

 <b>School of Pharmacy</b> TEMPLE UNIVERSITY Quality Assurance/Regulatory Affairs Graduate Program	Temple University - School of Pharmacy 425 Commerce Drive, Suite 175 Fort Washington, PA 19034 Phone: 267.468.8560 Fax: 267.468.8565
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## POST-MASTER'S CERTIFICATES in ADVANCED QUALITY ASSURANCE or REGULATORY AFFAIRS

### BACKGROUND

Temple University's School of Pharmacy continues to be the leader in providing world renowned graduate-level courses in Quality Assurance and Regulatory Affairs. As the program continues to pioneer new curriculum, it recognizes that many graduates with the MS in QA/RA want to continue taking courses to keep current with challenges facing the industry. The *Post-Master's Certificates in Advanced QA and RA* allow students to pursue additional coursework and receive formal recognition for their work.

For nearly four decades, the School of Pharmacy of Temple University has provided outstanding graduate-level course work in Quality Assurance and Regulatory Affairs. The School was the original institution of higher learning in the world to create a master's program in the Quality Assurance (QA) and Regulatory Affairs (RA) disciplines and continues to offer the most comprehensive curriculum of its kind.

Temple's renowned program specifically examines QA and RA issues facing the pharmaceutical and related industries by integrating pharmaceutical law and regulation, pharmaceutical technology, and quality assurance practices. Faculty are industry veterans with years of expertise in their specialties, sharing their vast knowledge with students through intimate classroom discussions and hands-on workshops.

The 36-credit hour QA/RA master's program is based in Fort Washington, PA, with courses also offered in Tarrytown (NY), Frazer (PA), and corporate sites (either live or through videoconferencing). Classes are conveniently scheduled on evenings and weekends to provide flexibility for working professionals.

Candidates must formally apply for the *Post-Master's Certificates in Advanced QA and RA* before registering for any courses. To receive the certificate, candidates must complete the required courses and application procedures. Students who completed master's degrees or higher from accredited US institutions of higher learning with extensive pharmaceutical industry experience may also petition the School to pursue one of the *Post-Master's Certificates in Advanced QA and RA*, but will be required to complete five courses.

## APPLICATION PROCESS

### Temple University Students:

Once you receive your MS from Temple, the University closes your academic file. If you wish to pursue the *Certificates in Advanced QA and RA*, you must formally apply, so we can reopen your file and register you. The application is available at:

[http://www.temple.edu/pharmacy\\_QARA/POSTMSCERTapp.pdf](http://www.temple.edu/pharmacy_QARA/POSTMSCERTapp.pdf).

Please mail the application along with a photocopy of your Temple University QA/RA transcript to:

QA/RA Graduate Program  
Temple University School of Pharmacy  
425 Commerce Drive, Suite 175  
Fort Washington, PA 19034

### Students with Advanced Science Degrees from Other Schools:

To apply for the Post-Master's Certificate in QA or RA, you must meet the following criteria:

- 1) You must have received an advanced degree in science (master's level or higher) from an accredited institution of higher learning and must have worked in the pharmaceutical industry in a specific specialty for a minimum of ten years. You must have sufficient industry experience and familiarity with basic QA/RA tenets to pursue one of the Advanced Certificates.
- 2) Please write a letter to the Assistant Dean (QA/RA Program, 425 Commerce Drive, Suite 175, Fort Washington, PA 19034), indicating which courses you wish to pursue and explaining your experience in the pharmaceutical industry. You must include a copy of your resume and copies of transcripts from all undergraduate and graduate programs you have attended. Formal permission to pursue the *Post-Master's Certificate in Advanced QA or RA* must be received from the Assistant Dean before the student starts any courses in the Advanced Certificate program.
- 3) Students with advanced science degrees from other schools will be required to take five Temple University QA/RA courses to receive either *Post-Master's Certificates in Advanced QA or RA*. Only one certificate may be pursued.

## TO RECEIVE THE CERTIFICATE

After you have finished the four courses, you must notify the QA/RA Office by fax (267.468.8565) indicating that you are eligible to receive the certificate. Please include your name, TUID, courses completed, daytime phone number, and the certificate you have completed.

The QA/RA Office issues certificates in early February, June, and September. In order to receive your certificate in one of those months, you must notify the Graduate Studies office by fax **at least one month in advance**. Otherwise you will have to wait until the

next time they are processed. The certificate must be completed within three years. Transfer credits are not accepted towards the Advanced Certificates.

