School of Pharmacy
TEMPLE UNIVERSITY
Regulatory Affairs and Quality Assurance
Graduate Program

Temple University School of Pharmacy
Regulatory Affairs and Quality Assurance Graduate Program
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POST-MASTER'S CERTIFICATE in ADVANCED QUALITY ASSURANCE and REGULATORY AFFAIRS

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 QA/RA*** 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 QA/RA*** 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 QA/RA***. 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 QA/RA*** 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 QA/RA***, 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 QA/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 RA and QA tenets to pursue a Post-Master's Certificate.

2) Submit the **Application Form** for the ***Post-Master's Certificate in Advanced QA/RA*** . 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 QA/RA*** must be received from the Assistant Dean before the student starts any courses in the ***Post-Master's Certificate in Advanced QA/RA***.

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 QA/RA.***

TO RECEIVE THE CERTIFICATE

The Post-Master's Certificate in Advanced QA/RA 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 Quality Assurance and Regulatory Affairs*:

Fundamentals of Pharmacology & Pharmacokinetics	*Pharmaceutics 5401*
Pharmacoeconomics	*Pharmaceutics 5408*
Statistical Quality Control	*Pharmaceutics 5451*
The Global Biopharmaceutical Industry	*Pharmaceutics 5458*
Drug Development	*Pharmaceutics 5459*
Pharmaceutical Laboratory Quality Systems & Operations	*Pharmaceutics 5469*
Biotechnology: Bioprocess Basics	*Pharmaceutics 5471*
Pharmaceutical Marketing	*Pharmaceutics 5472*
Generic Drug Regulation (ANDAs)	*Pharmaceutics 5473*
Process Validation	*Pharmaceutics 5474*
Good Laboratory Practices	*Pharmaceutics 5476*
Good Manufacturing Practices	*Pharmaceutics 5477*
High Purity Water Systems	*Pharmaceutics 5478*
Advanced GMPs – Defining “c”	*Pharmaceutics 5479*

Pre-Approval Inspections	*Pharmaceutics 5491*
Production of Sterile Products	*Pharmaceutics 5492*
Sterilization Processes	*Pharmaceutics 5493*
Quality Audit	*Pharmaceutics 5494*
IND/NDA Submissions	*Pharmaceutics 5495*
Regulation of Medical Devices: Compliance	*Pharmaceutics 5496*
Statistics for Clinical Trials	*Pharmaceutics 5497*
Computer Validation	*Pharmaceutics 5498*
Drug Dosage Forms	*Pharmaceutics 5499*
Development of Sterile Products	*Pharmaceutics 5501*
Regulation of Medical Devices: Submissions	*Pharmaceutics 5502*
Design Controls for Medical Devices and Combination Products	*Pharmaceutics 5503*
Global Regulation of Medical Devices	*Pharmaceutics 5505*
Environmental Law and Regulation (EPA)	*Pharmaceutics 5506*
Good Pharmacovigilance Operations	*Pharmaceutics 5508*
Advanced Audit Workshop of Quality Systems	*Pharmaceutics 5511*
Microbiological Concepts in Pharmaceutical Manufacturing	*Pharmaceutics 5512*
Active Pharmaceutical Ingredients (APIs)	*Pharmaceutics 5513*
Regulatory eSubmissions	*Pharmaceutics 5514*
Biologics/Biosimilars: A Regulatory Overview	*Pharmaceutics 5515*
Cleaning Validation	*Pharmaceutics 5516*
Global Labeling Regulation: Principles and Practices	*Pharmaceutics 5532*
Requirements for Product Labeling and Advertising	*Pharmaceutics 5533*
Regulatory Aspects of Biomedical/Technical Communications	*Pharmaceutics 5534*
Advanced Topics in Labeling Development	*Pharmaceutics 5535*
Good Clinical Practices	*Pharmaceutics 5536*

