

## POST-MASTER'S CERTIFICATE in ADVANCED REGULATORY AFFAIRS and QUALITY ASSURANCE

*Enabling post graduate students to pursue advanced courses in specialized areas  
of the industry*

### BACKGROUND

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

For nearly five decades, the School of Pharmacy of Temple University has provided outstanding graduate-level course work in Regulatory Affairs and Quality Assurance. 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 RA and QA issues facing the pharmaceutical and related industries by integrating pharmaceutical law and regulation, pharmaceutical technology, and quality assurance practices. Faculty are FDA and industry veterans with years of expertise in their specialties, sharing their vast knowledge with students through intimate classroom discussions and hands-on workshops.

Temple's RAQA graduate program is based in Fort Washington, PA. Courses are conveniently scheduled on evenings and weekends for working professionals and can be videoconferenced to corporate sites. Over sixty courses are offered online in real time.

Candidates must formally apply for the *Post-Master's Certificate in Advanced RAQA* before registering for any courses. To receive the certificate, candidates must complete the required courses and application procedures. Students who received the MS in RAQA from Temple will take four courses to complete a *Post-Master's Certificate in Advanced RAQA*. Students who completed master's degrees or higher from other accredited US institutions of higher learning with extensive pharmaceutical industry experience may also petition the School to pursue one of the *Post-Master's Certificate in Advanced RAQA* and 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 a *Post-Master's Certificate in Advanced RAQA*, you must formally apply, so we can reopen your file and register you.

The **Application Form** is available on the Certificates link of the RAQA homepage.

You will be required to take four courses in either quality assurance or regulatory affairs that were not previously completed as part of your MS in RAQA from Temple University.

Please mail the **Application Form** along with a photocopy of your Temple University RAQA transcript to:

Temple University School of Pharmacy  
Regulatory Affairs and Quality Assurance Graduate Program  
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 Advanced RAQA*, 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 RA and QA tenets to pursue a Post-Master's Certificate.
- 2) Submit the **Application Form** for the *Post-Master's Certificate in Advanced RAQA*. In addition, submit a letter to the Assistant Dean (Temple University, RAQA Graduate 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 RAQA* must be received from the Assistant Dean before the student starts any courses in the *Post-Master's Certificate in Advanced RAQA*.
- 3) Students with advanced science degrees from other schools will be required to take five Temple University RAQA courses to receive the *Post-Master's Certificates in Advanced RAQA*.

## TO RECEIVE THE CERTIFICATE

*The Post-Master's Certificate in Advanced RAQA* should be completed within three years. Transfer credits are not accepted.

After you have finished the required number of courses, you must submit the **Notice of Completion** to the RAQA Office (found in the Certificates section of the RAQA website)

The RAQA Office issues certificates in early February, June, and September. In order to receive your certificate in one of those months, you must submit the **Notice of Completion** to the RAQA Office by these deadlines:

**Jan 15** for certificates earned in the previous fall semester

**May 15** for certificates earned in the previous spring semester

**Aug 20** for certificates earned during the summer semesters

If you miss the deadline, you must wait until the next processing period. It takes the RAQA Office approximately 6 weeks to process certificates. If you have not received your certificate by Feb 28, June 30, or Sept 30, please contact the RAQA Office.

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

Fundamentals of Pharmacology & Pharmacokinetics	<i>RAQA 5401</i>
Pharmacoeconomics	<i>RAQA 5408</i>
Statistical Quality Control	<i>RAQA 5451</i>
The Global Biopharmaceutical Industry	<i>RAQA 5458</i>
Drug Development	<i>RAQA 5459</i>
Validation of Facilities, Utilities and Equipment (FUE)	<i>RAQA 5468</i>
Pharmaceutical Laboratory Quality Systems & Operations	<i>RAQA 5469</i>
Biotechnology: Bioprocess Basics	<i>RAQA 5471</i>
Pharmaceutical Marketing	<i>RAQA 5472</i>
Generic Drug Regulation (ANDAs)	<i>RAQA 5473</i>
Process Validation	<i>RAQA 5474</i>
Good Laboratory Practices	<i>RAQA 5476</i>
Good Manufacturing Practices	<i>RAQA 5477</i>

