



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 2021 - 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 _____ 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 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 ___ Pharmaceutical Dev ___ 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 \$3,216.00 Non-Resident: \$4,074.00

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, you must 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 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 testing site professionals (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 taking a proctored test is subject to disciplinary action. See: 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 PRNOW.

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 2021:

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 Dec 3 and 20, 2020, OR between Jan 3 and 18, 2021.

___ 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):

___ **5401. Fundamentals of Pharmacology and Pharmacokinetics (990) crn: 39751 (Wednesdays)**

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

___ *I have included my resume, which indicates a strong science background.*

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- _____ **5459. Drug Development (990) crn: 42713 (Thursdays)**
 ___ I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.
- _____ **5459. Drug Development (991) crn: 28687 (Mondays)**
 ___ I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.
- _____ **5459. Drug Development (992) crn: 28931 (Tuesdays)**
 ___ I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.
- _____ **5459. Drug Development (993) crn: 36993 (Saturdays)**
 ___ 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 completed Good Manufacturing Practices (5477) in _____ (list semester and year), OR ___ I have attached my resume which indicates manufacturing experience.
- _____ **5471. Biotechnology: Bioprocess Basics (990) crn: 28688 (Mondays) - CLOSED (waitlist only)**
 ___ I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.
 ___ I have attached my resume, which indicates that I am familiar with undergraduate-level, introductory courses in biochemistry and chemistry.
- _____ **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) - CLOSED (waitlist only)**
 ___ 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.
- _____ **5493. Sterilization Processes (990) crn: 39717 (Thursdays)**
 ___ I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.
 ___ I have attached my resume which shows an undergraduate or graduate degree in science, engineering, or related field.
- _____ **5494. Quality Audit (990) crn: 31574 (Thursdays) - CLOSED (waitlist only)**
 ___ 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) - CLOSED (waitlist only)**
 ___ 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).

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- _____ **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) or ___ Food & Drug Law (5592) in _____ (list semester & year).
- _____ **5496. Regulation of Medical Devices: Compliance (990) crn: 39722 (Thursdays) - CLOSED (waitlist only)**
 _____ I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.
- _____ **5505. Global Medical Device Regulation (990) crn: 42719 (Tuesdays) - CLOSED (waitlist only)**
 _____ I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.
- _____ **5513. Active Pharmaceutical Ingredients (APIs) (990) crn: 42722 (Wednesdays)**
 _____ I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.
 _____ I have completed Drug Development in _____ (list semester and year).
- _____ **5514. Regulatory eSubmissions (990) crn: 42720 (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) and ___ IND/NDA Submissions (5495) in _____ (list semester and year) OR ___ I included my resume.
- _____ **5533. Requirements for Product Labeling and Advertising (990) crn: 45579 (Tuesdays) - CLOSED (waitlist only)**
 _____ I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.
 _____ I have completed Food and Drug Law (5592) in _____ (list semester and year).
- _____ **5536. Good Clinical Practices (990) crn: 23276 (Wednesdays)**
 _____ I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.
- _____ **5536. Good Clinical Practices (991) crn: 42932 (Mondays)**
 _____ I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.
- _____ **5537. Clinical Trial Management (990) crn: 20667 (Tuesdays)**
 _____ 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).
- _____ **5538. Clinical Drug Safety and Pharmacovigilance (990) crn: 39708 (Tuesdays)**
 _____ I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.
 _____ I have completed Good Clinical Practices (5536) OR ___ I have attached my resume for permission to take this course.
- _____ **5571. Post-Marketing Safety Surveillance (990) crn: 42724 (Mondays & Wednesdays) – 7 week format**
 _____ I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.
- _____ **5572. Vaccines: RA and QA Issues (990) 45613 (Thursdays)**
 _____ 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).
- _____ **5574. Pharmaceutical Quality Management Systems (990) crn: 45581 (Tuesdays) - CLOSED (waitlist only)**
 _____ 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.
- _____ **5576. Global CMC Issues and Regulatory Dossiers (990) crn: 45590 (Wednesdays)**
 _____ I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.

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- _____ **5578. Risk Management and Safety Signaling of 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 Post Marketing Safety Surveillance (5571) in _____ (list semester and year) **OR***
 _____ *I have completed Clinical Drug Safety and Pharmacovigilance (5538) in _____ (list semester and*
 year).
- _____ **5591. Global Regulatory Affairs (990) crn: 20671 (Mondays) - CLOSED (waitlist only)**
 _____ *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) - CLOSED (waitlist only)**
 _____ *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.*
- _____ **5592. Food and Drug Law (991) crn: 25838 (Tuesdays) - CLOSED (waitlist only)**
 _____ *I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.*
- _____ **5594. Regulation of Dietary Supplements and Functional Food (990) crn: 42729 (Wednesdays)**
 _____ *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 (Mondays) - CLOSED (waitlist only)**
 _____ *I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.*
- _____ **5612. Bioethics for Pharmaceutical Professionals (990) crn: 28699 (Saturdays)**
 _____ *I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.*
- _____ **5612. Bioethics for Pharmaceutical Professionals (991) crn: 45584 (Wednesdays)**
 _____ *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 (Thursdays) - CLOSED (waitlist only)**
 _____ *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) and*
 Food and Drug Law (5592).
- _____ **5627. Statistical Design of Experiments (DOE) (990) crn: 45585 (Sundays)**
 _____ *I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.*
 _____ *I read the prerequisite of familiarity with math and understand that Minitab will be used in the course.*
- _____ **5650. Special Topics: Pediatric and Orphan Drug Regulation (990) crn: 45587 (Tuesdays)**
 _____ *I understand that I must pay a \$15.00 fee to PSI RPNOW or online proctoring.*
 _____ *I completed Drug Development in _____ (list semester and year), OR my resume is attached.*
- _____ **8004. Pharmaceutical Manufacturing II: Solid Dosage Forms (990) crn: 45588 (Mondays)**
 _____ *I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.*
 _____ *I have a science degree and understand this is required course in the Pharmaceutical Regulatory Science program.*
- _____ **8005. Pharmaceutical Biotechnology (990) crn: 45589 (Saturdays)**
 _____ *I have a science degree and understand that this is a required course in the Pharmaceutical Regulatory*
 Science program, and _____ *I have included my resume to take this course.*
- _____ **8007. Applied Biopharmaceutics 990) crn: 45733 (Wednesdays)**
 _____ *I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.*
 _____ *I have a science degree and understand that this is an elective course in the Pharmaceutical Regulatory Science*
 program, and _____ *I have included my resume to take this course.*