTEE YOUR SPOT IN A CLASS. PLEASE PRINT CLEARLY.**

Complete and email this entire form to qarareg@temple.edu (or fax to 267.468.8565). New students: 1) Watch the online course tutorial. Include the password at the end on page 3 of this form. 2) Include copies of undergraduate & graduate transcripts, 3) Include a resume, 4) Include the Temple U residency form, 5) Include a photo.

Students who earned degrees abroad must also include copies of TOEFL/IELTS scores & WES/ECE reports.

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

**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 include the State Residency form and the following documents**

\_\_\_ copy of CV/resume **and** \_\_\_ photocopies of all undergraduate and graduate transcripts **and** \_\_\_ color photo  
**(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 one: RAQA \_\_\_ PRS \_\_\_ GCPR \_\_\_ 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 (NEW!)

\_\_\_ Post Master's Certificate (indicate which one : \_\_\_\_\_)

**Applicant's Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**RAQA Tuition for each 3-Credit Course:** PA Resident \$3,297.00 Non-Resident: \$4,176.00

**University Services Fee (based on credits):** 1 – 4.9 credits: \$163.00 5 – 8.9 credits: \$319.00 9 + credits: \$445.00

**Drop Policy:** To receive a complete refund, submit the Course Withdrawal Form (see Forms on the RAQA website) **BEFORE** the second class (weekend courses) or **BEFORE** the third class (weeknight courses).

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 will complete, sign, and return the Proctoring Agreement form **by the deadline given by the RAQA Office**. I will also sign and return the Honor Statement provided by the RAQA Office by the stated deadline.
2. 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 will be charged a non-refundable fee of at least \$25 to take a makeup exam. 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.
3. I understand that an exam using RPNOW is an accepted proctor but that I must pay a \$15.00 fee to use RPNOW.
4. If my course is not using RPNOW, I will identify an acceptable proctor and pay applicable fees. Acceptable proctors are professional testing sites (Sylvan Learning, Huntingdon Learning Centers, etc.) or library proctors (most provide free proctoring). The RAQA Office must approve proctors. No friends, colleagues, relatives, work subordinates, or current RAQA students may be used. The RAQA Office provides free proctoring at its Ft Washington site.
5. I will select an acceptable test location. These include a library, professional testing site, or a college campus. Residences and home offices are not allowed (unless your course is using PSI Remote Proctor Now).
5. I will show photo ID at the start of the exam and observe appropriate conduct throughout the test.
6. 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).
7. 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: [www.temple.edu/pharmacy\\_qara/plagiarism.htm](http://www.temple.edu/pharmacy_qara/plagiarism.htm).
8. I will not discuss any content or aspect of the exam with students, work colleagues, or friends either verbally or through electronic means or social media (email, Twitter, Facebook, pagers, etc.) before, during, or after the exam.
9. **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). I also understand that I must pay a \$15.00 fee directly to RPNOW.

**Students who do not submit a signed Proctoring Agreement or Honor Statement will receive a zero for the exam.**

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 2022:**

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

\_\_\_ I have not previously taken a Temple RAQA online course. I have administrative rights to my computer (which means I can download programs).

\_\_\_ 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 Password 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. In subsequent semesters, the fee increases to \$35.00 per exam change. The third time the charge is \$50.00.

\_\_\_ **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) between January 3, 2022 – January 19, 2022.

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

\_\_\_ If my courses uses RPNOW online proctoring, I understand that I must have administrative rights to the computer I use. This means that I have permission to download programs (such as RPNOW). (Many work computers have firewalls which prevent 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 \_\_\_\_\_ Print Name \_\_\_\_\_

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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.**

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

*I wish to register for*

- 1)  Cleanroom Qualification: Disinfection & Contamination Control, Feb 21-23, Virtual and In-Person (Philadelphia)
- 2)  Validation: Process Validation, Equipment & Utilities Qualification, Mar 28 – 30, Virtual and In-Person (San Diego)
- 3)  Product Complaints & Adverse Events: Apr 25 – 27, Virtual and In-Person (Philadelphia)

*I plan to attend the conference(s)  in person OR  virtually.*

**5451. Statistical Quality Control (990) crn: 48469 (Sundays)**

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

**5459. Drug Development (990) crn: 42713 (Mondays)**

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

**5459. Drug Development (991) crn: 28687 (Tuesdays)**

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

**5459. Drug Development (993) crn: 36993 (Wednesdays)**

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

**5468. Validation of FUE (Facilities, Utilities and Equipment) (990) crn: 42717 (Thursdays)**

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

*I have completed Good Manufacturing Practices (5477) in \_\_\_\_\_ (semester and year) or  I have included my resume, which shows experience in industry manufacturing.*

