

CERTIFICATE IN BIOSIMILARS and GENERIC DRUGS

Temple offers the first specialized regulatory certificate for professionals in the generic and biosimilars 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 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 their companies create safe and effective bioequivalents? Explore these issues as you pursue the *Certificate in Biosimilars 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 biosimilars, 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 Biosimilars 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 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 original institution of higher learning in the world to create a master's program in the Regulatory Affairs (RA) and Quality Assurance (QA) areas, 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 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. Over 60 courses are offered online in real time.

It is possible to complete the *Certificate in Biosimilars and Generic Drugs* entirely online.

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

ACADEMIC REQUIREMENTS

1. The *Certificate in Biosimilars and Generic Drugs* may be earned on its own or on the way to the MS in RAQA. 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** (5459)
- **Generic Drug Regulation: ANDAs** (5473)

PLUS students must complete three electives from the following:

- **The Global Biopharmaceutical Industry (including Waxman Hatch)** (5458)
- **Pharmaceutical Manufacturing II** (8004)
- **Good Distribution Practices** (5543)
- **Biologics/Biosimilars: A Regulatory Overview** (5515)
- **Global Pharmaceutical Excipient Regulation** (5546)
- **Global CMCs for Biologics** (5577)
- **Analytical Chemistry in Pharmaceutical Laboratories** (5655)

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

2. Students must have a bachelor's degree from an accredited institution of higher learning to earn the *Certificate in Biosimilars and Generic Drugs*.

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 may be earned before students receive the MS.

6. The *Certificate in Biosimilars 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.

7. Students interested in pursuing the RAQA MS program may apply all credits earned from the *Certificate in Biosimilars 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 Biosimilars and Generic Drugs* 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 *Certificate in Biosimilars and 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:

- An **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.)
- **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 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 semester

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.

SPECIAL NOTE:

The *Certificate in Biosimilars and Generic Drugs* will change in 2018. Students who formally apply to the certificate before November 2017 may complete the requirements stated in this brochure. Students applying after November 1, 2017 will be required to complete the new requirements (to be announced.)

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 (including the Waxman-Hatch Act) (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.

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

Prerequisites: Drug Development (5459) and Food and Drug Law (5592). Students are expected to have a strong science background, including familiarity with undergraduate chemistry and 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 the 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 include: 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.

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.

5577. Global CMCs for Biologics (3 credits)

This course provides students with an introduction to the CMCs (Chemistry, Manufacturing and Controls) involved in the development and licensure of biologic products (biosimilars, vaccines) in the U.S., Europe and other highly regulated regions.

Topics will be discussed from the perspective of Regulatory and QA requirements and expectations. Basic microbiology, cell biology and chemistry concepts will be reviewed with an emphasis on their practical application to product development and RA/QA. The class is designed to orient RA/QA professionals, managers and scientists responsible for biopharmaceutical CMC development and preparation of dossiers to the CMC content matter. The course will cover technical issues that must be addressed in biologic product development and registration. Topics include: adventitious agents testing; cell and seed bank testing methods and requirements; drug substance production via cell culture; protein and virus purification methods; control and analysis of process impurities; analytical methods and potency testing for characterization and release; strategy for specification setting for release and stability; and comparability studies for biologics.

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.

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 U.S. GMP and non-U.S. manufacturing.

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stated in this brochure. Students applying after November 1, 2016 will be required to complete the new requirements (to be announced.)

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

Courses can be videoconferenced to corporate sites. Courses are also available online in real time.

This certificate is available 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), so you have a basic foundation of the pharmaceutical industry and its regulations. We recommend you then take **Generic Drug Regulation–ANDAs** (5473), if available. Remaining courses may be taken in any order.

How do I obtain a current class schedule?

See our website: www.temple.edu/pharmacy_QARA

How do I register for classes?

Please download the Registration and State Residency Forms from the RAQA website:

www.temple.edu/pharmacy_QARA/forms.htm

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 *Certificate in Biosimilars and 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 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 *Certificate in Biosimilars and 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 all undergraduate and graduate transcripts from any schools attended, and the **Notice of Completion**. You should complete the *Certificate in Biosimilars and 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 fax (267.468.8565). 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 *Certificate in Biosimilars 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 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 Biosimilars and Generic Drugs* (or another post-master's certificate) after earning the MS. Courses may be counted towards one certificate only. For more details, visit:

www.temple.edu/pharmacy_QARA/certificates.htm

For additional information:

Temple University School of Pharmacy
Regulatory Affairs and Quality Assurance Graduate Program
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Fort Washington, PA 19034

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www.temple.edu/pharmacy_QARA