



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 2018 - Registration Form for Online Courses

REGISTER EARLY TO RESERVE YOUR SPOT IN A CLASS. PLEASE PRINT CLEARLY.

Complete this entire form and email it to qarareg@temple.edu (or fax to 267.468.8565). New students must include the Adobe password, copies of undergraduate & graduate transcripts, a resume, a Temple U residency form and a recent photo. Students who only earned degrees abroad must include copies of TOEFL/IELTS scores & WES/ECE reports.

Continuing Students: 9-digit TUID _____ TUmial _____

All Students: Name _____

Home Address _____ (Check, if address change) []

City _____ State _____ Zip _____

Are you a Pennsylvania Resident? Yes ___ No ___ If yes, for how long? _____

Home Phone _____ 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 (or accepted into the MS degree program)

Do you plan to pursue the MS Degree? Yes ___ No ___ Expected year to graduate: _____

Which certificate do you intend to pursue?

- ___ Drug Development ___ Clinical Trial Management ___ Medical Devices ___ Global Pharmacovigilance
- ___ GMPs for the 21st Century ___ Generic Drugs ___ Pharmaceutical Dev ___ Labeling, Advertising & Promotions
- ___ Food RA and QA ___ Sterile Process Manufacturing ___ Biopharmaceutical Manufacturing (Biotechnology)
- ___ Post Master's Certificate (indicate which one: _____)

Applicant's Signature: _____ **Date:** _____

RAQA Tuition for 3 Credit Courses

PA Resident \$3,216.00 Non-Resident: \$4,074.00

University Services Fee

1 – 4.9 credits: \$163.00 5 – 8.9 credits: \$319.00 9 + credits: \$445.00

Drop Policy: To receive a complete refund, students must submit the Course Withdrawal Form (on the Forms link of the RAQA website)

BEFORE the second class (weekend courses) or BEFORE the third class (weeknight courses).

On the pages that follow, please check the Adobe Connect class for which you wish to register. The Proctoring Procedures page must be included.



Proctoring Procedures

STUDENT AGREES TO THESE PROCEDURES:

1. I will complete, sign, and return the Proctoring Agreement form **by deadline stipulated by the RAQA Office**. I will also sign and return the Honor Statement provided by the RAQA Office by the stipulated deadline.
2. I agree to take the exam on the designated exam date. If I change the exam date due to a documented emergency or hardship, 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 10 days (no exceptions). If I do not, the grade for the exam is an automatic 0.
3. 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 libraries provide free proctoring). The RAQA Office must approve all proctors. No friends, colleagues, relatives, work subordinates, or current RAQA students may be used. The RAQA Office provides free proctoring at Temple’s Fort Washington Campus.
4. 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 the Software Secure system).
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 includes 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 Software Secure proctoring).
7. I will abide by Temple University's code of academic honesty. Submitting false information on this form or not following RAQA graduate program 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 (email, Twitter, Facebook, pagers, etc.) before, during, or after the exam.
9. **If my course is using Software Secure for proctoring, I understand that I must have administrative rights to the computer I am using.** (This means I have the right to download programs to the computer). I also understand that I must pay a \$15.00 fee directly to Software Secure to use their system.

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 Fall 2018:

Before indicating your course choice, please check one of the required statements:

____ I have not taken a Temple U Online Course through Adobe Connect before.

____ I completed a Temple U Adobe class previously and have not changed my computer or location where I will be participating in the upcoming classes. (If I have changed either, I will complete the self-test of Adobe 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 Adobe 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 Adobe as stipulated in *Expectations of Online Students*. (The link for the Self-Test of Adobe is 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 for my computer, which is required to participate in RAQA online courses.** Students who do not have headsets with microphone will be dropped and not allowed to register in future semesters. This rule ensures that all students enjoy an online experience that is conducive to learning.

____ I agree to test my headset with Dave Brickett (dbrick@temple.edu) or Mike Doukas (mdoukas@temple.edu) between August 13, 2018 – September 7, 2018.

____ 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 **Software Secure** (online proctoring), I understand that I must have administrative rights to the computer I use. This means that I have permission to download computer programs (such as Software Secure). (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, so I can participate in the first class. If I do not have a TUmail account or a headset with microphone or have not tested Adobe Connect two days before the class starts, my registration will 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):

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

____ *I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.*

____ **5459. Drug Development (991) crn: 7407 (Tuesdays)**

Continued on next page.

