

POST-MASTER'S CERTIFICATE in BIOSIMILARS and GENERIC DRUGS

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

BACKGROUND

Temple University's School of Pharmacy continues to be the leader in providing world renowned graduate-level courses in Regulatory Affairs and Quality Assurance. As the program launches new programs, it recognizes that many graduates with the MS in RAQA wish to continue taking courses to keep current with industry issues and meet regulatory requirements for training. The *Post-Master's Certificate in Biosimilars and Generic Drugs* allows RAQA graduates to pursue additional coursework and receive formal recognition for their work. The certificate is also open to professionals with other master's or doctoral degrees.

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 *Post Master's 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 Quality Assurance (QA) and Regulatory Affairs (RA) disciplines and continues to offer the most comprehensive curriculum of its kind.

Temple's 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.

Candidates must formally apply for the *Post-Master's Certificate in Biosimilars and Generic Drugs* before registering for any courses. To receive the certificate, candidates must complete the required courses and application procedures. Students who completed master's degrees or higher from accredited US institutions of higher learning with extensive pharmaceutical industry experience may also petition the School to pursue the *Post-Master's Certificate in Biosimilars and Generic Drugs*, but will be required to complete five courses.

Temple's RAQA graduate program is based in Fort Washington, PA, with courses also offered in Frazer (PA). Courses can be videoconferenced to corporate sites. Classes are conveniently scheduled on evenings and weekends for working professionals. Courses are also offered online in real time.

This certificate may also be pursued entirely online.

APPLICATION PROCESS

Temple University Students:

Once you receive your MS from Temple, the University closes your academic file. If you wish to pursue the *Post Master's Certificate in Biosimilars and Generic Drugs*, you must formally apply, so we can reopen your file to register you. The application is available on the Certificates link of the RAQA website.

You will be required to take four courses relating to biosimilars and generic drugs to complete the Post Master's Certificate in this subject.

Please mail the application to:

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

Students with Advanced Science Degrees from Other Schools:

To apply for the *Post-Master's Certificate in Biosimilars and Generic Drugs*, you must meet the following criteria:

- 1) You must have received an advanced degree (master's level or higher) from an accredited institution of higher learning and must have worked in the pharmaceutical industry for a minimum of three years.
- 2) Please write a letter to the Assistant Dean (Temple University School of Pharmacy, RAQA Graduate Program, 425 Commerce Drive, Suite 175, Fort Washington, PA 19034), indicating which courses you wish to pursue and explaining your experience in the pharmaceutical industry. Include the Application for the *Post-Master's Certificate in Biosimilars and Generic Drugs*, a copy of your resume, and copies of transcripts from all undergraduate and graduate programs you have attended. Formal permission to pursue the *Post-*

Master's Certificate in Biopharmaceuticals and Generic Drugs must be received from the Assistant Dean before commencing any courses in the program.

- 3) Students with advanced degrees from other schools will be required to take five Temple University RAQA courses to receive the *Post-Master's Certificate in Biosimilars and Generic Drugs*. If the candidate subsequently decides to apply for the M.S. in Regulatory Affairs and Quality Assurance within five years, the credits earned in the *Post-Master's Certificate in Biosimilars and Generic Drugs* will count towards the master's degree, provided a grade of B or higher is earned in each course and the student is accepted into the M.S. program.

TO RECEIVE THE CERTIFICATE

After you have finished the required courses, fill out the **Notice of Completion** (available on the RAQA website) and forward it to the RAQA Office by fax (267.468.8565), email (qarareg@temple.edu), or hard copy.

The RAQA Office issues certificates in early February, June, and September. In order to receive your certificate in one of those months, you must notify the RAQA Office **at least one month in advance**. Otherwise you will have to wait until the next time they are processed. The certificate must be completed within four years. Transfer credits are not accepted towards the Post-Master's Certificate.

Courses Accepted for the Post-Master's Certificate in Biosimilars and Generic Drugs

To earn the certificate, four (for Temple U RAQA graduates) or five courses (for students with other advanced degrees) must be successfully completed within a four year period with an overall B (3.0) average:

- **Generic Drug Regulation: ANDAs** (5473)*
- **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)
- **Analytical Chemistry in Pharmaceutical Laboratories** (5655)
- **CMCs for Biologics** (5577)

*Students must take these courses, if they have not already done so. **Drug Development** (5459) is a prerequisite for **Generic Drug Regulation: ANDAs**.

QUESTIONS AND ANSWERS

Where is the RAQA Program Offered?

The 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 directly to corporate sites. Courses are also available online in real time.

This certificate may be completed entirely online.

When can I start the certificate?

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 starting this certificate with **Drug Development** (5459) or **The Global Biopharmaceutical Industry** (5458). **Drug Development** is a prerequisite for **Generic Drug Regulation: ANDAs** (5473). Unless courses have prerequisites, you may take the remaining courses in any sequence. Please be aware that several courses in this certificate require a strong science background.

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?

See the Schedule link on our website: www.temple.edu/pharmacy_QARA

How do I register for classes?

You must be formally admitted to the *Post-Master's Certificate in Biosimilars and Generic Drugs* before registering for any courses.

- If you received your MS from Temple, download the registration form from the RAQA homepage: http://www.temple.edu/pharmacy_QARA/forms.htm
You do not need to submit a state residency form, unless you have moved from one state to another.
- If you have not registered for Temple University RAQA courses before, 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. Fax, mail, and e-mail registrations do not guarantee your spot in a class, since sections do fill quickly. You will receive an email confirmation once you are registered and an electronic tuition bill through your Temple email account.

Do I need to take the GREs to complete the *Post-Master's Certificate in Biosimilars and Generic Drugs*?

No. GRE or other advanced test scores are not required for the certificate or the MS in RAQA.

Can I transfer any credits from another graduate institution towards the *Post-Master's Certificate in Biosimilars and Generic Drugs*?

Sorry, but credits for courses taken at other institutions are not accepted. All courses must be from Temple University's RAQA program. If you have taken identical or very similar courses at another institution, you may request to take an alternate course in its place.

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

No. You must notify the RAQA Office that you have finished the certificate by submitting the **Notice of Completion** by the stated deadlines. The form is available on the Certificates link of the RAQA website.

How much time do I have to complete the *Post-Master's Certificate in Biosimilars and Generic Drugs*?

You should complete the *Post-Master's 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.

Will new electives be added to the certificate programs?

Yes, the RAQA program continues to expand its curriculum. For a listing of new courses, please consult the RAQA website.

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
www.temple.edu/pharmacy_QARA**