

 <p>School of Pharmacy TEMPLE UNIVERSITY</p> <p>Quality Assurance/Regulatory Affairs Graduate Program</p>	<p>Temple University - School of Pharmacy 425 Commerce Drive, Suite 175 Fort Washington, PA 19034</p> <p>Phone: 267.468.8560 Fax: 267.468.8565</p>
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CERTIFICATE IN BASIC PHARMACEUTICAL DEVELOPMENT

Focusing on the Business of Pharmaceuticals

BACKGROUND

Temple University recognizes that professionals with business and non-science degrees may wish to enter or advance their careers in the pharmaceutical industry but need specialized training in its terminology, concepts, and regulatory milieu. Whether they are just entering the workforce or looking for ways to advance in a global corporation, they will benefit from a deeper understanding of how pharmaceutical products are discovered, manufactured, and distributed, plus a greater familiarity with the multitude of federal and international regulations governing every aspect of product quality.

The *Certificate in Basic Pharmaceutical Development* combines a general overview of the drug development process with pharmaceutical industry business practices. This certificate enables students to explore quality assurance and regulatory affairs as a prospective career path without committing to a master's degree in science. Students are exposed to the specialized language of the industry, the overriding concern for imbuing quality in the industry, and the regulations that directly impact industry business decisions.

For nearly four decades, the School of Pharmacy of Temple University has provided outstanding graduate-level course work in Quality Assurance (QA) and Regulatory Affairs (RA). The School was the original institution of higher learning in the world to create a master's program in the Quality Assurance and Regulatory Affairs 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. Classes are conveniently scheduled on evenings and weekends to provide flexibility for working professionals.

To receive the certificate, candidates must complete an application and complete the required courses listed below.

ACADEMIC REQUIREMENTS

1. The *Certificate in Basic Pharmaceutical Development* may be earned on its own or on the way to the MS in QA/RA. The following courses must be successfully completed within a three year period with an overall B (3.0) average. There are two requirements:

Drug Development (Pharmaceutics 5459)

Pharmaceutical Marketing (Pharmaceutics 5472)

PLUS students must select two of the following:

Pharmacoeconomics (Pharmaceutics 5408)

IND/NDA Submissions (Pharmaceutics 5494)

Requirements for Product Labeling & Advertising (Pharmaceutics 5533)

Food and Drug Law I (Pharmaceutics 5592)

Project Management for Pharmaceutical Professionals (Pharmaceutics 5615)

Students should start the program with *Drug Development*.

2. To be considered for the *Certificate in Basic Pharmaceutical Development*, candidates must have a business or non-science degree from an accredited institution of higher learning.

3. All courses must be completed from Temple University's QA/RA graduate program. No transfer credits from other institutions are accepted. If a student has taken an identical course at an accredited U.S. graduate school, the student may petition the QA/RA program to waive that requirement and take another approved elective in its place. This request must be made in writing and approved before the student pursues the certificate.

4. Candidates must formally apply and follow the application procedures stated below (application form, photocopies of transcripts, and notice of completion).

5. Only one certificate program may be completed before students receive the MS.

6. The certificate must be completed within three years. Students must apply for the certificate within one year of completing all required coursework for the program.

7. Students interested in pursuing the MS in QA/RA may apply all credits earned in the *Certificate in Basic Pharmaceutical Development* towards their graduate degree, provided they formally apply for admission to the MS program and are accepted by Temple University's Graduate School.

APPLICATION PROCESS

This program is part of Temple University's graduate program in Quality Assurance and Regulatory Affairs. The *Certificate in Basic Pharmaceutical Development* does not require the completion of GREs or GMATs. To earn the *Certificate in Basic*

Pharmaceutical Development, students must successfully complete the four required courses with an overall B average and formally apply for the certificate. To receive the certificate and letter of completion, the following must be submitted:

- An application form.
- Photocopies of all undergraduate and graduate transcripts from any schools previously attended, including Temple's QA/RA program. (Copies of transcripts are acceptable. Official transcripts are not required.)

These items must be mailed to:

QA/RA Graduate Program
Temple University School of Pharmacy
425 Commerce Drive, Suite 175
Fort Washington, PA 19340

Certificates are not automatically conferred when students complete the required courses. Students must formally apply and must also forward a notice of completion either by mail or fax to the QA/RA Office (267.468.8565) indicating that they have finished the required courses. The notice of completion must include the student's name, TUID, courses completed, certificate being requested, and a daytime phone number.

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 submit your application and notify the QA/RA Office that you have completed the certificates by these deadlines:

Jan 15th for certificates earned in the previous fall semester

May 15th for certificates earned in the previous spring semester

Aug 20th for certificates earned during the summer semesters

If you miss the deadline, you will need to wait until the next processing period.

It takes the QA/RA approximately 6 weeks to process certificates. If you have not received your certificate by Feb 28th, June 30th, or Sept 30th, please contact the QA/RA Office.

REQUIRED COURSES

Students must complete the following two courses:

5459. Drug Development (3 credits)

This course studies the drug development process from discovery through FDA marketing approval. It reviews the process of drug development and the interrelationships linking the various disciplines, introducing students to the regulations governing the process, including interactions with FDA, ICH, and other regulatory agencies.

5472. Pharmaceutical Marketing (3 credits)

This course describes the marketing dynamics of the healthcare industry and the ways in which pharmaceutical companies can better meet the changing needs of patients and

managed care. Focusing on individual marketing techniques, it stresses the development of multidisciplinary marketing teams. The product attributes discussed in the selling process are efficacy, safety, cost effectiveness, compliance, and treatment outcomes.

