

POST-MASTER'S CERTIFICATE IN GENERIC DRUGS

*A specialized certificate for professionals
in the generic product industry*

BACKGROUND

The *Post-Master's Certificate in Generic Drugs* allows RAQA graduates to pursue additional RAQA coursework beyond the MS and receive formal recognition for their work. The Certificate is also open to professionals with other master's or doctoral degrees with industry experience, who wish to learn more about the issues are unique to generic drug manufacturers, as well as the regulatory concepts and issues that are critical for safe and effective bioequivalent products.

This specialized curriculum delves into domestic and global regulations for generic product. Starting with an overview of the drug development process, courses explore the global marketplace for generic drugs, building a strong foundation in generic regulatory issues, including the ANDA process. Students learn the key trends and controversies facing the generic industry as well as how generic drugs are manufactured and regulated nationally and globally.

The *Post-Master's Certificate in Generic Drugs* enables students to sharpen their knowledge of this industry niche without committing to the entire master's degree.

For over five decades, the School of Pharmacy of Temple University has provided outstanding graduate-level course work in Regulatory Affairs and Quality Assurance (RAQA). The School was the world's first institution of higher learning to create a master's program in the RA and QA disciplines and continues to offer a comprehensive curriculum in these areas facing the regulated industries of pharmaceuticals, medical devices, and biopharmaceuticals.

Temple's 80+ RAQA courses integrate law and regulation, pharmaceutical science and technology, and quality assurance practices. Faculty are industry and FDA experts, who share their knowledge through interactive courses, which include time discussions of current issues and hands-on workshops.

Temple's RAQA graduate program is based in Fort Washington, PA. Courses are scheduled on evenings and weekends for working professionals. Students may attend courses on-campus or online. The *Post-Master's Certificate in Generic Drugs* may be completed entirely online.

To receive the certificate, candidates must complete the required courses and application procedures.

LEARNING OBJECTIVES

Students completing the Certificate will become familiar with:

- Domestic and global regulations for generic products;
- The competitive environment for generic products;
- Manufacturing science and quality practices.

ACADEMIC REQUIREMENTS

To pursue this Certificate, students must have a master's degree or higher in science, such as Biology, Chemistry, Engineering, Pharmacy, Physics, RAQA, or related fields from an accredited institution of higher learning.

In addition, students need a basic knowledge of pharmaceutical manufacturing processes, such as completion of *Good Manufacturing Practices* (5477) or *Advanced GMPs – defining “c”* (5479).

1. The ***Post-Master's Certificate in Generic Drugs*** may be earned on its own or on the way to the MS in RAQA. To earn the certificate, five courses must be successfully completed within a four year period with an overall B (3.0) average.

There are two required courses:

- **Drug Development** (5459)
- **Generic Drug Regulation: ANDAs** (5473)

If students already completed these courses as part of the MS in RAQA, they may substitute electives from the list below.

Students must also complete three electives from the following:

- **The Global Biopharmaceutical Industry** (5458)
- **Validation of FUE (Facilities, Utilities, and Equipment)** (5468)
- **Drug Dosage Forms** (5499) or **Solid Dosage Forms – Small Molecules** (8004)
- **Active Pharmaceutical Ingredients (APIs)** (5513)
- **Regulatory eSubmissions** (5514)
- **Good Distribution Practices** (Pharmaceutics 5543)
- **Global Pharmaceutical Excipient Regulation** (5546)
- **Pharmaceutical Quality Management Systems** (5574)
- **Global CMC Issues and Regulatory Dossiers** (5576)
- **Analytical Chemistry in Pharmaceutical Laboratories** (5655)
- **Special Topics: Current Issues Affecting the Generic Drug Industry** (5650)

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 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. The *Post-Master's Certificate in Generic Drugs* must be completed within four years. Students must apply for the certificate within one year of completing all required coursework for the program.

6. Students interested in pursuing the RAQA MS program may apply all credits earned from the *Post-Master's Certificate in Generic Drugs* 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 *Post-Master's Certificate in Generic Drugs* is part of Temple University's graduate program in Regulatory Affairs and Quality Assurance (RAQA). It does not require the completion of GREs, but students pursuing it must have a master's degree or higher from an accredited institution of higher learning. To earn the *Post-Master's Certificate in Generic Drugs*, students must successfully complete the five 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:

- **Application Form**
- Photocopies of all undergraduate and graduate transcripts from any schools previously attended, including Temple's RAQA program. (Photocopies of transcripts are acceptable. Official transcripts are not required.)
- **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 a **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 the certificate in one of those months, students 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 semester

Students who miss the deadline must wait until the next processing period. It takes the RAQA Office approximately 6 weeks to process certificates. Certificates processed in Jan should be received by Feb 28; those processed in May should be received by June 30, and those processed in Aug should be received by Sept 30. If there are problems, please contact the RAQA Office.

