POST-MASTER’S CERTIFICATE in
GLOBAL PHARMACOVIGILANCE:
BENEFIT-RISK ASSESSMENT

Temple created the first specialized certificate in global pharmacovigilance

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 continues to pioneer new curriculum, 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 Global Pharmacovigilance: Benefit-Risk Assessment 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.

The Certificate in Global Pharmacovigilance: Benefit-Risk Assessment provides a foundation in pharmacovigilance principles to both experienced professionals and those seeking entry into this career field from within and outside of the pharmaceutical industry. This discipline is constantly evolving in a dynamic regulatory, economic, and scientific environment. This five-course program provides a solid scientific and regulatory foundation in the key disciplines necessary for a successful career in the field. It focuses on establishing a platform for continuous learning in pharmacovigilance rather than on an unrealistic goal of seeking total subject mastery in the time allotted. Importantly, it focuses on pharmacovigilance in a global environment.

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 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.

Candidates must formally apply and be accepted into the Post-Master’s Certificate in Global Pharmacovigilance: Benefit-Risk Assessment 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 other accredited U.S. institutions of higher learning with extensive pharmaceutical industry experience may also petition the School to pursue the Post-Master’s Certificate in Global Pharmacovigilance: Benefit-Risk Assessment.

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.

The Post Master's Certificate in Global Pharmacovigilance: Benefit-Risk Assessment may 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 Global Pharmacovigilance: Benefit-Risk Assessment, you must formally apply, so we can reopen your file. The application is available at:
www.temple.edu/pharmacy_qara/pdf/app_advanced_pharmacovigilance.pdf

You will be required to take five courses relating to global pharmacovigilance to complete the Post Master's Certificate in this subject.

Please mail the 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 Global Pharmacovigilance: Benefit-Risk Assessment, 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 send the completed Application Form to:
Temple University School of Pharmacy
QA/RA Graduate Program
Attn: Assistant Dean Lebing
425 Commerce Drive, Suite 175
Fort Washington, PA 19034
Include a letter addressed to the Assistant Dean which indicates which courses you wish to pursue and explaining your experience in the pharmaceutical industry.

Include the completed Application Form for the Post-Master's Certificate in Global Pharmacovigilance: Benefit-Risk Assessment, 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 Global Pharmacovigilance: Benefit-Risk Assessment must be received from the Assistant Dean before students commence the program.

3) Students are required to take five Temple University QA/RA courses to receive the Post-Master’s Certificate in Global Pharmacovigilance: Benefit-Risk Assessment. 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 Global Pharmacovigilance: Benefit-Risk Assessment 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, you must notify the QA/RA Office by filling out the Notice of Completion (available on the QA/RA website) and sending it by mail, fax (267.468.8565) or email (qarareg@temple.edu) to the QA/RA Office.

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 notify 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 this certificate.

Courses Accepted for the Post-Master's Certificate in Global Pharmacovigilance: Benefit-Risk Assessment

To earn the certificate, five of the following courses must be successfully completed within a four year period with an overall B (3.0) average:

- **Post-Marketing Safety Surveillance** (Pharmaceutics 5571) or **Clinical Drug Safety and Pharmacovigilance** (Pharmaceutics 5538)* (Note: only one of these courses will count towards the program, regardless of when it was completed).
- **Good Pharmacovigilance Operations** (Pharmaceutics 5508)*
- **Pharmacoepidemiology** (Pharmaceutics 5573)*
- **The Regulatory and Legal Basis of Pharmacovigilance** (Pharmaceutics 5579)*
- **Risk Management and Safety Signaling of Healthcare Products** (Pharmaceutics 5578)*
- **Global Clinical Drug Development** (Pharmaceutics 5539)
• **Project Management for Clinical Trials** (Pharmaceutics 5547)
• **Bioethics for Pharmaceutical Professionals** (Pharmaceutics 5612)

*Students must take these courses, if they have not already done so. Elective courses (5539, 5547, 5612) may be pursued, only if students have already completed the five required courses in the Post-Master's Certificate in Global Pharmacovigilance: Benefit-Risk Assessment.

**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: [www.temple.edu/pharmacy_QARA/map.htm](http://www.temple.edu/pharmacy_QARA/map.htm)

Courses are also offered in Tarrytown (NY), Frazer (PA). Some corporate sites also videoconference our classes. This certificate is also available 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?**
It is suggested that students take Post-Marketing Safety Surveillance (Pharmaceutics 5571) or Clinical Drug Safety and Pharmacovigilance (Pharmaceutics 553) before taking the other classes. Both courses provide an overview of pharmacovigilance practices, but the focus of each is slightly different.

Students should have completed one of those two courses before taking Regulatory and Legal Basis of Pharmacovigilance (Pharmaceutics 5579), though this is not mandatory. Students are required to have completed at least one course in global pharmacovigilance before taking Risk Management and Safety Signaling in Healthcare Products (Pharmaceutics 5578).

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?**
Please refer to the QA/RA homepage for the most current schedule of classes.

**How do I register for classes?**
Please make sure you have been formally admitted into the Post-Master’s Certificate in Global Pharmacovigilance: Benefit-Risk Assessment before registering.
If you received your MS from Temple, download the registration form from the QA/RA homepage: 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: 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 fill quickly. We will contact you if there are problems with your registration. The QA/RA 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 pay your bill by the due date, so you do not incur a late fee.

**Do I need to submit GREs to complete the Post Master's Certificate in Global Pharmacovigilance: Benefit-Risk Assessment?**
No. GRE or other advanced test scores are not required for the certificate or the MS in QA/RA.

**Can I transfer credits from another graduate institution towards the Post-Master’s Certificate in Global Pharmacovigilance: Benefit-Risk Assessment?**
Sorry, but credits for courses taken at other institutions are not accepted for certificates. 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 each semester. 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 Global Pharmacovigilance: Benefit-Risk Assessment?**
You should complete the Post-Master’s Certificate in Global Pharmacovigilance: Benefit-Risk Assessment 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 list of new courses, please consult the QA/RA website.

*For additional information:*
Temple University School of Pharmacy
QA/RA Graduate Program
425 Commerce Drive, Suite 175
Fort Washington, PA  19034

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E-mail:  QARA@temple.edu
www.temple.edu/pharmacy_QARA