**Courses Accepted for the Certificate in Advanced Regulatory Affairs:**

Fundamentals of Pharmacology & Pharmacokinetics	<i>Pharmaceutics 5401</i>
Pharmaceutical Laboratory Quality Systems & Operations	<i>Pharmaceutics 5469</i>
The Global Pharmaceutical Industry (including Waxman Hatch)	<i>Pharmaceutics 5458</i>
Biotechnology: Bioprocess Basics	<i>Pharmaceutics 5471</i>
Pharmaceutical Marketing	<i>Pharmaceutics 5472</i>
Generic Drug Regulation (ANDAs)	<i>Pharmaceutics 5473</i>
Pharmaceutical Biotechnology	<i>Pharmaceutics 5475</i>
Good Laboratory Practices	<i>Pharmaceutics 5476</i>
Good Manufacturing Practices	<i>Pharmaceutics 5477</i>
High Purity Water Systems	<i>Pharmaceutics 5478</i>
Advanced GMPs – Defining “c”	<i>Pharmaceutics 5479</i>
Pre-Approval Inspections	<i>Pharmaceutics 5491</i>
Production of Sterile Parenteral Products	<i>Pharmaceutics 5492</i>
Sterilization Processes: Manufacturing	<i>Pharmaceutics 5493</i>
Quality Audit	<i>Pharmaceutics 5494</i>
IND/NDA Submissions	<i>Pharmaceutics 5495</i>
Drug Dosage Forms	<i>Pharmaceutics 5499</i>
Regulation of Medical Devices: Submissions	<i>Pharmaceutics 5502</i>
Global Regulation of Medical Devices: submissions	<i>Pharmaceutics 5505</i>
Environmental Law and Regulation (EPA)	<i>Pharmaceutics 5506</i>
Good pharmacovigilance Practices: Applied Drug Safety and Individual Case Report Forms	<i>Pharmaceutics 5508</i>
Advanced Audit Workshop of Quality Systems	<i>Pharmaceutics 5511</i>
Microbiological Concepts in Pharmaceutical Manufacturing	<i>Pharmaceutics 5512</i>

Biologic/Biosimilars: A Regulatory Overview	<i>Pharmaceutics 5515</i>
Cleaning Validation	<i>Pharmaceutics 5516</i>
Regulatory Issues in Pharmacogenomics	<i>Pharmaceutics 5518</i>
Requirements for Product Labeling and Advertising	<i>Pharmaceutics 5533</i>
Regulatory Aspects of Biomedical/Technical Communications	<i>Pharmaceutics 5534</i>
Advanced Topics in Labeling Development	<i>Pharmaceutics 5535</i>
Good Clinical Practices	<i>Pharmaceutics 5536</i>
Clinical Trial Management	<i>Pharmaceutics 5537</i>
Clinical Drug Safety and Pharmacovigilance	<i>Pharmaceutics 5538</i>
Global Clinical Drug Development	<i>Pharmaceutics 5539</i>
Pharmaceutical Packaging: Technology and Regulation	<i>Pharmaceutics 5541</i>
Regulation of Training: Compliance	<i>Pharmaceutics 5542</i>
Good Distribution Practices	<i>Pharmaceutics 5543</i>
Regulatory Intelligence	<i>Pharmaceutics 5544</i>
PAC (Post Approval Changes)	<i>Pharmaceutics 5545</i>
Global Excipient Regulation	<i>Pharmaceutics 5546</i>
Post-Marketing Safety Surveillance	<i>Pharmaceutics 5571</i>
Vaccines: QA/RA Issues	<i>Pharmaceutics 5572</i>
Pharmacoepidemiology	<i>Pharmaceutics 5573</i>
Regulatory Sciences: Managing the Guidelines to Quality	<i>Pharmaceutics 5575</i>
Global CMC Issues and the Regulatory Dossier	<i>Pharmaceutics 5576</i>
Regulatory & Legal Basis of Pharmacovigilance	<i>Pharmaceutics 5579</i>
Advanced Topics in Regulatory Aspects of Biomedical/Technical Communication	<i>Pharmaceutics 5589</i>
Global Regulatory Affairs	<i>Pharmaceutics 5591</i>
Regulation of Dietary Supplements, Botanicals,	<i>Pharmaceutics 5594</i>

and Nutraceuticals	
Industry Interactions with FDA and Health Authorities	<i>Pharmaceutics 5601</i>
Advanced Topics in Food and Drug Law	<i>Pharmaceutics 5605</i>
Advanced Topics: Regulation of Advertising & Promotions	<i>Pharmaceutics 5611</i>
Project Management for Pharmaceutical Professionals	<i>Pharmaceutics 5615</i>
Special Topics in QA/RA	<i>Pharmaceutics 5650</i>

