

 <p>School of Pharmacy TEMPLE UNIVERSITY</p> <p>Quality Assurance/Regulatory Affairs Graduate Program</p>	<p>Temple University - School of Pharmacy 425 Commerce Drive, Suite 175 Fort Washington, PA 19034</p> <p>Phone: 267.468.8560 Fax: 267.468.8565</p>
---	--

Graduate Certificate in Global Pharmacovigilance: Benefit-Risk Assessment

DESCRIPTION

The pharmaceutical industry is challenged with providing oversight of a drug's safety throughout the product lifecycle. This includes continually reviewing safety profiles and managing and assessing benefit and risk that arise during and after drug development. While a company's goal is to move a drug through all phases of development in a timely and cost-efficient manner, the obligation to protect public safety remains paramount. In light of recent safety issues related to well-established marketed products, adequate monitoring and assessment of the safety of drug during development is a vital concern of both industry and regulatory authorities.

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 the pharmaceutical area. This five-course program provides a solid scientific and regulatory foundation in the key disciplines necessary for a successful career in the field. The discipline itself is constantly evolving in a dynamic regulatory, economic, and scientific environment. Therefore, this program focuses on establishing a platform for continuous learning in the field rather than on an unrealistic goal of seeking total subject mastery in the time allotted. An important aspect is that the certificate focuses on pharmacovigilance in a global environment.

For nearly 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 industry veterans with years of expertise in their specialities, sharing their vast knowledge with students through intimate classroom discussions and hands-on workshops.

The 36-credit hour QA/RA master's program is based in Fort Washington, PA, with courses also offered in Tarrytown (NY), Frazer (PA), and corporate sites (either live or through videoconferencing). Classes are conveniently scheduled on evenings and weekends to provide flexibility for working professionals.

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

ACADEMIC REQUIREMENTS

1. The participant must have a bachelor's level degree or equivalent. While no specific major is required, most applicants should have a background in health care, natural science, biological sciences, or related disciplines.
2. The *Certificate in Global Pharmacovigilance: Benefit-Risk Assessment* may be earned on its own or on the way to the MS in QA/RA. To earn the certificate, the following five courses must be successfully complete within a four year period with an overall B (3.0 average):
 - **Post-Marketing Safety Surveillance or Clinical Drug Safety and Pharmacovigilance** (formerly *Clinical Safety & Risk Management*)
Good Pharmacovigilance Practices (GPhVP) - Applied Drug Safety and Individual Case Report Forms
 - **Pharmacoepidemiology** (including Quantitative Methods in Pharmacovigilance)
 - **The Regulatory and Legal Basis of Pharmacovigilance**
 - **Benefit-Risk Management of Healthcare Products**

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 course focuses primarily on Post-Marketing Safety Surveillance, whereas *Clinical Drug Safety* focuses on pre-clinical and clinical applications. .

2. All courses must be completed from Temple University's QA/RA graduate program. No transfer credits from other institutions are accepted.
3. Candidates must formally apply and follow the application procedures stated below (application form, photocopies of transcripts and notice of completion).
4. Only one certificate program (*Drug Development, Clinical Trial Management, Medical Device, Basic Pharmaceutical Development, Global Pharmacovigilance: Benefit-Risk Assessment, GMPs for the 21st Century*) may be completed before students receive the MS.
5. Students interested in pursuing the QA/RA MS program may apply all credits earned from the *Certificate in Global Pharmacovigilance: Benefit-Risk Assessment* towards their graduate degree, provided they formally apply for admission to the MS program and are accepted by Temple University's Graduate School.

DESCRIPTIONS OF REQUIRED COURSES

The certificate is composed of five 3-credit courses. The first four provide the foundation of knowledge for the final course on *Benefit-Risk Management of Healthcare Products*, which enables students to apply their knowledge in a semester-long project. It is suggested that students take the courses in the order listed. All courses build upon knowledge in global pharmacovigilance and provide students with hands-on knowledge of the field. *Students should start the certificate by taking Post-Marketing Safety Surveillance or Introduction to Pharmacovigilance:*

Either:

5571. Post-Marketing Safety Surveillance

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 an 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 (*formerly Clinical Safety & Risk Management*)

This course provides an overview of both American (FDA) and international (ICH-E2C) regulatory requirements for drug pharmacovigilance. This course will cover an 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 Practices (GPhVP) – Applied Drug Safety and Individual Case Report Forms

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 (including Quantitative Methods in Pharmacovigilance)

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.

