

## **BASIC PHARMACEUTICAL DEVELOPMENT CERTIFICATE**

*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 *Basic Pharmaceutical Development Certificate* 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 of science degree. 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 five decades, the School of Pharmacy of Temple University has provided outstanding graduate-level course work in Regulatory Affairs (RA) and Quality Assurance (QA). 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 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. More than 60 courses are offered online in real time.

This certificate may also be pursued entirely online.

### **ACADEMIC REQUIREMENTS**

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

**There are two required courses:**

- **Drug Development** (5459)
- **Pharmaceutical Marketing** (5472)

*Students should start the program with **Drug Development**.*

**In addition, students must select two of the following:**

- **Pharmacoeconomics** (5408)
- **IND/NDA Submissions** (5495)
- **Requirements for Product Labeling & Advertising** (5533)
- **Food and Drug Law** (5592)
- **Project Management for Pharmaceutical Professionals** (5615)

2. To be considered for the ***Basic Pharmaceutical Development Certificate***, candidates must have a degree from an accredited institution of higher learning. (A science degree is not mandatory.)

3. All courses must be completed from Temple University's RAQA 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 RAQA 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.

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

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

7. Students interested in pursuing the MS in RAQA may apply all credits earned in the ***Basic Pharmaceutical Development Certificate*** 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 Regulatory Affairs and Quality Assurance. The ***Basic Pharmaceutical Development Certificate*** does not require the completion of GREs or GMATs. To earn the ***Basic Pharmaceutical Development Certificate***, students must successfully complete the four required courses with an overall B (3.0) average and formally apply for the certificate. To receive the certificate and letter of completion, the following must be submitted:

- The **Application Form**.

- Photocopies of all undergraduate and graduate transcripts from any schools previously attended, including Temple's RAQA program. (Copies of transcripts are acceptable. Official transcripts are not required.)
- The **Notice of Completion**.

These items must be mailed to:

Temple University School of Pharmacy  
 Regulatory Affairs and Quality Assurance Graduate Program  
 425 Commerce Drive, Suite 175  
 Fort Washington, PA 19034

Certificates are not automatically conferred when students complete the required courses. Students must formally apply and must also forward the **Notice of Completion** by mail or fax to the RAQA Office (267.468.8565) indicating that they have finished the required courses.

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 **Application Form**, transcripts, and **Notice of Completion** 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.

### **REQUIRED COURSES**

**Two courses are required:**

#### **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.

### **5495. IND/NDA Submissions (3 credits.)**

*Prerequisites: Drug Development (5459) or Food and Drug Law (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: Food and Drug Law (5592) 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 (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: Drug Development (5459), Food and Drug Law (5592) 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 and 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 RAQA program offered?**

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

[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.

This certificate may be pursued entirely online.

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

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?**

We recommend you start by taking **Drug Development** (5459), since it provides an overview of the pharmaceutical industry and serves as the foundation of knowledge for the program. You may take the remaining courses 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 check the Schedule link on the RAQA homepage:

[www.temple.edu/pharmacy\\_qara](http://www.temple.edu/pharmacy_qara)

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

Please 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. The RAQA Office will send a confirmation when you are officially registered. You will also receive a notice via your TUmial account when your tuition statement is available, including the payment due date. Please make sure that you pay your bill by the due date, so you do not incur a late fee.

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

No. GRE scores are not required for this Certificate or for the MS in RAQA.

### **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 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 *Basic Pharmaceutical Development Certificate* and the Master's Degree in RAQA?**

Yes! You're welcome to complete both programs, but please be aware that the Master of Science in RAQA has an entirely different application process. For additional information on the Master of Science in RAQA, please request a **Program Guide** and an **Application for Graduate Study** by calling 267.468.8560.

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

Sorry, but since our RAQA program is unique, credits for courses taken at other institutions are not accepted. All four courses must be from Temple University's RAQA program. It is possible to have a requirement waived; however, another *approved* RAQA elective will have to be taken in its place. To waive a course, please submit a letter to the Assistant Dean for approval, before you start the certificate.

**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 the **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 15, May 15, Aug 20). Otherwise you will need to wait until the next processing period.

**Is there a deadline for completing the courses?**

You should complete the *Certificate in Basic Pharmaceutical Development* within three years. If you need an extension, please email [QARA@temple.edu](mailto:QARA@temple.edu).

**Can I complete two certificates in Temple's RAQA program?**

Temple's RAQA program now offers certificates in eleven specialties. Students may complete only one certificate before pursuing the MS in RAQA; however, you are welcome to earn additional certificates after earning the MS in RAQA. Courses may only be counted towards one certificate. Please refer to our homepage for more details: [www.temple.edu/pharmacy\\_QARA/certificates.htm](http://www.temple.edu/pharmacy_QARA/certificates.htm).

**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)**