**5471. Biotechnology: Bioprocess Basics (990) crn: 28688 (Tuesdays)**

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

*I have completed undergraduate chemistry or biochemistry courses as part of my undergraduate degree.*

**5473. Generic Drug Regulation (990) crn: 48470 (Wednesdays)**

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

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

**5476. Good Laboratory Practices (990) crn: 45575 (Wednesdays)**

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

**5477. Good Manufacturing Practices (990) crn: 3439 (Mondays)**

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

**5477. Good Manufacturing Practices (991) crn: 39719 (Sundays)**

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

**5477. Good Manufacturing Practices (992) crn: 45578 (Tuesdays)**

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

**5478. High Purity Water Systems (990) crn: 48471 (Tuesdays)**

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

*I have completed a college-level chemistry course as part of my undergraduate degree.*

**5491. Pre-Approval Inspections (990) crn: 48472 (Tuesdays)**

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

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

*I have completed Good Manufacturing Practices (5477) in \_\_\_\_\_ list semester and year.*

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- \_\_\_ **5494. Quality Audit (990) crn: 31574 (Thursdays)**  
 \_\_\_ I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.  
 \_\_\_ I have completed \_\_\_ GLPs (5476), \_\_\_ GMP (5477), \_\_\_ Advanced GMPs (5479), or \_\_\_ GCPs (5536) in \_\_\_\_\_ (list semester and year).
- \_\_\_ **5494. Quality Audit (991) crn: 39720 (Wednesdays)**  
 \_\_\_ I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.  
 \_\_\_ I have completed \_\_\_ GLPs (5476), \_\_\_ GMP (5477), \_\_\_ Advanced GMPs (5479), or \_\_\_ GCPs (5536) in \_\_\_\_\_ (list semester and year).
- \_\_\_ **5495. IND/NDA Submissions (990) crn: 20675 (Tuesdays)**  
 \_\_\_ I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.  
 \_\_\_ I have completed \_\_\_ Drug Development (5459) in \_\_\_\_\_ (list semester and year) OR \_\_\_ I have completed Food & Drug Law (5592) in \_\_\_\_\_ (list semester & year).
- \_\_\_ **5495. IND/NDA Submissions (991) crn: 31567 (Saturdays)**  
 \_\_\_ I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.  
 \_\_\_ I have completed \_\_\_ Drug Development (5459) in \_\_\_\_\_ (list semester and year) OR \_\_\_ I have completed Food & Drug Law (5592) in \_\_\_\_\_ (list semester & year).
- \_\_\_ **5496. Regulation of Medical Devices: Compliance (990) crn: 39722 (Wednesdays)**  
 \_\_\_ I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.
- \_\_\_ **5497. Statistics for Clinical Trials (990) crn: 48473 (Thursdays)**  
 \_\_\_ I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.
- \_\_\_ **5498. Computerized Systems Validation (990) crn: 48474 (Tuesdays and Thursdays DAYTIME)**  
 \_\_\_ I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.
- \_\_\_ **5503. Design Controls for Medical Devices and Combination Products (990) crn: 48475 (Thursdays)**  
 \_\_\_ I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.
- \_\_\_ **5508. Good Pharmacovigilance Operations (990) crn: 48477 (Tuesdays)**  
 \_\_\_ I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.  
 \_\_\_ I have completed either Clinical Drug Safety and Pharmacovigilance (5548) or Post Marketing Safety Surveillance (5579) in \_\_\_\_\_ (list semester and year).
- \_\_\_ **5532. Global Labeling Regulation: Principles and Practices (990) crn: 48478 (Tuesdays)**  
 \_\_\_ I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.  
 \_\_\_ I have completed Drug Development (5459) or have included my resume to indicate my industry experience.
- \_\_\_ **5536. Good Clinical Practices (991) crn: 42932 (Saturdays)**  
 \_\_\_ I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.
- \_\_\_ **5537. Clinical Trial Management (990) crn: 20667 (Mondays)**  
 \_\_\_ I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.  
 \_\_\_ I completed Good Clinical Practices (5536) in \_\_\_\_\_ (list semester and year) OR \_\_\_ I have attached my resume which indicates industry GCP experience.
- \_\_\_ **5538. Clinical Drug Safety and Pharmacovigilance (990) crn: 39708 (Mondays and Wednesdays DAYTIME)**  
 \_\_\_ I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.  
 \_\_\_ I have completed Good Clinical Practices (5546) in \_\_\_\_\_ list semester and year OR  
 \_\_\_ I have GCP experience in industry (include resume).

