![Temple University T logo] **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 2025 - 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 <u>and</u> photocopies of all undergraduate and graduate transcripts __4) Include a color photo of yourself OR email the photo to <u>qarareg@temple.edu</u>. 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.

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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 will show photo ID at the start of the exam and observe appropriate conduct throughout the test.

3. During the exam, I will observe appropriate test procedures, <u>which include staying in the room</u>.
   Unless otherwise specified by written instructions on the exam, **I will not** use books, notes, cell phones, pagers, additional laptops, computers or electronic devices or the Internet (except for using the Proctorio online system).

4. 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.

5. 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.

6. **I understand that I must have administrative rights for my computer to use Proctorio.**

7. 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 Spring 2025:
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 December 3 – 20, 2024, or between January 6 – 20, 2025.

_____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 Proctorio online proctoring, I understand that I must have administrative rights to the computer I use, so I can download Proctorio. (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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COURSE SELECTION for SPRING 2025
Check the course(s) for which you wish to register (maximum of two):

_____**5000. KENX Conference (1.5 credits earned for each conference attended). Visit the KENX website (KENX.org/conferences/) to download the conference brochure. You must also register with RAQA to receive credit.**

_____**Validation U: Driving Excellence in Validation & Qualification Processes (March 26-27) – PHILADELPHIA**

_____**5459. Drug Development (990) crn: 42713 (Thursdays)**

_____**5459. Drug Development (991) crn: 28687 (Wednesdays)**

_____**5459. Drug Development (992) crn: 51026 (Saturdays)**

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

_____**5477. Good Manufacturing Practices (991) crn: 55325 (Tuesdays)**

_____**5493. Sterilization Processes (990) crn: 53063 (Mondays)**
    __*I included my resume to confirm my science background.*

_____**5494. Quality Audit (990) crn: 31574 (Tuesdays)**
    __*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: 20675 (Mondays)**
    __*I completed __Drug Development (5459) or __Food & Drug Law (5592) in _____ (list semester and year).*

_____**5495. IND/NDA Submissions (991) crn: 31567 (Saturdays)**
    __*I completed __Drug Development (5459) or __Food & Drug Law (5592) in _____ (list semester and year).*

_____**5501. Development of Sterile Products (990) crn: 55322 (Wednesdays)**
    ____*I included my resume, which indicates my science background (2 years of general chemistry, including one organic and one analytical course).*

_____**5503. Design Controls for Medical Devices and Combination Products (990) crn: 48475 (Tuesdays)**

_____**5505. Global Medical Device Regulation (990) crn: 51059 (Mondays)**

_____**5508. Good Pharmacovigilance Operations (990) crn: 53066 (Wednesdays)**

_____**5509. Pediatric and Orphan Drug Regulation (990) crn: 55323 (Thursdays)**

_____**5512. Microbiological Concepts in Pharmaceutical Manufacturing (990) crn: 55321 (Thursdays)**
    __*I attached a copy of my resume to indicate my science background.*

_____**5514. Regulatory eSubmissions (990) crn: 42720 (Wednesdays)**
    __*I completed __Drug Development (5459) in _____ (list semester and year)* <u>and</u> *___IND/NDA Submissions (5495) in _____(list semester and year).*
    ___*I did not complete 5459 and 5495 but have attached my resume for special approval to register.*

_____**5536. Good Clinical Practices (990) crn: 51052 (Mondays)**

_____**5538. Clinical Drug Safety and Pharmacovigilance (990) crn: (Mondays)**

Continued on next page….

_____ **5537. Clinical Trial Management (990) crn: 20667 (Wednesdays)**
_____*I completed GCPs (5536 or P383) in_____ (list semester and year) OR ____ I have attached my resume which indicates industry GCP experience.*

_____**5544. Regulatory Intelligence (990) crn: 51035 (Sundays)**
____*I completed Drug Development (5459) on _____(list semester and year)* **and** ____*Food & Drug Law (5592) in _____ (list semester and year).*

_____**5572. Vaccines: RA and QA Issues (990) crn: 45613 (Thursdays)**
____*I completed ____Drug Development (5459) in _____ (list semester and year).*
____*I have included my resume which indicates my science background.*

_____**5573. Pharmacoepidemiology (990) crn: 51062 (Mondays)**

_____**5574. Quality Management Systems (990) crn: 51029 (Mondays)**
____*I completed ____Drug Development (5459) in _____ (list semester and year).*

_____**5575. Regulatory Sciences: Managing the Guidelines for Quality (990) crn: 53069 (Tuesdays)**
____*I have included my resume which indicates my science background.*

_____**5577. Global CMC – Biopharmaceuticals and Other Biologics (990) crn: 55328 (Tuesdays)**

_____ **5578. Risk Management and Safety Signaling of Healthcare Products (990) crn: 53070 (Thursdays)**
__*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: 20671 (Mondays)**
__*I completed __Drug Development (5459) OR __Food and Drug Law (5592) in_____(semester and year).*

_____ **5592. Food and Drug Law (990) crn: 9424 (Wednesdays)**

_____ **5592. Food and Drug Law (991) crn: 25838 (Tuesdays)**

_____ **5594. Regulation of Dietary Supplements and Functional Food (990) 42729 (Wednesdays)**

_____ **5597. Food Good Manufacturing Practices (990) crn: 51045 (Mondays)**

_____ **5611. Regulation of Advertising and Promotions (990) crn: 51038 (Tuesdays)**

_____**5612. Bioethics for Pharmaceutical Professionals (990) crn: 28699 (Thursdays).**

_____**5615. Project Management for Pharmaceutical Professionals (990) crn: 31575 (Mondays)**
____*I have completed at least four courses in the RAQA graduate program by Spring 2025.*

_____**5650. Critical Analysis of Media Coverage of the Pharmaceutical Industry (990) crn: 45587 (Tuesdays)**

_____**5650. Regulation of Artificial Intelligence & Machine Learning (AI/ML) Medical Devices (991) crn: 55327 (ONLINE) (Tuesdays)**
____*I completed __Drug Development (5459) OR __Food & Drug Law (5592) in_____(list semester and year).*

Pharmaceutical Science Courses: Science Background Required

_____**8004. Solid Dosage Forms – Small Molecules (990) crn: 55324 (Wednesdays)**
____*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: 51044 (Thursdays)**
____*I included my resume, which indicates my science background (2 years of general chemistry, including one organic and one analytical course).*