5593. The Regulatory and Legal Basis of Pharmacovigilance

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 environment. While the emphasis is focused on FDA, EU, Japan, and ICH, discussions of emerging systems are also included. The course provides an overview of the pharmaceutical product vigilance as well as related areas, such as medical devices, over-the-counter products, and drug-device combinations. After providing the regulatory, additional discussions ensue regarding partnership agreements, pharmacovigilance aspects of due diligence and licensing and acquisitions, and product liability issues.

5578. Benefit-Risk Management of Healthcare Products

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.

APPLICATION PROCESS

The *Certificate in Global Pharmacovigilance: Benefit-Risk Assessment* is part of Temple University's graduate program in Quality Assurance and Regulatory Affairs. It does not require the completion of GREs. To earn the *Certificate in Global Pharmacovigilance: Benefit-Risk Assessment*, 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 mail an application form and photocopies of all undergraduate and graduate transcripts (including Temple transcripts for QA/RA courses) to:

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

TO RECEIVE THE CERTIFICATE

After you have finished the five courses, you must notify the QA/RA Office by fax (215.468.8565) indicating that you are eligible to receive the certificate. Please include your name, TUID, courses completed, daytime phone number, and the certificate you

have completed.

Certificates are issued in early February, June, and September. In order to receive your certificate in one of those months, you must notify the QA/RA office by fax **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 *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:

http://www.temple.edu/pharmacy_QARA/map.htm

Courses are also offered in Tarrytown, NY, and Frazer, PA. Some corporate sites also videoconference our classes.

When can I start the program?

Courses in the QARA 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 you start by taking *Post-Marketing Safety Surveillance or Clinical Drug Safety and Pharmacovigilance*, since either course provides an overview of the pharmaceutical industry and serves as the foundation of knowledge for the program. You may then take the other courses in any sequence.

How do I obtain a current class schedule?

Please check the QA/RA homepage:

http://www.temple.edu/pharmacy_gara/schedule.htm

How do I register for classes?

Please 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. Faxed and e-mail registrations do not guarantee your spot in a class, since sections fill quickly. We will contact you if there are problems with your registration. Otherwise you will receive a paperless bill through your Temple email account which confirms that you are officially registered.

Do I need to submit GRE scores to complete the certificate?

No. GRE scores are not required for this certificate.

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 *Certificate in Global Pharmacovigilance: Benefit-Risk Assessment* and the MS in QA/RA?

Yes! You're welcome to complete both programs, but please be aware that the MS in QA/RA has an entirely different application process and requires GREs. For additional information on the Master's of Science in QA/RA, please request a Program Guide and an application form by calling 267.468.8560.

Can I transfer any credits from another graduate institution towards the *Certificate in Global Pharmacovigilance: Benefit-Risk Assessment*?

Sorry, but credits for courses taken at other institutions are not accepted. All five courses must be from Temple University's QA/RA 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 the application and copies of all undergraduate and graduate transcripts from any schools previously attended. You should complete the *Certificate in Global Pharmacovigilance: Benefit-Risk Assessment* within four years. When you have finished your courses, you must notify the QA/RA by fax (267.468.8565) that you are eligible to receive the certificate. The fax must include your name, TUID, courses completed, daytime phone number, and certificate you have completed. You must submit the fax at least one month before certificates are issued (early in February, June, and September). Otherwise you will have to wait until the next time they are processed.

Can I take other courses in Temple's MS program?

Temple University allows non-matriculated students to complete only one certificate before pursuing the MS in QA/RA. You may complete the *Certificate in Global Pharmacovigilance: Benefit-Risk Assessment* and have all of the credits apply towards the MS; however, you must formally apply to the MS program by the time you complete the Certificate.

For additional information:

Temple University School of Pharmacy
QA/RA Office

425 Commerce Drive, Suite 175

Fort Washington, PA 19034-2713

Voice: 267.468.8560

Fax: 267.468.8565

E-mail: QARA@temple.edu

www.temple.edu/pharmacy_QARA