

## GLOBAL PHARMACOVIGILANCE: BENEFIT-RISK ASSESSMENT CERTIFICATE

*Temple created the first academic certificate in pharmacovigilance*

### BACKGROUND

Pharmacovigilance focuses on the detection, assessment, understanding and prevention of adverse effects associated with the use of health care products, including drugs, biologics, devices, vaccines, *in vitro* diagnostics, human cell and tissue products, and consume products.

The health care industry is challenged with providing safety oversight throughout the product life cycle. This includes continually reviewing safety profiles and managing and assessing benefit and risk that arise during and after product development. While a company's goal is to move products through all phases of development in a timely and cost-efficient manner, the obligation to protect public safety remains paramount.

The discipline of pharmacovigilance is constantly evolving in a dynamic regulatory, economic, and scientific environment. The *Global Pharmacovigilance: Benefit-Risk Assessment Certificate* provides a strong foundation in pharmacovigilance principles to both experienced professionals and those seeking entry into this career field from within and outside of regulated industry. Its five courses explore pharmacovigilance in a global environment, combining key regulatory, scientific, demographic, and analytical concepts that define the field. Upon completing the certificate, students will better appreciate the need for continuous learning in this complex discipline.

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 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 sixty courses are offered online in real time.

The *Global Pharmacovigilance: Benefit-Risk Assessment Certificate* may be pursued entirely online.

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

## **LEARNING OBJECTIVES**

Upon completion of the certificate, students will understand:

- The need for pharmacovigilance regulations;
- The evolution of pharmacovigilance regulations;
- The domestic and international pharmacovigilance requirements and regulations for healthcare products;
- The differences in regulations between product types and regions
- Pharmacovigilance data throughout product lifecycles;
- How to contextualize and interpret safety data;
- Common pharmacovigilance terminology and key stakeholders;
- Pharmacovigilance quality management systems and preparation for pharmacovigilance inspections;
- Key concepts and rationales for Benefit-Risk Assessments of healthcare products throughout their lifecycles.

## **ACADEMIC REQUIREMENTS**

1. The ***Global Pharmacovigilance: Benefit-Risk Assessment Certificate*** 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):

- **Post-Marketing Safety Surveillance** (5571) or **Clinical Drug Safety and Pharmacovigilance** (5538)
- **Good Pharmacovigilance Operations** (5508)
- **Pharmacoepidemiology** (5573)
- **The Regulatory and Legal Basis of Pharmacovigilance** (5579)
- **Risk Management and Safety Signaling of Healthcare Products** (5578)

It is **suggested** that students take **Post-Marketing Safety Surveillance** or **Clinical Drug Safety and Pharmacovigilance** before taking the other classes. Both courses provide an overview of pharmacovigilance practices, but the focus of each course is slightly different. As the titles suggest, **Post-Marketing Safety Surveillance** focuses primarily on pharmacovigilance practices after a product is created, whereas **Clinical Drug Safety and Pharmacovigilance** focuses on pre-clinical and clinical applications. Students may also begin the program with **Pharmacoepidemiology**. Students with prior educational or professional experience in regulatory affairs, clinical research, or clinical drug safety may also begin the program with **Regulatory and Legal Basis of Pharmacovigilance**.

2. Participants must have a bachelor's level degree from an accredited institution of higher learning. While no specific major is required, most applicants should have a background in health care, natural science, biological sciences, or related disciplines.

3. All courses must be completed from Temple University's RAQA graduate program. No transfer credits from other institutions are accepted.
4. Candidates must formally apply and follow the application procedures stated below (**Application Form**, photocopies of transcripts and **Notice of Completion**).
5. Only one certificate may be completed before students receive the MS.
6. Students should complete the required courses for the certificate 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 *Global Pharmacovigilance: Benefit-Risk Assessment Certificate* 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 *Global Pharmacovigilance: Benefit-Risk Assessment Certificate* 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 *Global Pharmacovigilance: Benefit-Risk Assessment Certificate*, 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, students must submit the following:

- **Application Form**
- Photocopies of all undergraduate and graduate transcripts, including Temple transcripts for RAQA courses completed. (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

### **TO RECEIVE THE CERTIFICATE**

Certificates are not automatically conferred when students complete the required courses. Students must formally apply and must also forward a **Notice of Completion** either by mail or fax to the RAQA Office (267.468.8565) indicating that they have finished the required courses. Photocopies of all undergraduate and graduate transcripts must be included.

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 semesters

If you miss the deadline, you will need to wait until the next processing period.

It takes the RAQA 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.

## **DESCRIPTIONS OF REQUIRED COURSES**

The certificate is composed of five courses. *It is suggested that students start the certificate by taking **Post-Marketing Safety Surveillance** or **Clinical Drug Safety and Pharmacovigilance**, but they may also begin with **Pharmacoepidemiology**.* Students will find it helpful to take courses in the order listed, since each builds upon knowledge in global pharmacovigilance. However, since courses are rotated each semester, students are urged 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.

