



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 2018 - Registration Form for Online Courses

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

Complete all sections of this form and email 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)
- ___ Post Master's Certificate (indicate which one: _____)

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

RAQA Tuition for 3 Credit Courses

PA Resident \$3,123.00 Non-Resident: \$3,954.00

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 \$20 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 Spring 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 have taken a Temple U Adobe class before 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 cannot process registrations without signatures.

____ By registering for any RA and QA 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*. (Note: the link for the Self-Test of Adobe is in that document). **The Password is: _____ (REQUIRED).**

____ I understand that I will be required to take a proctored exam on a specific date and will make every effort to do so. **If I know in advance that I cannot take the exam on the date designated on the schedule, I will select another course.** If I need to change the exam date, I understand that I will be charged a \$20.00 fee. In subsequent semesters, the fee increases to \$30.00 per exam change. The third time the charge is \$50.00.

____ **I have purchased a headset with a microphone for my computer.** If the RAQA Office learns that I am not using a headset with microphone for participation, I understand that I will be dropped from RAQA Online courses and will not be 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 7 - Dec 20, 2017 or Jan 3 - 12, 2018.

____ I agree to purchase a webcam for my computer (if one is not already built in) to participate in Online Courses.

____ If I am taking a course that uses **Software Secure** (or 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 _____

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

____ **5459. Drug Development (991) crn: 28687 (Thursdays)**

____ **5459. Drug Development (992) crn: 28931 (Saturdays)**

Continued on next page.

- _____ **5459. Drug Development (993) crn: 36993 (Tuesdays)**
- _____ **5471. Biotechnology: Bioprocess Basics (990) crn: 28688 (Mondays)**
 _____ *I have attached my resume which indicates my science background.*
 _____ *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.*
- _____ **5491. Pre-Approval Inspections (990) crn: 31572 (Wednesdays)**
 _____ *I have completed Drug Development (5459) in _____ (list semester and year).*
 _____ *I have completed Good Manufacturing Practices (5477) in _____ (list semester and year).*
- _____ **5494. Quality Audit (990) crn: 31574 (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: 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 (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).*
- _____ **5502. Regulation of Medical Devices: Submissions (990) crn: 31565 (Tuesdays)**
 _____ *I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.*
- _____ **5505. Global Medical Device Regulation (990) crn: 28689 (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).*
- _____ **5514. Regulatory eSubmissions (990) crn: 28692 (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 ___IND/NDA Submissions (5495) in _____ (list semester and year).*
 _____ *Or, if I have not completed the suggested prerequisites, ___ I have submitted a resume for permission to register.*
- _____ **5533. Requirements for Product Labeling and Advertising (990) crn: 31562 (Thursdays)**
 _____ *I understand that I must pay a \$15.00 fee to Software Secure for online proctoring.*
 _____ *I have completed Food and Drug Law (5592) in _____ (list semester and year).*
 _____ *Or, if I have not completed Food and Drug Law, I have attached my resume for permission to register.*
- _____ **5536. Good Clinical Practices (990) crn: 23276 (Thursdays)**
- _____ **5571. Post Marketing Safety Surveillance (990) crn: 28696 (Wednesdays)**
- _____ **5572. Vaccines: RA and QA Issues (990) crn: 37055 (Mondays)**
- _____ **5573. Pharmacoepidemiology (990) crn: 31616 (Mondays)**

Continued on next page

_____ **5576. Global CMC Issues and Regulatory Dossiers (990) crn: 36991 (Tuesdays)**

_____ **5591. Global Regulatory Affairs (990) crn: 20671 (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).*

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

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

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

_____ **5594. Regulation of Dietary Supplements, Botanicals, and Nutraceuticals (990) crn: 36994 (Tuesdays)**

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

_____ **5601. Industry Interactions with FDA and Health Authorities (990) crn: 8726 (Thursdays) CLOSED.
WAIT LIST ONLY.**

_____ *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 (Wednesdays)**

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

_____ *I completed Food and Drug Law (5592) in _____ (list semester and year)*

_____ *Or, I have attached my resume for special permission to register _____.*

_____ **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 (Tuesdays)**

_____ *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 (Tuesdays)**

_____ *I have completed at least four courses in the RAQA Program, including Drug Development (5459) and
Food and Drug Law (5592).*

_____ **5618 Clinical Data Management (990) crn: 36995 (Mondays)**

_____ *I have completed Drug Development (5459) in _____ list semester and year.*

_____ *I have completed Good Clinical Practices (5536) in _____ list semester and year.*

_____ **5650. Current Global Regulatory Issues (990) crn: 36996 (Mondays)**

_____ **8004. Pharmaceutical Manufacturing II: Solid Dosage Forms (990) crn: 36992 (Mondays)**

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

_____ *Strong science background required. I have included my resume with the registration form.*