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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DRUG DEVELOPMENT CERTIFICATE

An Overview of the Drug Development Process and the Language of the Pharmaceutical Industry

BACKGROUND

Regulations governing the pharmaceutical industry at the state, federal, and global levels continue to expand and change. Quality assurance principles are the core of pharmaceutical discovery, manufacturing, clinical trials, and validation processes. Familiarity with the latest trends and current practices in Regulatory Affairs is critical to any industry professional's success.

The ***Drug Development Certificate*** is specifically designed for pharmaceutical and healthcare professionals who actively contribute to the drug development process or aspire to pursue a career in the pharmaceutical industry. 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 for new drug discovery, the Federal Food, Drug, and Cosmetic Act, and good pharmaceutical practices as they apply to the clinical, laboratory or manufacturing components of the drug development process.

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 first 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.

The RAQA master's program is based in Fort Washington, PA. Courses can also be videoconferenced to corporate sites. Classes are conveniently scheduled on evenings and weekends to provide flexibility for working professionals. The ***Drug Development Certificate*** is also offered in a synchronous online format. To receive the certificate, candidates must complete the required courses and application procedures.

ACADEMIC REQUIREMENTS

1. The ***Drug Development Certificate*** may be earned on its own or on the way to the MS in RAQA. 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 (5459)
- Food and Drug Law (5592)
- **One Good Practices course – either**
  Good Laboratory Practices (5476) **or**
  Good Manufacturing Practices (5477) **or**
  Advanced GMPs – Defining "c" (5479) **or**
  Good Clinical Practices (5536)
- **One elective from Temple's RAQA program**

Students should take Drug Development or Food and Drug Law before other courses.

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

3. Candidates must formally apply and follow the application procedures stated below.

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

5. The certificate must be completed within three years. Students must apply for the certificate no more than one year after completing the course requirements.

5. Students interested in pursuing the RAQA MS program may apply all credits earned in the ***Drug 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

The ***Drug Development Certificate*** is part of Temple University's graduate program in Regulatory Affairs and Quality Assurance. It does not require the completion of GREs. To earn the ***Drug Development Certificate***, 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:

- 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** (available on the RAQA website) either by mail or fax (267.468.8565) to the RAQA Office 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 your application and notify the RAQA Office that you have completed the required courses 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 will need to 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

Students must complete the following four 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.

5592. Food and Drug Law (3 credits)
This course examines the governance of intrastate 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.

One of the following four GXP courses:
5476. Good Laboratory Practices (3 credits)
This course explores the regulatory and quality assurance issues pertinent to pre-clinical safety research. Research study design and processes will be analyzed in the sciences of pharmacology, toxicology, carcinogenicity, and reproductive toxicology. In addition, some time will be devoted to mutagenicity and pharmacokinetics. These studies will be discussed in the context of developing a safety profile and determining the potential risk to humans in subsequent clinical trials.

OR

5477. Current Good Manufacturing Practices (3 credits)

This course studies the current Good Manufacturing Practices regulations under the Federal Food, Drug, and Cosmetic Act for drugs and their implication for personnel, buildings, equipment and records; including a study of pertinent legal decisions and regulatory actions.

OR

5479. Advanced GMPs – Defining "c" (3 credits)

Prerequisite: Good Manufacturing Practices (5477). Students with five or more years of GMP experience may petition the School to complete Advanced GMPs instead of GMPs (5477).

This course brings students from the basic GMP concepts presented in Pharmaceutics 5477 to a fuller understanding of the concepts of current good manufacturing practices. Discussions include how to evaluate FDA 483s and Warning Letters, the routine review of periodicals, including the *Pink Sheet*, *Gold Sheet*, and other GMP-oriented documents, and how to evaluate information provided by the FDA. Recalls are discussed.

OR

5536. Good Clinical Practices (3 credits)

This course examines the federal regulatory requirements and processes necessary to conduct valid drug trials on human volunteers. Emphasis is placed on managing the clinical drug study and auditing its processes and generated data. The course also addresses ethical issues and volunteer informed consent.

Students must also complete:

One Pharmaceutical RAQA elective (3 credits)

For a current list of accepted elective courses, please refer to our website:
http://www.temple.edu/pharmacy_qara/courses-electives.htm

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:
http://www.temple.edu/pharmacy_qara/map.htm
Courses can be videoconferenced to corporate sites. Over 60 courses are also available online in real time.

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) or **Food and Drug Law** (5592), since these courses 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.

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 electives when they are scheduled or to write to the RAQA Office if they wish to see an elective scheduled in a particular semester.

How do I obtain a current class schedule?
Please check the RAQA homepage: http://www.temple.edu/pharmacy_qara

How do I register for classes?
Please download the Registration and State Residency Forms from the RAQA homepage: http://www.temple.edu/pharmacy_QARA/forms.htm

Both are required the first time you register. Faxed and electronic registrations do not guarantee your spot in a class, since sections fill quickly. We will contact you immediately 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 TUmail 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 the MS in RAQA.

When should I indicate that I plan to pursue the certificate?
You do not need to submit an application 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 complete your application to the MS by the end of your third course, so that all of your coursework applies to your degree.

Can I complete both the *Drug Development Certificate* and the Master's Degree in RAQA?
Yes! You're welcome to complete both programs, but please be aware that the MS in RAQA has an entirely different application process. For additional information on the Master of Science in RAQA, please request an information packet and an application by calling 267.468.8560.

Can I transfer any credits from another graduate institution towards the *Drug Development Certificate*?
Sorry, but 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* Temple University RAQA elective will have to be taken in its place. To receive approval to waive a course, please submit a letter to the Assistant Dean of RAQA before pursuing the certificate.

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: 1) the **Application Form**, and 2) copies of 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 certificate you have completed. You must submit this information by the stipulated deadline (Jan 15, May 15, or Aug 20). Otherwise you will have to wait until the next time they are processed.

Is there a deadline for completing the courses?
You should complete the ***Drug Development Certificate*** within three years. If you need an extension, please email 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. Thus, if you prefer to earn the ***Drug Development Certificate*** before completing the MS, you may subsequently earn the ***Post-Master's Certificate in Global Biosimilars 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

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