- _____ **5459. Drug Development (992) crn: 28608 (Saturday mornings)**
- _____ **5459. Drug Development (993) crn: 32363 (Thursdays)**
- _____ **5472. Pharmaceutical Marketing (990) crn: 39772 (Wednesdays)**
- _____ **5473. Generic Drug Regulation (ANDAs) (990) crn: 20853 (Thursdays)**
 _____ *I have completed Drug Development (5459) in _____ (list semester and year).*
- _____ **5474. Process Validation (990) crn: 28712 (Wednesdays)**
 _____ *I have a science degree.*
 _____ *I have experience in manufacturing*
 _____ *I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.*
- _____ **5477. Good Manufacturing Practices (990) crn: 9357 (Wednesdays)**
 _____ *I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.*
- _____ **5477. Good Manufacturing Practices (991) crn: 34740 (Mondays)**
 _____ *I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.*
- _____ **5479. Advanced Good Manufacturing Practices – defining “c” (990) crn: 39795 (Mondays)**
 _____ *I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.*
 _____ *I have completed GMPs (5477) or I have at least five years of experience in industry GMPs and have attached my resume.*
- _____ **5494. Quality Audit (990) crn: 25897 (Thursdays)**
 _____ *I have completed ___GLPs (5476), ___ GMP (5477), ___ Advanced GMPs (5479), or ___GCPs (5536) in _____ (list semester and year).*
- _____ **5494. Quality Audit (991) crn: 39767 (Wednesdays)**
 _____ *I have completed ___GLPs (5476), ___ GMP (5477), ___ Advanced GMPs (5479), or ___GCPs (5536) in _____ (list semester and year).*
- _____ **5495. IND/NDA Submissions (990) crn: 34741 (Mondays)**
 _____ *I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.*
 _____ *I have completed ___ Drug Development (5459) or ___ Food and Drug Law (5592) in _____ (list semester and year).*
- _____ **5495. IND/NDA Submissions (991) crn: 32029 (Tuesdays)**
 _____ *I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.*
 _____ *I have completed ___ Drug Development (5459) or ___ Food and Drug Law (5592) in _____ (list semester and year).*
- _____ **5496. Regulation of Medical Devices: Compliance (990) crn: 25899 (Wednesdays)**
 _____ *I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.*
- _____ **5498. Computer Validation (990) crn: 39770 (DAYTIME Tuesdays and Thursdays)**
 _____ *I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.*
 _____ *I understand this course includes weekly recordings that I must watch in a timely fashion.*
- _____ **5503. Design Controls for Medical Devices and Combination Products (990) crn: 39768 (Thursdays)**
 _____ *I understand this course will use WebEx (not Adobe Connect). WebEx is a supported platform offered by Temple U.*
- _____ **5505. Global Medical Device Regulation (990) crn: 20855 (Tuesdays)**
 _____ *I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.*

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- _____ **5508. Good Pharmacovigilance Operations (990) crn: 25900 (Tuesdays)**
 _____ I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.
 _____ I have completed Drug Development (5459) in _____ (list semester and year) or I have
 Included my resume.
- _____ **5513. Active Pharmaceutical Ingredients (APIs) (990) crn: 34745 (Wednesdays)**
 _____ I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.
 _____ I have completed Drug Development (5459) in _____ (list semester and year).
- _____ **5515. Biologics/Biosimilars: A Regulatory Overview (990) crn: 28574 (Mondays)**
 _____ I have completed ___ Drug Development (5459) in _____ (list semester and year).
 Or, if I have not completed the suggested prerequisites, ___ I have submitted a resume for permission to register.
- _____ **5532. Global Labeling Regulation: Principles and Practices (990) crn: 32030 (Tuesdays)**
 _____ I have completed Drug Development (5459) in _____ (list semester and year).
- _____ **5536. Good Clinical Practices (990) crn: 9358 (Tuesdays)**
- _____ **5537. Clinical Trial Management (990) crn: 23438 (Mondays)**
 _____ I understand that I must pay a \$15.00 fee to Software Secure for online proctoring
 _____ I have completed Good Clinical Practices (5536) in _____ (list semester and year).
- _____ **5538. Clinical Drug Safety and Pharmacovigilance (990) crn: 28576 (Thursdays)**
 _____ I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.
 _____ I have completed Good Clinical Practices (or submitted a resume indicating my experience in the area).
- _____ **5539. Global Clinical Drug Development (990) crn: 39784 (Tuesdays)**
 I have completed (check two):
 _____ Drug Development (5459) _____ Good Clinical Practices (5536) _____ Global Regulatory Affairs (5591)
 _____ Food and Drug Law (5592).
- _____ **5547. Project Management for Clinical Trials (990) crn: 34715 (Wednesdays)**
- _____ **5572. Vaccines: RA and QA Issues (990) crn: 39783 (Mondays)**
 _____ I understand that I must pay a \$15.00 fee to Software Secure for online proctoring
 _____ I have completed Drug Development (5459) in _____ (list semester and year) or attached my
 resume.
- _____ **5576. Global CMC Issues and Regulatory Dossiers (990) crn: 39787 (Tuesdays)**
- _____ **5577. CMCs – Biologics (990) crn: 25878 (Mondays)**
 _____ I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.
- _____ **5578. Benefit-Risk Management and Safety Signaling of Healthcare Products (990) crn: 32033 (Thursdays)**
 _____ I have completed one of the following courses: Clinical Drug Safety and Pharmacovigilance (5538) OR Post
 Marketing Safety Surveillance (5571).
 _____ OR, I have submitted my resume for permission to register.
- _____ **5579. Regulatory and Legal Basis of Pharmacovigilance (990) crn: 28579 (Wednesdays)**
 _____ I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.
- _____ **5591. Global Regulatory Affairs (990) crn: 23442 (Thursdays)**
 _____ I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.
 _____ I have completed Drug Development (5459) or _____ Food and Drug Law (5592) in _____
 (list semester and year).

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- _____ **5592. Food and Drug Law (990) crn: 7202 (Wednesdays)**
_____ *I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.*
- _____ **5592. Food and Drug Law (991) crn: 23754 (Tuesdays)**
_____ *I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.*
- _____ **5592. Food and Drug Law (992) crn: 34749 (Mondays)**
- _____ **5597. Food GMPs (990) crn: 32037 (Mondays)**
_____ *I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.*
- _____ **5611. Regulation of Advertising and Promotions (990) crn: 34751 (Tuesdays)**
_____ *I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.*
- _____ **5650. Current Global Regulatory Issues (990) crn: 39769 (Wednesdays)**
- _____ **8005. Pharmaceutical Biotechnology (990) crn: 34772 (Thursdays)**
_____ *I have included my resume, which indicates a strong science background, including a degree in science (chemistry, pharmacy, biology, biochemistry or chemical engineering.).*