DESCRIPTIONS OF 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 development and the interrelationships linking the various disciplines, introducing students to regulations governing the process, including the interactions with FDA, ICH, and other regulatory agencies.

5473. Generic Drug Regulation: ANDAs (3 credits)

Prerequisite: Drug Development (5459).

When marketing exclusivity or the patent for a drug product expires, or the courts rule that the patent is not valid, other manufacturers can gain approval to market and sell a similar product. The manufacturers of these generic forms may obtain FDA approval based on an Abbreviated New Drug Application (ANDA), which documents the bioequivalence of their product to the pioneer brand product. This course reviews specific case studies of generic drug product approvals using ANDA regulations and court decisions. It provides an understanding of the current regulatory environment for generic drugs and introduces students to the problems and situations that are unique to this industry. A review of generic product categories (authorized generics, generic biosimilars, generic vaccines) includes different approaches used to develop generic products, explaining terms such as a Paragraph IV filing. After discussing the interaction between generic drug companies and the FDA, foreign market regulations for generic drugs will be studied, covering global generic markets in Europe, Asia, South America, and other selected jurisdictions. Post-marketing regulation and pharmacovigilance will also be included.

ELECTIVE COURSES:

Students must complete three courses from this group:

5458. The Global Biopharmaceutical Industry (3 credits)

Prerequisite: Drug Development (5459).

What social and economic factors contributed to the development of innovator and generic pharmaceutical companies, and what are their current and future trends? This course introduces students to the basic structure of the industry, examining the growth

and relationships among various sectors, including the fully-integrated companies of big pharma, generic and biotech industries, and specialty and service companies, such as CROs and CMOs. Social, political, demographic, economic, and technological influences will be examined not only in the US domestic market, but also across major world economies, including the differences between national health and single-payer systems. A segment of the course focuses on the impact of the Waxman-Hatch Act on drug price competition and patent term restoration.

5468. Validation of FUE (Facilities, Utilities and Equipment)

Prerequisite: Good Manufacturing Practices (5477) or appropriate industry experience in GMPs.

The production of FDA regulated products (pharmaceutical, medical device, food, etc.) is highly dependent on both the initial qualification of facilities, utilities, and equipment (FUE) along with the ongoing efforts to maintain the qualified/validated state by meeting current user and regulatory needs. This course focuses on the key validation elements specific to qualifying and validating facilities, utilities, and equipment. In practice, validation of these items is also a prerequisite for other validation efforts including process, cleaning and test method. The class will examine the key concepts of FUE qualification/validation as well as the life-cycle through retirement of the FUE.

5499. Drug Dosage Forms

Prerequisite: strong science background.

Through an overview of drug dosage form design and manufacturing technology, principles of pharmaceutical processing and pharmaceutical dosage form design (including preformulation and biopharmaceutics) are discussed, including dosage forms such as tablets, capsules, modified dosage forms, semi-solid products, and transdermal delivery systems.

OR

8004. Solid Dosage Forms – Small Molecules

This course presents processing and principles that apply to solid dosage form design and product development. Conventional and specific techniques of industrial pharmacy, including direct compression, wet and dry granulation, fluid bed and coating operations, tableting machine instrumentation and compactibility measurements, and solid product evaluations are presented. Novel oral dosage forms and technologies associated with solid products as well as product quality and performance assessment are covered.

Not open to students who have taken Pharmaceutics 407.

5513. Active Pharmaceutical Ingredients (APIs)

Prerequisite: Drug Development (5459).

This course will provide a working background on active pharmaceutical ingredients as used in pharmaceutical dosage forms with areas of focus on the development, manufacturing and global regulations that impact successful marketing approval of products. The course will primarily focus on small molecule synthetic API's with biologics being out of scope.

5514. Regulatory eSubmissions

Prerequisite: Drug Development (5459) and IND/NDA Submissions (5495) are suggested. Students who have not taken these courses should submit a resume which indicates industry experience.

This course will explore the evolution of global regulatory submissions from the original paper format to the current electronic common technical document (eCTD) and non-eCTD electronic submissions (NeeS). This course will primarily focus on current regulations, tools, and specifications associated with electronic submissions and electronic requirements of included documentation.

5543. Good Distribution Practices (GDPs) (3 credits)

Students will study the organizational, managerial and technology issues related to the supply chain, logistics, and distribution functions of the pharmaceutical industry, particularly generic pharmaceuticals. They will be introduced to the tools and technologies that companies use to optimize their supply chain, logistics, and distribution functions, with specific emphasis on how generic companies configure and operate these aspects. Topics include: anticipatory and response-based systems; postponement; technology; cash flow effects; lean logistics; warehousing; inventory flow; carrying costs; information flow; customer delivery and service expectations; service reliability; supply chain integration with distributors, drug wholesalers and other channel members; managing demand timing and uncertainty; transportation; and regulatory and compliance considerations.