**Courses Accepted for the *Post-Master's Certificate in Advanced Quality Assurance*:**

Fundamentals of Pharmacology & Pharmacokinetics	<i>Pharmaceutics 5401</i>
Pharmacoeconomics	<i>Pharmaceutics 5408</i>
Statistical Quality Control	<i>Pharmaceutics 5451</i>
Acceptance Sampling	<i>Pharmaceutics 5452</i>
The Global Pharmaceutical Company (including Waxman Hatch)	<i>Pharmaceutics 5458</i>
Pharmaceutical Laboratory Quality Systems & Operations	<i>Pharmaceutics 5469</i>
Biotechnology: Bioprocess Basics	<i>Pharmaceutics 5471</i>
Pharmaceutical Marketing	<i>Pharmaceutics 5472</i>
Process Validation	<i>Pharmaceutics 5474</i>
Pharmaceutical Biotechnology	<i>Pharmaceutics 5475</i>
Good Laboratory Practices	<i>Pharmaceutics 5476</i>
Good Manufacturing Practices	<i>Pharmaceutics 5477</i>
High Purity Water Systems	<i>Pharmaceutics 5478</i>
Advanced GMPs – Defining “c”	<i>Pharmaceutics 5479</i>
Pre-Approval Inspections	<i>Pharmaceutics 5491</i>
Production of Sterile Parenteral Products	<i>Pharmaceutics 5492</i>
Sterilization Processes: Manufacturing	<i>Pharmaceutics 5493</i>

Quality Audit	<i>Pharmaceutics 5494</i>
Regulation of Medical Devices: Compliance	<i>Pharmaceutics 5496</i>
Statistics for Clinical Trials	<i>Pharmaceutics 5497</i>
Computer Validation	<i>Pharmaceutics 5498</i>
Drug Dosage Forms	<i>Pharmaceutics 5499</i>
Development of Sterile Parenterals	<i>Pharmaceutics 5501</i>
Environmental Law and Regulation (EPA)	<i>Pharmaceutics 5506</i>
Good Pharmacovigilance Practices: Applied Drug Safety and Individual Case Report Forms	<i>Pharmaceutics 5508</i>
Advanced Audit Workshop of Quality Systems	<i>Pharmaceutics 5511</i>
Microbiological Concepts in Pharmaceutical Manufacturing	<i>Pharmaceutics 5512</i>
Biologics/Biosimilars: A Regulatory Overview	<i>Pharmaceutics 5515</i>
Cleaning Validation	<i>Pharmaceutics 5516</i>
Regulatory Aspects of Biomedical/Technical Communications	<i>Pharmaceutics 5534</i>
Good Clinical Practices	<i>Pharmaceutics 5536</i>
Clinical Trial Management	<i>Pharmaceutics 5537</i>
Clinical Safety and Pharmacovigilance	<i>Pharmaceutics 5538</i>
Global Clinical Drug Development	<i>Pharmaceutics 5539</i>
Pharmaceutical Packaging: Technology and Regulation	<i>Pharmaceutics 5541</i>
Regulation of Training: Compliance	<i>Pharmaceutics 5542</i>
Good Distribution Practices	<i>Pharmaceutics 5543</i>
PAC (Post Approval Changes)	<i>Pharmaceutics 5545</i>
Clinical Project Management	<i>Pharmaceutics 5547</i>
Post Marketing Safety Surveillance	<i>Pharmaceutics 5571</i>
Vaccines: QA/RA Issues	<i>Pharmaceutics 5572</i>
Pharmacoepidemiology	<i>Pharmaceutics 5573</i>
Regulatory Sciences: Managing the Guidelines	<i>Pharmaceutics 5575</i>

to Quality	
Global CMC Issues and the Regulatory Dossier	<i>Pharmaceutics 5576</i>
Regulatory & Legal Basis of Pharmacovigilance	<i>Pharmaceutics 5579</i>
Clinical Aspects of Pharmaceutical Medicine I	<i>Pharmaceutics 5599</i>
Industry Interactions with FDA and Health Authorities	<i>Pharmaceutics 5601</i>
Clinical Aspects of Pharmaceutical Medicine II	<i>Pharmaceutics 5602</i>
Bioethics for Pharmaceutical Professionals	<i>Pharmaceutics 5612</i>
Project Management for Pharmaceutical Professionals	<i>Pharmaceutics 5615</i>
Clinical Data Management	<i>Pharmaceutics 5618</i>
Unit Operations	<i>Pharmaceutics 5622</i>
Process Analytical Technology (PAT)	<i>Pharmaceutics 5625</i>
Statistical Design of Experiments (DOE)	<i>Pharmaceutics 5627</i>
Process Monitoring	<i>Pharmaceutics 5629</i>
Analytical Chemistry in Pharmaceutical Laboratories	<i>Pharmaceutics 5655</i>