ELECTIVE COURSES

Students must complete two of the following courses:

5408. Pharmacoeconomics (3 credits)

The economic methodologies used to evaluate the cost effectiveness of drug therapy are reviewed. Cost effectiveness is examined in terms of outcome assessment and quality of life measurements. The course explores the dynamic environment of health care and the process of drug product selection in managed care.

5494. IND/NDA Submissions (3 credits.)

Prerequisites: Drug Development (Pharmaceutics 5459) or Food and Drug Law I (Pharmaceutics 5592)

This course covers the development of IND and NDA submissions for FDA review. The major emphasis is directed toward developing an understanding of the philosophies and requirements FDA imposes on data submitted to support INDs and NDAs. It covers the process of producing INDs and NDAs (managing the teams, producing the submission, using electronic media) and emphasizes how to work with FDA to gain approval of a submission. FDA meetings, advisory panel hearings, appeals, strategies for review and approval of NDAs, use of Orphan Drug status, and the various avenues for expedited review are discussed.

5533. Requirements for Product Labeling and Advertising (3 credits)

Prerequisite: Pharmaceutics 592 or permission of the instructor.

This course examines strategies for creating drug labeling during new product development, for updating existing product labeling, and for creating “harmonized” core data sheets for products marketed globally. Students gain insight and awareness of current trends in advertising and promotional regulation.

5592. Food and Drug Law I (3 credits)

This course studies the governance of intra- and interstate commerce in foods, drugs, cosmetics, and medical devices and the effects of the Federal Food, Drug and Cosmetic Act upon research, manufacture, marketing, and distribution of drugs.

5615. Project Management for Pharmaceutical Professionals (3 credits)

Prerequisite: Pharmaceutics 5459 and completion of at least two other Pharmaceutics courses.

This course discusses the strategic positioning of drugs, specifically focusing on domestic and international registration strategies. It explores why a company seeks a particular indication in labeling and how RA/QA professionals play a critical role in understanding and developing regulatory intelligences. It covers how project teams should be created, including the effective clarification of roles and responsibilities, so regulatory timeliness

can be achieved. Workshops include an overview of project planning tools, techniques and critical path management, including negotiating registration strategies with the FDA and foreign agencies.

QUESTIONS AND ANSWERS

Where is the QA/RA program offered?

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

http://www.temple.edu/pharmacy_QARA/map.htm

When can I start the program?

Courses in the QARA 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?

We recommend you start by taking *Drug Development* (Pharmaceutics 5459), since this course provide an overview of the pharmaceutical industry and serve as the foundation of knowledge for the program. You may take the remaining courses in any sequence.

How do I obtain a current class schedule?

Please check the QA/RA homepage:

http://www.temple.edu/pharmacy_qara/schedule.htm

How do I register for classes?

Please download the Registration and State Residency Forms from the QA/RA homepage (http://www.temple.edu/pharmacy_QARA/forms.htm). Both are required the first time you register. Fax-in and e-mail registrations do not guarantee your spot in a class, since sections do fill quickly. We will contact you immediately if there are problems with your registration. Otherwise you will receive a paperless bill on Temple's OWLnet System which is your confirmation that you are officially registered.

Do I need to submit GRE scores to complete the certificate?

No. GRE scores are not required for this Certificate.

When should I indicate that I plan to pursue the certificate?

You do not need to submit an application form to start taking courses. In fact, you may simply complete the four required courses and then submit your application. If you intend to pursue the MS, however, it is important that you apply to the MS program by the end of your third course. Otherwise subsequent coursework may not be credited towards your MS degree.

Can I complete both the *Certificate in Basic Pharmaceutical Development* and the *Master's Degree in QA/RA*?

Yes! You're welcome to complete both programs, but please be aware that the Master's Degree in QA/RA has an entirely different application process and requires GREs. For

additional information on the Master of Science in QA/RA, please request a Program Guide and an application form by calling 267.468.8560.

Can I transfer any credits from another graduate institution towards the *Certificate in Basic Pharmaceutical Development*?

Sorry, but since our QA/RA program is unique, credits for courses taken at other institutions are not accepted. All four courses must be from Temple University's QA/RA program. It is possible to have a requirement waived; however, another *approved* QA/RA elective will have to be taken in its place.

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

No. You must formally apply for the certificate. This consists of submitting: 1) the application form, and 2) copies of all undergraduate and graduate transcripts from any schools previously attended.

When you have finished your courses, you must submit a notice of completion by mail or fax (267.468.8565) indicating that you are eligible to receive the certificate. It must include your name, TUID, courses completed, daytime phone number, and the certificate you have earned. The notice of completion must be submitted by the stipulated semester deadlines (Jan 15th, May 15th, Aug 20th). Otherwise you will need to wait until the next processing period.

Is there a deadline for completing the courses?

You should complete *Certificate in Basic Pharmaceutical Development* within three years. If you need an extension, please email qara@temple.edu.

Can I complete two certificates in Temple's QA/RA program?

Temple's QA/RA program now offers certificates in seven specialties. Students may complete only one certificate before pursuing the MS in QA/RA; however, you are welcome to earn additional certificates after earning the MS in QA/RA. Thus, if you prefer to earn the *Certificate in Basic Pharmaceutical Development* before completing the MS, you may subsequently earn the *Post-Master's Certificate in Global Biopharmaceuticals and Generic Drugs* (or another post-master's certificate) after earning the MS. Courses may only be counted towards one certificate. Please refer to our homepage for more details: www.temple.edu/pharmacy_QARA/certificates.htm

**For additional information:
QA/RA Graduate Program
Temple University School of Pharmacy
425 Commerce Drive, Suite 175
Fort Washington, PA 19034-2713**

**Voice: 267.468.8560
Fax: 267.468.8565
E-mail: QARA@temple.edu
www.temple.edu/pharmacy_QARA**