### **Either:**

#### **5571. Post-Marketing Safety Surveillance (3 credits)**

This course provides an overview of post-marketing safety surveillance (PMSS) in the context of both American (FDA) and international (ICH-E2C) regulatory requirements. It begins with a historical overview of PMSS, then reviews the role of epidemiological methods in identifying signals and quantifying, assessing, and preventing adverse drug reactions (ADR). Medical/legal issues, benefits and limitations of safety surveillance systems, labeling changes, the ability to refute false signals, and social and ethical obligations inherent in the conduct of PMSS are discussed.

**OR**

#### **5538. Clinical Drug Safety and Pharmacovigilance (3 credits)**

This course provides an overview of both American (FDA) and international (ICH-E2C) regulatory requirements for drug pharmacovigilance. This course will cover a historical overview of IND and safety requirements, the processes and systems in place to support the compliance to regulations and guidelines for monitoring and reporting drug safety, and the strategic documentation required for applications in regard to safety. It explores the role of risk management and epidemiological methods to identify signals used to quantify, assess, and communicate adverse drug reactions. Topics covered will include pre-clinical and clinical safety, pharmacovigilance and pharmacoepidemiology, collection and analysis of safety data pre- and post-marketing, and regulatory, legal and ethical aspects of drug safety.

#### **5508. Good Pharmacovigilance Operations (3 credits)**

Pharmacovigilance's basic platform involves the receipt and processing of safety data from multiple sources. The mechanics and operations of a pharmacovigilance processing center will be reviewed, including discussions around organizational structure and the

business environment, safety database design and structure, MeDDRA coding, Medicinal Product Dictionary, human resource management, process excellence, continuous quality improvement, and data exchange agreements. Also covered are the production of regulatory documents (such as CIOMS forms and Periodic Safety Update reports) and regulatory inspections and pharmacovigilance QA.

### **5573. Pharmacoepidemiology (3 credits)**

Pharmacovigilance is a quantitative discipline. Understanding how to interpret data in an objective and scientific manner is critical to prudent decision-making. While this is not a course in statistics, it is designed to provide even the non-mathematically inclined student with a comfort level in key areas of pharmacovigilance. Basic statistical principles will be reviewed, including epidemiology concepts of ratios and rates, quantitative measures of benefit, and exposure estimation. Signaling and surveillance will be covered, along with the interpretation of clinical, post-marketing, and epidemiologic studies, business metrics, and compliance science.

### **5579. Regulatory and Legal Basis of Pharmacovigilance (3 credits)**

This course provides students with a basic understanding of the key regulations and laws that influence the development and management of a pharmacovigilance system, either in a manufacturer or health agency environments. The main emphasis will be on FDA, EU, and Japan and ICH, but discussions of emerging countries' systems will also be included. The course provides an overview of pharmaceutical product vigilance as well as related areas, such as medical devices, over-the-counter products, and drug-device combinations. In addition to understanding the regulatory framework, discussions will include partnership agreements, pharmacovigilance aspects of due diligence, licensing and acquisitions, and product liability issues.

### **5578. Risk Management and Safety Signaling of Healthcare Products (3 credits)**

This course focuses on problem-solving, utilizing a combination of workshops, seminars, and student projects geared to the practical application of knowledge acquired from the foundation courses. This course addresses a practical approach to: 1) the identification and framing of issues; 2) data acquisition and analysis; 3) the formulation of conclusions; and 4) ethical aspects of decision making and communication.

## **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.

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

This certificate may be completed 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?**

It is suggested that students take **Post-Marketing Safety Surveillance** (5571) or **Clinical Drug Safety and Pharmacovigilance** (5538) before taking the other classes. Both courses provide an overview of pharmacovigilance practices, but the focus of each is slightly different. However, this is not mandatory.

Students should have completed one of those two courses before taking **Regulatory and Legal Basis of Pharmacovigilance** (5579), unless they have prior educational or professional experience in regulatory affairs, clinical research, or clinical drug safety. Students must complete 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 check our website: [www.temple.edu/pharmacy\\_QARA](http://www.temple.edu/pharmacy_QARA) Click: **Schedule**

### **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](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 immediately if there are problems with your registration. The RAQA Office will send a confirmation statement that you are officially registered. You will also receive a notice via your TUmial 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 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 five 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 *Global Pharmacovigilance: Benefit-Risk Assessment Certificate* 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's 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 *Global Pharmacovigilance: Benefit-Risk Assessment Certificate*?**

Sorry, but credits for courses taken at other institutions are not accepted. All five courses must be from Temple University's RAQA program.

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

No. You must formally apply to receive the certificate. This consists of submitting: 1) the **Application Form**; 2) copies of undergraduate and graduate transcripts from any schools previously attended, 3) a resume or CV, and the **Notice of Completion**.

When you have finished your courses, you must submit a **Notice of Completion** by mail or fax (267.468.8565) indicating that you are eligible to receive the certificate. You must submit this information 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 *Global Pharmacovigilance: Benefit-Risk Assessment Certificate* within four years. If you need an extension, please email [qara@temple.edu](mailto: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 Global Pharmacovigilance: Benefit-Risk Management* (or another post-master's certificate) after earning the MS. Courses may only be counted towards one certificate. Please refer to our homepage for more details: [www.temple.edu/pharmacy\\_QARA/certificates.htm](http://www.temple.edu/pharmacy_QARA/certificates.htm).

**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)**