High Purity Water Systems	<i>RAQA 5478</i>
Advanced GMPs – Defining “c”	<i>RAQA 5479</i>
Pre-Approval Inspections	<i>RAQA 5491</i>
Production of Sterile Products	<i>RAQA 5492</i>
Sterilization Processes	<i>RAQA 5493</i>
Quality Audit	<i>RAQA 5494</i>
IND/NDA Submissions	<i>RAQA 5495</i>
Regulation of Medical Devices: Compliance	<i>RAQA 5496</i>
Statistics for Clinical Trials	<i>RAQA 5497</i>
Computerized System Validation	<i>RAQA 5498</i>
Drug Dosage Forms	<i>RAQA 5499</i>
Development of Sterile Products	<i>Pharmaceutics 5501</i>
Regulation of Medical Devices: Submissions	<i>RAQA 5502</i>
Design Controls for Medical Devices and Combination Products	<i>RAQA 5503</i>
Global Regulation of Medical Devices	<i>RAQA 5505</i>
Environmental Law and Regulation (EPA)	<i>RAQA 5506</i>
Regulation of Non-Prescription Drugs (OTCs)	<i>PENDING</i>
Good Pharmacovigilance Operations	<i>RAQA 5508</i>
Advanced Audit Workshop of Quality Systems	<i>RAQA 5511</i>
Microbiological Concepts in Pharmaceutical Manufacturing	<i>RAQA 5512</i>
Active Pharmaceutical Ingredients (APIs)	<i>RAQA 5513</i>
Regulatory eSubmissions	<i>RAQA 5514</i>
Biologics/Biosimilars: A Regulatory Overview	<i>RAQA 5515</i>
Cleaning Validation	<i>RAQA 5516</i>
Global Labeling Regulation: Principles and Practices	<i>RAQA 5532</i>
Requirements for Product Labeling and Advertising	<i>RAQA 5533</i>

Regulatory Aspects of Biomedical/Technical Communications	<i>RAQA 5534</i>
Advanced Topics in Labeling Development	<i>RAQA 5535</i>
Good Clinical Practices	<i>RAQA 5536</i>
Clinical Trial Management	<i>RAQA 5537</i>
Clinical Drug Safety & Pharmacovigilance	<i>RAQA 5538</i>
Global Clinical Drug Development	<i>RAQA 5539</i>
Pharmaceutical Packaging: Technology and Regulation	<i>RAQA 5541</i>
Good Distribution Practices	<i>RAQA 5543</i>
Regulatory Intelligence	<i>RAQA 5544</i>
PAC (Post Approval Changes)	<i>RAQA 5545</i>
Global Pharmaceutical Excipient Regulation	<i>RAQA 5546</i>
Project Management for Clinical Trials	<i>RAQA 5547</i>
Risk Management of Pharmaceutical and Medical Devices	<i>RAQA 5548</i>
Post-Marketing Safety Surveillance	<i>RAQA 5571</i>
Vaccines: RA and QA Issues	<i>RAQA 5572</i>
Pharmacoepidemiology	<i>RAQA 5573</i>
Pharmaceutical Quality Management Systems	<i>RAQA 5574</i>
Regulatory Sciences: Managing the Guidelines to Quality	<i>RAQA 5575</i>
Global CMCs and the Regulatory Dossier	<i>RAQA 5576</i>
Global CMCs - Biologics	<i>RAQA 5577</i>
Risk Management and Safety Signaling in Healthcare Products	<i>RAQA 5578</i>
Regulatory & Legal Basis of Pharmacovigilance	<i>RAQA 5579</i>
Global Regulatory Affairs	<i>RAQA 5591</i>
Food and Drug Law	<i>RAQA 5592</i>
Regulation of Dietary Supplements and	<i>RAQA 5594</i>

