

 <p>School of Pharmacy TEMPLE UNIVERSITY</p> <p>Quality Assurance/Regulatory Affairs <small>Graduate Program</small></p>	<p>Temple University - School of Pharmacy 425 Commerce Drive, Suite 175 Fort Washington, PA 19034-2713</p> <p>Phone: 267.468.8560 Fax: 267.468.8565</p>
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CERTIFICATE IN BIOPHARMACEUTICALS and GENERIC DRUGS

*Temple offers the first specialized certificate for professionals
in the generic and biopharmaceutical industry*

BACKGROUND

What issues are unique to generic drug manufacturers? How can companies best manufacture and distribute their products when competition for generic counterparts continues to expand due to interest and pressure from consumers and insurance companies for less expensive alternatives? What regulatory issues are critical for generic industry professionals to understand, so they can help companies create safe and effective bioequivalents? Find out the answers by pursuing the *Certificate in Biopharmaceuticals and Generic Drugs*.

This specialized curriculum delves into four key areas: the global business environment, domestic and global regulations for generic products, manufacturing science, and good distribution practices. Starting with an overview of the drug development process, the certificate explores the global marketplace for generic drugs and biopharmaceuticals, building a strong foundation in generic regulatory issues, including the ANDA process and distribution practices used domestically and worldwide. The courses also expose students to key trends and controversies facing the generic industry: GIVE (Generic Initiative for Value and Efficiency), Citizen's Petitions, and Authorized Generics.

The *Certificate in Biopharmaceuticals and Generic Drugs* enables students to sharpen their knowledge of this industry niche without committing to the entire master's degree. This certificate provides the tools and information to understand how generic drugs are manufactured and regulated locally, nationally, and globally. Focus is also placed on the unique dynamics of generic drug distribution throughout the world.

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

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

ACADEMIC REQUIREMENTS

1. The ***Certificate in Biopharmaceuticals and Generic Drugs*** may be earned on its own or on the way to the MS in QA/RA. To earn the certificate, the following 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 (Pharmaceutics 5459)

Generic Drug Regulation: ANDAs (Pharmaceutics 5473)

PLUS students must complete three electives from the following:

The Global Biopharmaceutical Industry (including Waxman Hatch)
(Pharmaceutics 5458)

Pharmaceutical Manufacturing II (Pharmaceutics 8004)

Good Distribution Practices (Pharmaceutics 5543)

Biologics/Biosimilars: A Regulatory Overview (Pharmaceutics 5515)

Global Pharmaceutical Excipient Regulation (Pharmaceutics 5546)

The Analytical Laboratory

Students should start the program with *Drug Development*.

2. To be considered for the Certificate in Biopharmaceuticals and Generic Drugs, candidates must have a bachelor's 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 may be earned before students receive the MS.
6. The ***Certificate in Biopharmaceuticals and 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 QA/RA MS program may apply all credits earned from the *Certificate in Biopharmaceuticals and 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 *Certificate in Biopharmaceuticals and Generic Drugs* is part of Temple University's graduate program in Quality Assurance and Regulatory Affairs. It does not require the completion of GREs. To earn the *Certificate in Biopharmaceuticals and Generic Drugs*, 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 19034.

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.

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 biopharmaceuticals, 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 (including the Waxman-Hatch Act)* (3 credits)

Prerequisite: Drug Development (Pharmaceutics 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 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.

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, and carrying costs. Also covered will be 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.

5515. *Biologics/Biosimilars: A Regulatory Overview* (3 credits)

Prerequisites: Drug Development (Pharmaceutics 5459). Food and Drug Law I (Pharmaceutics 5592) is also suggested. Students are expected to have a strong science background, including familiarity with undergraduate chemistry & biology. An undergraduate course in general biochemistry is also recommended.

Since the first biopharmaceutical product approval in 1982 (recombinant human insulin), the biotechnology derived product market has been rapidly growing with introduction of a number of promising advances in medicine such as therapeutic monoclonal antibodies, cancer vaccines, cytokines, antisense technology, interference RNA, and growth factors. As with traditional drugs (small molecules), the regulatory framework for approval of a biotechnology derived product (biologics) is complicated. In addition, there has been much debate about the introduction of biosimilars using an abbreviated approval process. An overall biologics-based process map beginning with pre-clinical through the post-marketing stage will be discussed. Topics such as therapeutic proteins/peptides, gene therapy, stem cells, vaccines, interference RNAs, PK-PD, world-wide regulatory filings, pre-clinical IND-enabling studies, BLA/CTD filing, biosimilars/follow-on-biologics, selected case studies, immunogenicity, comparability studies, manufacturing challenges, clinical trials, market exclusivity, and related regulatory guidelines will be discussed.

8004. *Pharmaceutical Manufacturing II* (3 credits)

Prerequisite: familiarity with basic science.

Students are introduced to key concepts and practices of manufacturing in the generic industry, including the need to balance economic considerations with ethical and regulatory compliance requirements of safety, effectiveness, strength, quality, and purity of products manufactured by or for the company. Reviewing regulatory QC and GMP principles, this course covers basic formulation development and unit operations, including pharmaceutical chemical process technology, equipment, and procedures. Particle science and technology (mixing, powder flow) and dosage form design and manufacture will be discussed. While the main focus will be on solid dosage forms (powders, capsules, tablet manufacturing, coating operations), semisolids, liquids, aerosols, aseptic, and transdermal systems will also be discussed. Topics include chemical process technologies of API ingredients, simple solution systems, semi-solid dispersed systems, packaging operations, and the design of pharmaceutical facilities for US GMP and non-US manufacturing.

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.

The Analytical Laboratory (3 credits)

To be announced.

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

Courses are also offered in Tarrytown, NY, and Frazer, PA. Some corporate sites also videoconference our classes. Some classes are also available in an on-line format.

When can I start the program?

Courses in the QA/RA 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* (Pharmaceutics 5459), so you have a basic foundation of the pharmaceutical industry and its regulations. We then recommend you take *Generic Drug Regulation – ANDAs* (Pharmaceutics 5573), if available. The remaining courses may be taken in any order.

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. Faxed and e-mailed 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. Otherwise you will receive a paperless bill through your Temple email account which confirms 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 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 *Certificate in Biopharmaceuticals and Generic Drugs* and the MS in QA/RA?

Yes! You're welcome to complete both programs, but please be aware that the MS in QA/RA has an entirely different application process and requires GREs. For additional information on the Master's of Science in QA/RA, please request a Program Guide and an application by calling 267.468.8560.

Can I transfer any credits from another graduate institution towards the *Certificate in Biopharmaceuticals and Generic Drugs*?

Sorry, but 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* Temple University QA/RA elective will have to be taken in its place. To waive a course, please submit a letter to the Office of Graduate Studies 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 and copies of all undergraduate and graduate transcripts from any schools previously attended. You should complete the *Certificate in Biopharmaceuticals and Generic Drugs* 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 the certificate you have completed. You must submit your application and notice of completion by the stipulated deadline (Jan 15th, May 15th, or Aug 20th). 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 *Certificate in Biopharmaceuticals and 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 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 *Drug Development Certificate* 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 be counted towards one certificate only. Please refer to our homepage for more details: www.temple.edu/pharmacy_QARA/certificates.htm

For additional information:

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