

## **POST-MASTER'S CERTIFICATE in GLOBAL PHARMACOVIGILANCE: BENEFIT-RISK ASSESSMENT**

*Temple created the first graduate certificate in global pharmacovigilance*

### **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 continues to pioneer new curriculum, it recognizes that many graduates with the MS in RAQA 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 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.

The ***Post Master's 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 certificate 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 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 renowned 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 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 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.

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 online at:

[www.temple.edu/pharmacy\\_qara/pdf/Application-Global-Pharmacovigilance-Post-Master-Certificate.pdf](http://www.temple.edu/pharmacy_qara/pdf/Application-Global-Pharmacovigilance-Post-Master-Certificate.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  
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 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  
Regulatory Affairs and Quality Assurance 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 RAQA 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 Regulatory Affairs and Quality Assurance 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 RAQA Office by filling out the **Notice of Completion** (available on the RAQA website) and sending it by mail, fax (267.468.8565) or email ([qarareg@temple.edu](mailto:qarareg@temple.edu)) to the RAQA Office.

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 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** (5571) or **Clinical Drug Safety and Pharmacovigilance** (5538)\* (Note: *only one of these courses will count towards the program*)
- **Good Pharmacovigilance Operations** (5508)\*
- **Pharmacoepidemiology** (5573)\*
- **The Regulatory and Legal Basis of Pharmacovigilance** (5579)\*
- **Risk Management and Safety Signaling of Healthcare Products** (5578)\*
- **Risk Management of Pharmaceutical and Medical Devices** (5548)
- **Global Clinical Drug Development** (5539)
- **Project Management for Clinical Trials** (5547)
- **Bioethics for Pharmaceutical Professionals** (5612)

\*Students must take these courses, if they have not already done so. Elective courses (5539, 5547, 5548, 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 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](http://www.temple.edu/pharmacy_QARA/map.htm)

Some corporate sites also videoconference our classes. This certificate is also available 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?**

It is suggested that students take **Post-Marketing Safety Surveillance** (5571) or **Clinical Drug Safety and Pharmacovigilance** (5573) before taking the other classes. Both courses provide an overview of pharmacovigilance practices, but the focus is different.

Students should have completed one of those two courses before taking **Regulatory and Legal Basis of Pharmacovigilance** (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** (5578).

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?**

Please refer to the RAQA 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 RAQA homepage: [www.temple.edu/pharmacy\\_QARA/forms.htm](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: [www.temple.edu/pharmacy\\_QARA/forms.htm](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 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 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 advanced test scores are not required for the certificate or the MS in RAQA.

**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 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 each semester. The form is available on the RAQA 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.

**Will new electives be added to the certificate programs?**

Yes, the RAQA program continues to expand its curriculum. For a list of 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](mailto:QARA@temple.edu)**

**[www.temple.edu/pharmacy\\_QARA](http://www.temple.edu/pharmacy_QARA)**