Functional Foods	
Food Law	<i>RAQA 5595</i>
Food Labeling and Regulatory Affairs	<i>RAQA 5596</i>
Food GMPs	<i>RAQA 5597</i>
Regulatory and Safety Requirements for New Innovative Food Ingredients	<i>RAQA 5598</i>
Clinical Aspects of Pharmaceutical Medicine I	<i>RAQA 5599</i>
Industry Interactions with FDA and Health Authorities	<i>RAQA 5601</i>
Advanced Topics in Food and Drug Law	<i>RAQA 5605</i>
Regulation of Advertising & Promotions	<i>RAQA 5611</i>
Bioethics for Pharmaceutical Professionals	<i>RAQA 5612</i>
Project Management for Pharmaceutical Professionals	<i>RAQA 5615</i>
Clinical Data Management	<i>RAQA 5618</i>
Regulatory Bioanalysis	<i>RAQA 5621</i>
Unit Operations	<i>RAQA 5622</i>
Process Analytical Technology (PAT)	<i>RAQA 5625</i>
Statistical Design of Experiments (DOE)	<i>RAQA 5627</i>
Process Monitoring	<i>RAQA 5629</i>
Special Topics	<i>RAQA 5650</i>
Analytical Chemistry in Pharmaceutical Laboratories	<i>RAQA 5655</i>
Pharmaceutical Analysis	<i>Pharmaceutics 8002</i>
Pharmaceutical Manufacturing I: Preformulation/Formulation	<i>Pharmaceutics 8003</i>
Pharmaceutical Manufacturing II: Solid Dosage Forms	<i>Pharmaceutics 8004</i>
Pharmaceutical Biotechnology	<i>Pharmaceutics 8005</i>
Physical Pharmacy I	<i>Pharmaceutics 8006</i>
Applied Biopharmaceutics	<i>Pharmaceutics 8007</i>

Pharmacogenomics	<i>Pharmaceutics 8403</i>
Introduction to Toxicology	<i>Pharmaceutics 8111</i>
Physical Pharmacy II	<i>Pharmaceutics 8582</i>

## **QUESTIONS AND ANSWERS**

### **Where is the RAQA Program Offered?**

The RAQA 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 can be videoconferenced to corporate sites. Over sixty courses are available online in real time.

The *Post Master's Certificate in Advanced RAQA* may be completed entirely online.

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

Courses in the RAQA 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.

The RAQA program offers over 80 different courses, which are rotated over a 2 to 3 year period. Courses are not necessarily offered every semester. We urge students to take courses when they are scheduled or to write to the RAQA Office if they wish to see a course scheduled in a particular semester.

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

Please see the RAQA website: [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 Advanced RAQA* before registering.

- If you received your MS from Temple, download the registration form from the RAQA homepage: [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.
- If you have not registered for Temple University classes before, download the Registration and State Residency forms from the RAQA homepage: [www.temple.edu/pharmacy\\_QARA/forms.htm](http://www.temple.edu/pharmacy_QARA/forms.htm)

Both are required the first time you register. Fax, mail, and electronic 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. Once we officially register you, we will send you an email confirmation and you will also receive a paperless bill through your Temple email account.

**Do I need to take the GREs to complete the *Post Master's Certificate*?**

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

**Can I complete more than one Post-Master's Certificate?**

Temple University students who have already received the MS in RAQA are welcome to complete more than one Post-Master's certificate, but please be aware that you must take different electives for each.

**Can I transfer any credits from another graduate institution towards the *Post-Master's Certificates in Advanced RAQA*?**

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

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

No. When you have finished your courses, you must submit the **Notice of Completion** (available on the RAQA website) to the RAQA Office by fax (267.468.8565) or email. Please submit the **Notice of Completion** by the stated deadlines (Jan 15, May 15, Aug 20). Otherwise you will have to wait until the next time they are processed.

Temple University MS in RAQA recipients should complete the *Post-Master's Certificate in Advanced RAQA* in three years. Students with advanced degrees from other universities should complete the *Post-Master's Certificate in Advanced RAQA* in four years.

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

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

**For additional information**

**Temple University School of Pharmacy  
Regulatory Affairs and Quality Assurance Graduate Program  
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)**