

 <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 in the pharmaceutical industry but need additional training in its terminology, concepts, and regulatory milieu. The *Certificate in Basic Pharmaceutical Development* program exposes students to these ideas and enables them to receive a certificate upon completing specific requirements.

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.

The *Certificate in Basic Pharmaceutical Development* is specifically designed for anyone who needs an overview of the drug development process or aspires to pursue a career in the pharmaceutical industry without pursuing an advanced degree in the sciences. This certificate enables students to explore quality assurance and regulatory affairs as a prospective career path without committing to the entire master's degree. The certificate provides the tools and information needed to understand the basis of new drug discovery, the Federal Food, Drug, and Cosmetic Act, and business practices, as they specifically relate to the pharmaceutical industry.

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. To earn the certificate, the following four courses must be successfully completed within a three year period with an overall B (3.0) average:

Drug Development (Pharmaceutics 5459)

Pharmaceutical Marketing (Pharmaceutics 5472)

PLUS 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)

- To be considered for the ***Certificate in Basic Pharmaceutical Development***, candidates must have a business or non-science degree from an accredited U.S. 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. (Official transcripts are not required.)

These items must be submitted by mail 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 send a fax to the QA/RA Office (267.468.8565) indicating that they have completed the required courses. The fax must include the student's name, TUID, courses completed, certificate being requested, and a daytime phone number.

Course Descriptions

REQUIRED 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

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 & 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 to receive the certificate. This consists of submitting the application form and copies of all undergraduate and graduate transcripts from any schools previously attended. You should complete *Certificate in Basic Pharmaceutical Development* 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.

Can I complete both the *Certificate in Basic Pharmaceutical Development* and another QA/RA certificate?

Students may only complete one certificate program before pursuing the MS in QA/RA.

For more information, or to receive an application, call 267.468.8560.

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