5546. Global Pharmaceutical Excipient Regulation (3 credits)

An integral part of almost all pharmaceutical dosage forms, excipients play an important role in drug development. This course discusses the function of excipients, providing an in-depth examination of their unique yet globally diverse regulatory requirements in major world markets. Excipient selection, assessment, and supplier qualifications will be discussed, as well as Adverse Events (AEs) related to excipient quality. This course stresses how global pharmaceutical excipient regulation is critical in developing formulations that have the potential for international approvals.

5574. Pharmaceutical Quality Management Systems

Prerequisites Drug Development (5459)

This course provides a detailed overview of Pharmaceutical Quality Management Systems through evaluating federal regulations and guidelines. Emphasis is placed on the development and management of total Quality Systems that meet regulatory expectations. Topics covered include the development, management, usage and maintenance of Standard Operating Procedures (SOPs), Deviation/Non-conformance Systems, Corrective and Preventative Action Systems, Supplier Management Systems, Change Management Systems, Validation, and Process controls via Key Performance Indicators. Focus is placed on the key areas for inspection readiness and robust Quality Systems development. Current guidelines in Pharmaceutical Quality Systems, including Q10, are evaluated. This course presents a total Quality Management Systems approach to the pharmaceutical industry, including traditional pharma (small molecule), biologics, and medical devices.

5576. Global CMC Issues and Regulatory Dossiers

This course provides students with an in-depth knowledge of the major chemistry, manufacturing, and controls (CMC) issues facing the global pharmaceutical industry. Students learn the practical and theoretical skills necessary to develop successful CMC dossiers from the initial clinical application through marketing and post-marketing support. The class emphasizes long range CMC planning to combine technical and regulatory knowledge with strategic thinking. The class is designed for regulatory professionals, managers, and scientists with significant responsibility for CMC dossiers.

5655. Analytical Chemistry in Pharmaceutical Laboratories (3 credits)

Prerequisite: Drug Development (5459). Students are expected to have some laboratory background in chemistry or related science and familiarity with laboratory practices.

Analytical chemistry plays a critical role in the development of pharmaceutical products. An effective laboratory system ensures that quality data is generated for the release of raw materials and finished products. An analytical chemist develops methods, evaluates data, reports results, and writes development findings according to regulation and compliance standards. This course provides an overview of the laboratory operations and the critical role of an analytical scientist. It introduces several regulatory requirements for lab operations in the industry and provides a framework for a quality laboratory supporting drug development process. Although this course is designed for pharmaceutical scientists, many operations discussed are also applicable to the chemical and environmental industries.

565. Special Topics: Current Topics Affecting the Generic Drug Industry (3 credits)

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. Courses are available on-campus and online in real time. It is possible to complete this certificate 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?

You should start by taking **Drug Development (5459)** and then **Generic Drug Regulation – ANDAs (5473)**. The remaining courses may be taken in any order.

How do I obtain a current class schedule?

See our website: pharmacy.temple.edu/RAQA

How do I register for classes?

Please download the Registration and State Residency Forms from the RAQA website:
pharmacy.temple.edu/RAQA

Both forms 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 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 or other advanced test 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 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 as soon as possible, so all of your coursework applies to your degree.

Can I complete both the *Post Master's Certificate in Generic Drugs* and the MS in RAQA?

Yes! You're welcome to complete both programs, but please be aware that the MS in RAQA has a different application process. For additional information on the Master's 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 *Post-master's Certificate in Generic Drugs*?

Sorry, but credits for courses taken at other institutions are not accepted. All five 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 waive a course, please submit a letter to the Assistant Dean for approval.

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

No. You must formally apply to receive the certificate, which includes submitting the **Application Form**, copies of undergraduate and graduate transcripts, and the **Notice of Completion**. You should complete the *Post-Master's Certificate in Generic Drugs* within four years.

When you have finished your courses, you must submit the **Notice of Completion** to the RAQA Office by mail or email (QARAREG@temple.edu). You must submit your **Application Form**, transcripts, and **Notice of Completion** 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 *Post Master's Certificate in Generic Drugs* within four years. If you need an extension, please email qara@temple.edu.

Can I complete two certificates in Temple's MS program?

Temple's RAQA program offers certificates in several specialties. Students may complete one certificate before pursuing the MS in RAQA; however, you are welcome to earn additional certificates after earning the MS in RAQA. For more details, visit: pharmacy.temple.edu/RAQA.

For additional information:

**Temple University School of Pharmacy
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