POST-MASTER’S CERTIFICATE in
BIOPHARMACEUTICALS 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 Quality Assurance and Regulatory Affairs. As the program launches new programs, it recognizes that many graduates with the MS in QA/RA want to continue taking courses to keep current with industry issues and meet regulatory requirements for training. The Post-Master’s Certificate in Biopharmaceuticals and Generic Drugs allows QA/RA 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 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 over 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 continues to offer the most comprehensive curriculum of its kind.

Temple’s 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.

Candidates must formally apply for the Post-Master’s Certificate in Biopharmaceuticals 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 Biopharmaceuticals and Generic Drugs, but will be required to complete five courses.

Temple's QA/RA 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. Fifty courses are 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 Biopharmaceuticals and Generic Drugs, you must formally apply, so we can reopen your file to register you. The application is available at:
www.temple.edu/pharmacy_qara/pdf/PostMS.GenericDrugs.pdf

You will be required to take four courses relating to Biopharmaceuticals and Generic Drugs to complete the Post Master's Certificate in this subject.

Please mail the completed Application Form to:
   Temple University School of Pharmacy
   QA/RA 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 Biopharmaceuticals 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 QA/RA 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 Form, 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 QA/RA courses to receive the Post-Master's Certificate in Biopharmaceuticals and Generic Drugs. If the candidate subsequently decides to apply for the M.S. in Quality Assurance/Regulatory Affairs within five years, the credits earned in the Post-Master's Certificate in Biopharmaceuticals 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 QA/RA website) and forward it to the QA/RA Office by fax (267.468.8565), email (qarareg@temple.edu), or hard copy.

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 a Notice of Completion to the QA/RA Office at least one month in advance. Otherwise you must wait until the next time they are processed. The certificate must be completed within four years. Transfer credits are not accepted towards the Advanced Certificate.

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

To earn the certificate, four (for Temple U QA/RA 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** (Pharmaceutics 5473)*
- **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)
- **Analytical Chemistry in Pharmaceutical Laboratories** (Pharmaceutics 5655)
- **CMCs for Biologics** (Pharmaceutics 5577).

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

Where is the QA/RA Program Offered?
The QA/RA program is based at Temple University Fort Washington in suburban Montgomery County, PA. For directions, visit our website: www.temple.edu/pharmacy_QARA/map.htm

Courses are also offered online in real time. This certificate may be completed entirely online.

When can I start the certificate?
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?
We recommend starting this certificate with Drug Development (Pharmaceutics 5459) or The Global Biopharmaceutical Industry (Pharmaceutics 5458). Drug Development is a prerequisite for Generic Drug Regulation: ANDAs (Pharmaceutics 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 QA/RA program offers over 70 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 QA/RA Office if they wish to see a course scheduled in a particular semester.

How do I obtain a current class schedule?
See: www.temple.edu/pharmacy_QARA/schedule.htm

How do I register for classes?
You must be formally admitted to the Post-Master’s Certificate in Biopharmaceuticals and Generic Drugs before registering for any courses.

- If you received your MS from Temple, download the registration form from the QA/RA 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 QA/RA courses before, 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. Fax, mail, and electronic 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 Biopharmaceuticals and Generic Drugs*?
No. GRE or other advanced test scores are not required for the certificate or the MS in QA/RA.

Can I transfer any credits from another graduate institution towards the *Post-Master’s Certificate in Biopharmaceuticals and Generic Drugs*?
Sorry, but credits for courses taken at other institutions are not accepted. All courses must be from Temple University’s QA/RA 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 QA/RA Office that you have finished the certificate by submitting the Notice of Completion by the stated deadlines. The form is available on the QA/RA website, under Certificates.

How much time do I have to complete the *Post-Master's Certificate in Biopharmaceuticals and Generic Drugs*?
You should complete the *Post-Master’s Certificate in Biopharmaceuticals and Generic Drugs* within four years. When you have finished your courses, you must submit the Notice of Completion to the QA/RA Office.

Will new electives be added to the certificate programs?
Yes, the QA/RA program continues to expand its curriculum. For a listing of new courses, please consult the QA/RA website.

**For additional information:**
Temple University School of Pharmacy
QA/RA Graduate Program
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Fort Washington, PA 19034

Voice: 267.468.8560
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E-mail: QARA@temple.edu
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