



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 2019 - 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 _____ 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? _____

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)
- ___ Validation Sciences (NEW!)
- ___ 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 for my computer.** (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 Spring 2019:

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 Dec 3 - 20, 2018 OR Jan 3 - 15, 2019. (Temple will be closed from Dec 21, 2018 through Jan 2, 2019).

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 TUmial account, I will forward the address to the RAQA Office, so I can participate in the first class. If I do not have a TUmial 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 TUmial to receive the link for the first and all subsequent class meetings.

Signature _____ Print Name _____

All rights reserved. This document or portions of this document may not be reproduced or copied without written permission of the Regulatory Affairs and Quality Assurance Graduate Program of the Temple University School of Pharmacy.

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

5401. Fundamentals of Pharmacology and Pharmacokinetics (990) crn: 39751 (Wednesdays)
 I have included my resume to indicate that I have a strong science background.

5459. Drug Development (990) crn: 7447 (Thursdays)
 I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.

Continued on next page.

- ____ 5459. Drug Development (991) crn: 28687 (Tuesdays)
- ____ 5459. Drug Development (992) crn: 28931 (Saturday mornings)
- ____ 5459. Drug Development (993) crn: 36993 (Mondays)
- ____ 5471. Biotechnology: Bioprocess Basics (990) crn: 28688 (Mondays)
 ____ I have included a copy of my resume to indicate my background in biochemistry and/or chemistry.
 ____ I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.
- ____ 5474. Process Validation (990) crn: 39786 (Mondays)
 ____ I have attached my resume to indicate my background in science.
 ____ I have experience in pharmaceutical manufacturing.
 ____ I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.
- ____ 5477. Good Manufacturing Practices (990) crn: 3439 (Wednesdays)
 ____ I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.
- ____ 5477. Good Manufacturing Practices (991) crn: 39719 (Mondays)
 ____ I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.
- ____ 5491. Pre-Approval Inspections (990) crn: 31572 (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) AND
 ____ I have completed ____ GMPs (5477) OR Advanced GMPs (5479) in ____ (list semester and year).
- ____ 5493. Sterilization Processes (990) crn: 39717 (Thursdays)
 ____ I have included my resume to indicate my science background.
 ____ I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.
- ____ 5494. Quality Audit (990) crn: 31574 (Thursdays)
 ____ I have completed ____ GLPs (5476) , ____ GMP (5477), ____ Advanced GMPs (5479), or ____ GCPs (5536) in
 ____ (list semester and year).
- ____ 5494. Quality Audit (991) crn: 39720 (Wednesdays) **CLOSED. WAIT LIST ONLY.**
 ____ I have completed ____ GLPs (5476) , ____ GMP (5477), ____ Advanced GMPs (5479), or ____ GCPs (5536) in
 ____ (list semester and year).
 ____ I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.
- ____ 5495. IND/NDA Submissions (990) crn: 20675 (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: 31567 (Wednesdays)
 ____ 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: 39722 (Tuesdays) **CLOSED. WAIT LIST ONLY.**
 ____ I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.
- ____ 5498. Computer Validation (990) crn: 39725 (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.

Continued on next page

- _____ **5502. Regulation of Medical Devices: Submissions (990) crn: 31565 (Wednesdays)**
 _____ *I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.*
- _____ **5508. Good Pharmacovigilance Operations (990) crn: 28690 (Thursdays)**
 _____ *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.*
- _____ **5515. Biologics/Biosimilars: A Regulatory Overview (990) crn: 39724 (Tuesdays)**
 _____ *I have completed ___ Drug Development (5459) in _____ (list semester and year).*
 _____ *I have submitted a resume indicating my science background.*
- _____ **5533. Requirements for Product Labeling and Advertising (990) crn: 31562 (Thursdays)**
 _____ *I have completed Food and Drug Law (5592) in _____ (list semester and year).*
 _____ *I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.*
- _____ **5536. Good Clinical Practices (990) crn: 23276 (Tuesdays) **CLOSED. WAIT LIST ONLY.****
 _____ *I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.*
- _____ **5537. Clinical Trial Management (990) crn: 20667 (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: 39708 (Tuesdays) **CLOSED. WAIT LIST ONLY.****
 _____ *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: 39709 (Thursdays)**
 _____ *I have completed ___ Drug Development (5459) OR ___ Good Clinical Practices (5536). (Note: this*
 _____ *is not mandatory. You may still register if you have not completed either course.)*
- _____ **5545. Post Approval Changes (990) crn: 39710 (Mondays)**
 _____ *I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.*
- _____ **5548. Risk Management of Pharmaceutical and Medical Devices (990) crn: 39747 (Thursdays) (Uses WebEx)**
 _____ **CLOSED. WAIT LIST ONLY.**
 _____ *I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.*
- _____ **5573. Pharmacoepidemiology (990) crn: 31616 (Mondays) **CLOSED. WAIT LIST ONLY****
 _____ *I understand that I must pay a \$15.00 fee to Software Secure for online proctoring*
- _____ **5578. 5578. Risk Management and Safety Signaling of Healthcare Products (990) crn: 39872**
 _____ *I have completed either Post Marketing Safety Surveillance (5571) OR Clinical Drug Safety and Pharmacovigilance*
 _____ *(5538) in _____ (list semester and year).*
 _____ *If I have not completed 5571 or 5538, I have attached my resume for special permission to take this course.*
- _____ **5591. Global Regulatory Affairs (990) crn: 20671 (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).*
- _____ **5592. Food and Drug Law (990) crn: 9424 (Wednesdays)**
 _____ *I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.*
- _____ **5592. Food and Drug Law (992) crn: 39712 (Tuesdays)**

Continued next page....

_____ **5592. Food and Drug Law (991) crn: 25838 (Thursdays) CLOSED. WAIT LIST ONLY.**
_____ *I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.*

_____ **5596. Food Labeling and Regulatory Affairs (990) crn: 39749 (Mondays)**
_____ *I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.*

_____ **5605. Advanced Topics in Food and Drug Law (990) crn: 36997 (Tuesdays)**
_____ *I have completed Food and Drug Law (5592) in _____ (list semester and year).*
_____ *I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.*

_____ **5611. Regulation of Advertising and Promotions (990) crn: 28698 (Tuesdays)**
_____ *I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.*

_____ **5612. Bioethics for Pharmaceutical Professionals (990) crn: 28699 (Wednesdays)**
_____ *I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.*

_____ **5615. Project Management for Pharmaceutical Professionals (990) crn: 31575 (Wednesdays) CLOSED. WAIT LIST ONLY.**
_____ *I have completed at least four RAQA courses, including Drug Development (5459) and Food and Drug Law (5592).*

_____ **5618. Clinical Data Management (990) crn: 36995 (Thursdays)**
_____ *I have completed Drug Development (5459) in _____ (list semester and year), and _____ I have also completed Good Clinical Practices (5536) in _____ (list semester and year).*
_____ *I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.*

_____ **5650. Current Global Regulatory Issue: ICH Quality Guidelines (990) crn: 36996 (Tuesdays) CLOSED. WAIT LIST ONLY**
_____ *I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.*

_____ **8004. Pharmaceutical Manufacturing II: Solid Dosage Forms (990) crn: 36992 (Wednesdays) CLOSED. WAIT LIST ONLY.**
_____ *I have included my resume, which indicates a strong science background).*
_____ *I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.*