



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 2023 - 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. Jot down the password 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 \$3,558.00 Non-Resident: \$4,425.00

University Services Fee (based on credits): 1 - 4.9 credits: \$177.00 5 - 8.9 credits: \$347.00 9 + credits: \$484.00

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 understand that I may pay a \$15.00 fee for each exam which uses RPNOW and that the fee is paid directly 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 Fall 2023:

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 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. For subsequent exams, the fee increases to \$35.00 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) between August 10, 2023 and September 8, 2023.

___ 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 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 _____

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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 RPNOW for online proctoring. I wish to register for:

- 1) ___ **Cleaning University Available Online**
- 2) ___ **GMP University Available Online**
- 3) ___ **Medical Device Validation & Compliance (Oct 24 – 26) (San Diego)**
___ I plan to attend the above conference(s) ___ in person OR ___ virtually.

_____ **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 (Mondays)**

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

_____ **5459. Drug Development (992) crn: 28608 (Wednesdays)**

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

_____ **5459. Drug Development (993) crn: 46247 (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 have a degree in science and have attached a copy of my resume.

_____ **5476. Good Laboratory Practices (990) crn: 54365 (Wednesdays)**

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

_____ **5477. Good Manufacturing Practices (990) crn: 9357 (Thursdays)**

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

_____ **5477. Good Manufacturing Practices (991) crn: 34740 (Mondays)**

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

_____ **5477. Good Manufacturing Practices (992) crn: 46249 (Saturdays)**

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

_____ **5494. Quality Audit (990) crn: 25897 (Wednesdays)**

___ 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).

_____ **5494. Quality Audit (991) crn: 51968 (Thursdays) -- CLOSED. WAIT LIST ONLY.**

___ 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: 46250 (Tuesdays) – CLOSED. WAIT LIST ONLY.**

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

___ I have completed ___ Drug Development (5459) or ___ Food and Drug Law (5592) in _____ (list semester and year).

_____ **5495. IND/NDA Submissions (992) crn: 54616 (Saturdays)**

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

___ I have completed ___ Drug Development (5459) or ___ Food and Drug Law (5592) in _____ (list semester and year).

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- 5496. Regulation of Medical Devices: Compliance (990) crn: 51969 (Tuesdays)**
 I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.
- 5497. Statistics for Clinical Trials (990) crn: 54366 (Thursdays)**
 I understand that I must pay a \$15.00 fee to RPNOW for online proctoring
- 5498. Computer Systems Validation (990) crn: 54367 (DAYTIME – Tuesdays and Thursday)**
 I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.
- 5501. Development of Sterile Products (990) crn: 54368 (Mondays)**
 I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.
 I have a science background and have attached a copy of my resume.
- 5508. Good Pharmacovigilance Operations (990) crn: 51972 (Thursdays)**
 I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.
 I am enrolled in the MS in GCPR degree or the Global Pharmacovigilance Certificate.
- 5512. Microbiological Concepts in Pharmaceutical Manufacturing (990) crn: 51973 (Tuesdays and Thursdays)**
 I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.
 I have a science background and have attached a copy of my resume.
 I have completed ___ GMPs or ___ GCPs or ___ GLPs or ___ Advanced GMPs in _____ (list semester and year)
- 5513. Active Pharmaceutical Ingredients (990) crn: 49389 (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).
- 5514. Regulatory eSubmissions (990) crn: 54370 (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).
- 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 have completed ___ Drug Development (5459) in _____ (list semester and year).
 I have a science background and have attached a copy of my resume.
- 5516. Cleaning Validation (990) crn: 46251 (Sundays)**
- 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 have completed Food and Drug Law (5592) in _____ list semester and year
OR *I have included my resume for permission to register.*
- 5536. Good Clinical Practices (990) crn: 9358 (Tuesdays) – CLOSED. WAIT LIST ONLY.**
 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 GCP (5536 or P383) in _____ (list semester and year) OR ___ I have attached my resume which indicates industry GCP experience.
- 5546. Global Excipient Regulations (990) crn: 46254 (Wednesdays)**
 I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.
- 5548. Risk Management for Pharmaceutical/ Medical Devices (990) crn: 42737 (Monday) CLOSED. WAIT LIST ONLY.**
 I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.

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_____ **5572. Vaccines: RA and QA Issues (990) crn: 39783 (Tuesdays) – starts in October – CLOSED. WAIT LIST ONLY.**
_____ *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).*

_____ **5574. Pharmaceutical Quality Management Systems (990) crn: 46256 (Mondays) – CLOSED. WAIT LIST ONLY.**
_____ *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: Biopharmaceutical & Other Biologics (990) crn: 28578 (Monday) – CLOSED. WAIT LIST ONLY.**
_____ *I understand that I must pay a \$15.00 fee to PSI RPNOW for online proctoring.*

_____ **5591. Global Regulatory Affairs (990) crn: 23442 (Thursdays) - CLOSED. WAIT LIST ONLY.**
_____ *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) **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 PSI 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 (Mondays)**
_____ *I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.*

_____ **5612. Bioethics for Pharmaceutical Professionals (990) crn: 42739 (Saturdays)**
_____ *I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.*

Pharmaceutical Science courses (strong science background required)

_____ **8002. Pharmaceutical Analysis (990) crn: 46377 (Mondays)**
_____ *I have a strong science background and have included a copy of my resume with this registration form.*

_____ **8003. Preformulation – Small Molecules (990) crn: 54371 (Tuesdays)**
_____ *I understand that I must pay a \$15.00 fee to RPNOW for online proctoring.*
_____ *I have a strong science background and have included a copy of my resume with this registration form.*