



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

FALL 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 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 agree to pay a \$15.00 fee to RPNOW 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, cell phones, pagers, electronic devices, additional 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, X, 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 Fall 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 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 August 12, 2024 and September 7, 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 (KENX.org/conferences/) 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) **Medical Device Validation – Sept 17 - 19, Chicago, IL**, section 007 crn: 46338 (in-person only)
- 2) **GMP U – Oct 22-24**, RTP Research Triangle, NC, section 008, crn: 54373 (in-person only)
- 3) **CSV and CSA – Dec 10-12**, Washington, DC, section 009, crn: 54387 (in-person only)

 5459. Drug Development (990) crn: 17910 (Thursdays)

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

 5459. Drug Development (991) crn: 7407 (Wednesdays)

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

 5459. Drug Development (992) crn: 28608 (Saturdays)

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

 5474. Process Validation (990) crn: 54364 (Thursdays)

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

 I included my resume, which indicates a BS or MS in Biology, Chemistry, Engineering, Pharmacy or other science background.

 I have a basic understanding of pharmaceutical manufacturing practices.

 5477. Good Manufacturing Practices (990) crn: 9357 (Mondays)

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

 5477. Good Manufacturing Practices (991) crn: 34740 (Thursdays)

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

 5494. Quality Audit (990) crn: 25897 (Tuesdays)

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

 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: 46250 (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).

 5496. Regulation of Medical Devices: Compliance (990) crn: 51969 (Wednesdays)

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

 5497. Statistics for Clinical Trials (990) crn: 54366 (Tuesdays)

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

 5498. Computerized Systems Validation (990) crn: 54367 (Tuesdays/Thursdays – DAYTIME)

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

NEW COURSE:

 5504. Patient Focused Regulatory Policy for Medical Products (990) crn: (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) and Food and Drug Law (5592) _____ (list semester and year).

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- _____ **5508. Good Pharmacovigilance Operations (990) crn: 51972 (Mondays)**
 _____ I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.
 _____ I completed either _____ Clinical Drug Safety and Pharmacovigilance (5538) OR _____ Post Marketing Safety Surveillance (5571) in _____ (list semester and year).
- _____ **5515. Biologics/Biosimilars: A Regulatory Overview (990) crn: 28574 (Wednesdays)**
 _____ 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).
 _____ I included a copy of my resume which indicates my science background.
- _____ **5533. Requirements for Product Labeling and Advertising (990) crn: 51974 (Tuesdays)**
 _____ I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.
 _____ I completed _____ Food and Drug Law (5592) in _____ list semester and year).
- _____ **5534. Regulatory Aspects of Biomedical/Technical Communication (990) crn: 56688 (Wednesdays)**
 _____ 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).
- _____ **5536. Good Clinical Practices (990) crn: 9358 (Tuesdays)**
 _____ I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.
- _____ **5536. Good Clinical Practices (991) crn: 56678 (Saturdays)**
 _____ I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.
- _____ **5537. Clinical Trial Management (990) crn: 49401 (Wednesdays)**
 _____ I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.
 _____ 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: 56672 (Thursdays)**
 _____ I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.
 _____ I completed GCPs (5536 or P383) in _____ (list semester and year) OR
 _____ I have industry GCP experience and have attached my resume.
- _____ **5543. Good Distribution Practices (GDPs) (990) crn: 56677 (Mondays)**
 _____ I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.
 _____ I completed GMPs (5477) or _____ Advanced GMPs (5479) in _____ (list semester and year).
- _____ **5545. Post Approval Changes (990) crn: 56689 (Tuesdays)**
 _____ 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).
- _____ **5546. Global Excipient Regulation (990) crn: 46254 (Wednesdays)**
 _____ I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.
- _____ **5548. Risk Management for Pharmaceutical and Medical Devices (990) crn: 42737 (Mondays)**
 _____ I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.
- _____ **5572. Vaccines: RA and QA Issues (990) crn: 39783 (Mondays)**
 _____ 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).
 _____ I have included my resume which indicates my science background.

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_____ **5574. Quality Management Systems (990) crn: 46256 (Mondays)**

_____ *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).*

_____ **5577. Global CMC – Biopharmaceuticals and Other Biologics (990) crn: 28578 (Tuesdays)**

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

_____ **5579. Regulatory and Legal Basis of Pharmacovigilance (990) crn: 56674 (Wednesdays)**

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

_____ *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: 23442 (Wednesdays)**

_____ *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).*

_____ **5592. Food and Drug Law (990) crn: 7202 (Wednesdays)**

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

_____ **5592. Food and Drug Law (991) crn: 23754 (Tuesdays)**

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

_____ **5595. Food Law (990) crn: 54379 (Thursdays)**

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

_____ **5612. Bioethics for Pharmaceutical Professionals (990) crn: 42739 (Thursdays).**

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

Pharmaceutical Science Courses: Science Background Required
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_____ **5492. Production of Sterile Products (990) crn: 56673 (Thursdays)**

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

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

_____ **8002. Pharmaceutical Analysis (990) crn: 46377 (Mondays)**

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

_____ **8003. Preformulation – Small Molecules (990) crn: 54371 (Tuesdays)**

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

_____ *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: 54372 (Thursdays)**

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