Clinical Trial Management	*Pharmaceutics 5537*
Clinical Drug Safety & Pharmacovigilance	*Pharmaceutics 5538*
Global Clinical Drug Development	*Pharmaceutics 5539*
Pharmaceutical Packaging: Technology and Regulation	*Pharmaceutics 5541*
Good Distribution Practices	*Pharmaceutics 5543*
Regulatory Intelligence	*Pharmaceutics 5544*
PAC (Post Approval Changes)	*Pharmaceutics 5545*
Global Pharmaceutical Excipient Regulation	*Pharmaceutics 5546*
Project Management for Clinical Trials	*Pharmaceutics 5547*
Risk Management of Pharmaceutical and Medical Devices	*Pharmaceutics 5548*
Post-Marketing Safety Surveillance	*Pharmaceutics 5571*
Vaccines: RA and QA Issues	*Pharmaceutics 5572*
Pharmacoepidemiology	*Pharmaceutics 5573*
Pharmaceutical Quality Management Systems	*Pharmaceutics 5574*
Regulatory Sciences: Managing the Guidelines to Quality	*Pharmaceutics 5575*
Global CMCs and the Regulatory Dossier	*Pharmaceutics 5576*
Global CMCs - Biologics	*Pharmaceutics 5577*
Risk Management and Safety Signaling in Healthcare Products	*Pharmaceutics 5578*
Regulatory & Legal Basis of Pharmacovigilance	*Pharmaceutics 5579*
Global Regulatory Affairs	*Pharmaceutics 5591*
Food and Drug Law	*Pharmaceutics 5592*
Regulation of Dietary Supplements, Botanicals, and Nutraceuticals	*Pharmaceutics 5594*
Food Law	*Pharmaceutics 5595*
Food Labeling and Regulatory Affairs	*Pharmaceutics 5596*
Food GMPs	*Pharmaceutics 5597*

Clinical Aspects of Pharmaceutical Medicine I	*Pharmaceutics 5599*
Industry Interactions with FDA and Health Authorities	*Pharmaceutics 5601*
Clinical Aspects of Pharmaceutical Medicine II	*Pharmaceutics 5602*
Advanced Topics in Food and Drug Law	*Pharmaceutics 5605*
Advanced Topics: Regulation of Advertising & Promotions	*Pharmaceutics 5611*
Bioethics for Pharmaceutical Professionals	*Pharmaceutics 5612*
Project Management	*Pharmaceutics 5615*
Clinical Data Management	*Pharmaceutics 5618*
Regulatory Bioanalysis	*Pharmaceutics 5621*
Unit Operations	*Pharmaceutics 5622*
Process Analytical Technology (PAT)	*Pharmaceutics 5625*
Statistical Design of Experiments (DOE)	*Pharmaceutics 5627*
Process Monitoring	*Pharmaceutics 5629*
Special Topics	*Pharmaceutics 5650*
Analytical Chemistry in Pharmaceutical Laboratories	*Pharmaceutics 5655*
Pharmaceutical Analysis	*Pharmaceutics 8002*
Pharmaceutical Manufacturing I: Preformulation/Formulation	*Pharmaceutics 8003*
Pharmaceutical Manufacturing II: Solid Dosage Forms	*Pharmaceutics 8004*
Pharmaceutical Biotechnology	*Pharmaceutics 8005*
Physical Pharmacy I	*Pharmaceutics 8006*
Applied Biopharmaceutics	*Pharmaceutics 8007*
Pharmacogenomics	*Pharmaceutics 8403*
Introduction to Toxicology	*Pharmaceutics 8111*
Physical Pharmacy II	*Pharmaceutics 8582*

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**

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

The ***Post Master's Certificate in Advanced QA/RA*** 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**

How do I register for classes?

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

- If you received your MS from Temple, download the registration form from the RAQA homepage**:** **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**
  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 Certificates in Advanced QA/ RA?*

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 QA/RA*?
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 QA/RA*** in three years. Students with advanced degrees from other universities should complete the ***Post-Master's Certificate in Advanced QA/RA*** 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

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