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- \_\_\_\_\_ **5539. Global Clinical Drug Development (990) crn: 48479 (Mondays)**  
 \_\_\_\_\_ *I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.*
- \_\_\_\_\_ **5571. Post Marketing Safety Surveillance (990) crn: 42724 (Mondays)**  
 \_\_\_\_\_ *I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.*
- \_\_\_\_\_ **5572. Vaccines: RA and QA Issues (990) crn: 45613 (Wednesdays)**  
 \_\_\_\_\_ *I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.*  
 \_\_\_\_\_ *I completed \_\_\_ Drug Development (5459) in \_\_\_\_\_ (list semester and year).*  
 \_\_\_\_\_ *I completed an undergraduate course in general biology and chemistry.*
- \_\_\_\_\_ **5578. Risk Management and Safety Signaling in Healthcare Products (990) crn: 45583 (Thursdays)**  
 \_\_\_\_\_ *I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.*  
 \_\_\_\_\_ *I have completed at least one RAQA course in Pharmacovigilance \_\_\_\_\_ (title and semester) OR*  
 \_\_\_\_\_ *I have attached my resume indicating appropriate industry experience in Pharmacovigilance.*
- \_\_\_\_\_ **5591. Global Regulatory Affairs (990) crn: 20671 (Mondays)**  
 \_\_\_\_\_ *I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.*  
 \_\_\_\_\_ *I have completed \_\_\_ Drug Development (5459) in \_\_\_\_\_ (list semester and year) **OR***  
 \_\_\_\_\_ *Food and Drug Law (5592) in \_\_\_\_\_ (list semester and year).*
- \_\_\_\_\_ **5591. Global Regulatory Affairs (991) crn: 48480 (Saturdays)**  
 \_\_\_\_\_ *I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.*  
 \_\_\_\_\_ *I have completed \_\_\_ Drug Development (5459) in \_\_\_\_\_ (list semester and year) **OR***  
 \_\_\_\_\_ *Food and Drug Law (5592) in \_\_\_\_\_ (list semester and year).*
- \_\_\_\_\_ **5592. Food and Drug Law (990) crn: 9424 (Wednesdays)**  
 \_\_\_\_\_ *I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.*
- \_\_\_\_\_ **5592. Food and Drug Law (991) crn: 25838 (Tuesdays)**  
 \_\_\_\_\_ *I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.*
- \_\_\_\_\_ **5592. Food and Drug Law (993) crn: 42728 (Thursdays)**  
 \_\_\_\_\_ *I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.*
- \_\_\_\_\_ **5596. Food Labeling and Regulatory Affairs (990) crn: 39749 (Thursdays)**  
 \_\_\_\_\_ *I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.*
- \_\_\_\_\_ **5601. Industry Interactions with FDA and Health Authorities (990) crn: 42730 (Saturdays)**  
 \_\_\_\_\_ *I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.*
- \_\_\_\_\_ **5612. Bioethics for Pharmaceutical Professionals (990) crn: 28699 (Thursdays)**  
 \_\_\_\_\_ *I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.*
- \_\_\_\_\_ **5615. Project Management for Pharmaceutical Professionals (990) crn: 31575 (Mondays)**  
 \_\_\_\_\_ *I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.*  
 \_\_\_\_\_ *I have completed **at least four courses** in the RAQA graduate program, including Drug Development (5459) in \_\_\_\_\_ (list semester and year) and Food and Drug Law (5592) in \_\_\_\_\_ list semester and year.*
- \_\_\_\_\_ **5650. Special Topics: Accelerated Regulatory Pathways: From Fast Track to Reliance (990) crn: 45587 (Thursdays)**  
 \_\_\_\_\_ *I have completed Drug Development (5459) in \_\_\_\_\_ (list semester and year).*
- \_\_\_\_\_ **5650. Special Topics: Critical Analysis of Media Coverage of the Pharmaceutical Industry (991) crn: 48481 (Mondays)**  
 \_\_\_\_\_ *I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.*

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**Pharmaceutical Science Courses – Strong Science background required**

\_\_\_\_\_ **8003. Pharmaceutical Manufacturing I: Preformulation/Formulation (990) crn: 48482 (Tuesdays)**

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

\_\_\_\_\_ *I have included a resume which indicates that I have a science degree.*

\_\_\_\_\_ **8005. Pharmaceutical Biotechnology (990) crn: 45589 (Saturdays)**

\_\_\_\_\_ *I have included a resume which indicates that I have a science degree.*

\_\_\_\_\_ **8006. Physical Pharmacy I (990) crn: 48483 (Thursdays)**

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

\_\_\_\_\_ *I have included a resume which indicates that I have a science degree and have taken a physical chemistry course.*

\_\_\_\_\_ **8007. Applied Biopharmaceutics (990) crn: 45733 (Mondays)**

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

\_\_\_\_\_ *I have included a resume which indicates that I have a science degree.*