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 2016 - 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 tutorial password, a Temple U residency form, copies of undergraduate & graduate transcripts, a resume, and a recent photograph. Students who only earned degrees abroad must include 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_____

Work or Home Email ______________________ Fax_________________________

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 ___________________________ University Services Fee

PA Resident  $3,033.00 Non-Resident: $3,840.00 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 Fall 2016: 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:____________________

___ 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 or a RAQA technician between August 15 and September 2, 2016.

___ 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 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.

<table>
<thead>
<tr>
<th>Signature</th>
<th>Print Name</th>
</tr>
</thead>
</table>

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):

___ 5459. Drug Development (990) crn: 17910 (Tuesdays)

___ 5459. Drug Development (991) crn: 7407 (Mondays)

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

Continued on next page....
5459. Drug Development (992) crn: 28608 (Sundays)
5459. Drug Development (993) crn: 32262 (Thursdays)
I understand that I must pay a $15.00 fee to Software Secure for online proctoring.

5473. Generic Drug Regulation - ANDAs (990) crn: 20853 (Mondays)
I have completed Drug Development (5459) in _________________ semester.

5474. Process Validation (990) crn: 28712 (Mondays) CLOSED. WAIT LIST ONLY.
I understand that I must pay a $15.00 fee to Software Secure for online proctoring.
I have attached a resume which indicates my science background and familiarity with pharmaceutical manufacturing.

5477. Good Manufacturing Practices (990) crn: 9357 (Tuesdays) CLOSED. WAIT LIST ONLY.
I understand that I must pay a $15.00 fee to Software Secure for online proctoring.

5478. High Purity Water Systems (990) crn: 28571 (Wednesdays)
I understand that I must pay a $15.00 fee to Software Secure for online proctoring.

5494. Quality Audit (990) crn: 25897 (Thursdays) CLOSED. WAIT LIST ONLY.
I completed the following GxP course during _________________ (list semester and check which course):
GMPs (5477) or GCPs (5536) or GLPs (5476) or Advanced GMPs (5479).

5495. IND/NDA Submissions (991) crn: 32029 (Tuesdays)
I understand that I must pay a $15.00 fee to Software Secure for online proctoring.

5496. Regulation of Medical Devices: Compliance (990) crn: 25899 (Tuesdays)
I understand that I must pay a $15.00 fee to Software Secure for online proctoring.

5505. Global Medical Device Regulation (990) crn: 20855 (Wednesdays)
I understand that I must pay a $15.00 fee to Software Secure for online proctoring.

5508. Good Pharmacovigilance Operations (990) crn: 25900 (Tuesdays) CLOSED. WAIT LIST ONLY.
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).

5508. Good Pharmacovigilance Operations (991) crn: 32325 (Mondays)
I understand that I must pay a $15.00 fee to Software Secure for online proctoring.
I have completed ___Drug Development (5459) or ___GCPs (5536) in ____________ (list semester and year).

5515. Biologics/Biosimilars: A Regulatory Overview (990) crn: 28574 (Wednesdays)

I have completed Drug Development (5459) or have attached a copy of my resume.

5536. Good Clinical Practices (990) crn: 9358 (Thursdays)

5537. Clinical Trial Management (990) crn: 23438 (Mondays)
I completed GCPs (5536) in ____________ (list year and semester) or __attached my resume with GCP experience.
I understand that I must pay a $15.00 fee to Software Secure for online proctoring.

5538. Clinical Drug Safety and Pharmacovigilance (990) crn: 28576 (Thursdays)
I completed Drug Development (5459) in ____________ (list year and semester).
I understand that I must pay a $15.00 fee to Software Secure for online proctoring.

5545. Post Approval Changes (PAC) (990) crn: 32032 (Mondays) CLOSED. WAIT LIST ONLY.
I understand that I must pay a $15.00 fee to Software Secure for online proctoring.

Continued on next page...
____5547. Project Management for Clinical Trials (990) crn: 31929 (Wednesdays)
Not open to students who have completed Project Management for Pharmaceutical Professionals (5615).

____5577. CMCs - Biologics (990) crn: 28578 (Thursdays)
_____I understand that I must pay a $15.00 fee to Software Secure for online proctoring.

_____I have completed the first required course of the Global Pharmacovigilance certificate (Clinical Drug Safety and Pharmacovigilance or Post Marketing Safety Surveillance) or have attached a copy of my resume to show my experience with pharmacovigilance.

____5579. Regulatory and Legal Basis of Pharmacovigilance (990) crn: 28579 (Wednesdays)
_____I have completed one of the following Pharmacovigilance courses in _______________semester:
_____ Post Marketing Safety Surveillance (5571) or _____Clinical Drug Safety and Pharmacovigilance (5538)
or _____Pharmacoepidemiology (5573) or _____Good Pharmacovigilance Operations (5508) or _____Benefit Risk Management and Safety Signaling of Healthcare Products (5578).
OR _____I have attached my resume indicating 2 - 3 years of industry pharmacovigilance experience.

____5597. Global Regulatory Affairs (990) crn: 31929 (Wednesdays)
_____I understand that I must pay a $15.00 fee to Software Secure for online proctoring.

____5512. Bioethics for Pharmaceutical Professionals (991) crn: 32039 (Friday MORNINGS)

____5612. Bioethics for Pharmaceutical Professionals (990) crn: 31998 (Wednesdays)

____8004. Pharmaceutical Manufacturing II (990) crn: 32041 (Thursdays)
_____I have included my resume which indicates that I have a science background.
_____I understand that I must pay a $15.00 fee to Software Secure for online proctoring.