## **QUESTIONS AND ANSWERS**

### **Where is the QA/RA Program Offered?**

The QA/RA program is based at Temple University Fort Washington in suburban Montgomery County, PA. For directions, visit our website:

[http://www.temple.edu/pharmacy\\_QARA/map.htm](http://www.temple.edu/pharmacy_QARA/map.htm)

Courses are also offered in Tarrytown (NY), Frazer, PA, and some corporate sites.

### **When can I start the certificate?**

Courses in the QA/RA program are offered during the fall, spring, and summer semesters every year. You may start the certificate program at your convenience.

### **What course sequence is recommended?**

Unless the courses have prerequisites, you may take them in any sequence.

### **How do I obtain a current class schedule?**

Please refer to the QA/RA homepage:

[www.temple.edu/pharmacy\\_QARA/schedule.htm](http://www.temple.edu/pharmacy_QARA/schedule.htm)

### **How do I register for classes?**

Please make sure you have been formally admitted into the Post-Master's Certificate in QA or RA before registering.

- If you received your MS from Temple, download the registration form from the QA/RA homepage: [http://www.temple.edu/pharmacy\\_QARA/forms.htm](http://www.temple.edu/pharmacy_QARA/forms.htm)  
You do not need to submit a state residency form, unless you have moved from one state to another. Priority registration is given to Temple QA/RA graduates.
- If you have not registered for Temple University classes before, download the Registration and State Residency forms from the QA/RA homepage: [http://www.temple.edu/pharmacy\\_QARA/forms.htm](http://www.temple.edu/pharmacy_QARA/forms.htm)  
Both are required the first time you register. Faxed and e-mail registrations do not guarantee your spot in a class, since sections do fill quickly. We will contact you if there are problems with your registration. Otherwise you will receive a paperless bill through your Temple email account which confirms that you are officially registered.

### **Do I need to take the GREs to complete the *Certificates in Advanced QA or RA*?**

No. GRE or other advanced test scores are not required for the certificate.

### **Can I complete both *Certificates in Advanced QA and Advanced RA*?**

Temple University students who have already received the MS in QA/RA are welcome to complete both certificates, but please be aware that you must take different electives for each. In other words, if you wish to receive both certificates, you must complete eight courses. Students who did not receive the MS in QA/RA from Temple may only pursue one *Post-Master's Certificate in Advanced QA or RA*.

### **Can I transfer any credits from another graduate institution towards the *Post-Master's Certificates in QA or RA*?**

Sorry, but credits for courses taken at other institutions are not accepted. All courses must be from Temple University's QA/RA program.

### ***I'm doing an Advanced Certificate in RA, but I want to include one course from the QA list. Is that permissible?***

Yes, but you must get approval first. Please write to the Assistant Dean of QA/RA stating which courses you'd like to substitute.

### **Will the certificate automatically be awarded when I complete the required courses?**

No. You must formally apply to receive the certificate. This consists of submitting the application form and copies of undergraduate and graduate transcripts from any schools previously attended. You should complete the *Post-Master's Certificate in QA or RA* within three years. When you have finished your courses, you must notify the QA/RA Office by fax (267.468.8565) that you are eligible to receive the certificate. The fax must

include your name, TUID, courses completed, daytime phone number, and certificate you have completed. You must submit the fax at least one month before certificates are issued (early in February, June, and September). Otherwise you will have to wait until the next time they are processed.

**Will new electives be added to the certificate programs?**

Yes, the QA/RA program continues to expand its curriculum. For a listing of new courses, please consult the QA/RA website.

**For additional information:**

QA/RA Graduate Program  
Temple University School of Pharmacy  
425 Commerce Drive, Suite 175  
Fort Washington, PA 19034  
**Voice: 267.468.8560**  
**Fax: 267.468.8565**  
**E-mail: [QARA@temple.edu](mailto:QARA@temple.edu)**  
**[www.temple.edu/pharmacy\\_QARA](http://www.temple.edu/pharmacy_QARA)**