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

Summer 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 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 $3,672.00   Non-Resident: $4,566.00
University Services Fee (based on credits): 1 – 4 credits: $116.00   5 – 8 credits: $193.00   9 + credits: $256.00

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 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, which include staying in the room. **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_____

Student 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 Summer 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 time the charge is $100.00. After that, the fee becomes $125.00.

_____ **I have purchased a headset (with 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 keep my webcam on during all course meetings and use the microphone for discussions.

_____ I agree to test my headset with Dave Brickett (dbrick@temple.edu) or Jessie Chen (Jessie.chen@temple.edu) on a weekday between April 15 and May 17, 2025.

_____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_____

COURSE SELECTION for SUMMER 2025
Check the course(s) for which you wish to register (maximum of two):

_____**5000. FDA Inspection Readiness (111) crn: 13923 1.5 credits (Tuesdays)**

_____**5000. Critical Case Study: Analysis of Mainstream Pharmaceutical Literature (112) crn: 14468**
  (1.5 credits) (Thursdays)

_____**5459. Drug Development (990) crn: 2539 (Wednesdays)**

_____**5472. Pharmaceutical Marketing (990) crn: 13919 (Wednesdays)**

_____ **5477. Good Manufacturing Practices (990) crn: 4136 (Mondays) CLOSED. WAIT LIST ONLY.**

_____**5479. Advanced Good Manufacturing Practices – Defining 'c" (990) crn: 7676 (Wednesdays)**
  __I completed Good Manufacturing Practices (5477) in _____(list semester and year) OR ___I have
  attached my resume which indicates at least 5 years of GMP experience.

_____**5494. Quality Audit (990) crn: 4137 (Wednesdays)**
  __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: 13915 (WEEKEND COURSE - Saturdays)**
  __I completed __Drug Development (5459) or __Food & Drug Law (5592) in _____ (list semester and
  year).

_____**5496. Regulation of Medical Devices: Compliance (990) crn: 14469 (Thursdays)**

_____**5514. Regulatory eSubmissions (990) crn: 13918 (Tuesdays)**
  *__I completed __Drug Development (5459) in _____ (list semester and year) **OR** ___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.

_____**5515. Biologics/Biosimilars: A Regulatory Overview (990) crn: 14470 (Wednesdays)**
  ___I have attached a copy of my resume which indicates an undergraduate or graduate degree in science.
  ___I completed Drug Development (5459) in _____ (list semester and yea).r

_____ **5536. Good Clinical Practices (990) crn: 3423 (Mondays) – CLOSED. WAIT LIST ONLY.**

_____ **5537. Clinical Trial Management (990) crn: 5872 (Tuesdays)**
  ___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: 13333 (Thursdays)**

_____**5545. Post-Approval Changes (PAC) (990) crn: 14472 (Mondays)**

_____**5591. Global Regulatory Affairs (990) crn: 1733 (Thursdays)**
  __I completed __Drug Development (5459) OR __Food and Drug Law (5592) in_____(list
  semester and year).

_____ **5592. Food and Drug Law (990) crn: 1734 (Tuesdays) – CLOSED. WAIT LIST ONLY.**

_____ **5596. Food Labeling and Regulatory Affairs (990) crn: 13921 (Thursdays)**

_____**5612. Bioethics for Pharmaceutical Professionals (990) crn: 14473 (WEEKENDS - SATURDAYS)**

_____**5650. Investigations in Industry (Internal, Quality and Criminal) (990) crn: 13922 (Mondays)**
  ____I completed Good Manufacturing Practices (5477) in_____(list semester and year).

ON-CAMPUS Course with ONLINE Sessions: If you are interested in the course below but can't attend on-campus sessions, please email QARAREG@temple.edu:

_____5650 Pharmaceutical Regulatory Leadership (101) crn: 13914 (Wednesdays)
___I have completed ____ Drug Development (5459) in _____(list semester and year OR ____ *Food and Drug Law* (5592) in _____(list semester and year).