

Graduate Certificate: Global Pharmacovigilance/ Benefit-Risk Management

SCHOOL OF PHARMACY

About the Certificate

Pharmacovigilance focuses on the detection, assessment, understanding and prevention of adverse effects associated with the use of healthcare products, including biologics, consumer products, devices, drugs, human cell and tissue products, in vitro diagnostics, and vaccines. The healthcare industry is challenged with providing safety oversight throughout the product lifecycle, including continually reviewing safety profiles as well as managing and assessing benefits and risks 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 graduate certificate in Global Pharmacovigilance/Benefit-Risk Assessment provides a strong foundation in pharmacovigilance principles for both experienced professionals and those seeking entry into the career field from within and outside of regulated industry. Coursework explores pharmacovigilance in a global environment, combining key regulatory, scientific, demographic and analytical concepts that define the field. Upon completion of the certificate, students can better appreciate the need for continuous learning in this complex discipline.

Time Limit for Certificate Completion: 4 years

Campus Location: Online and Fort Washington

Full-Time/Part-Time Status: The certificate may be completed on a part-time basis. NOTE: International students may not be eligible to apply for a student visa based on admission to the certificate program. Please contact the School of Pharmacy's program coordinator for more information.

Non-Matriculated Student Policy: Non-matriculated students may take up to 9 credits of coursework before applying to the certificate program.

Admission Requirements and Deadlines

Application Deadline:

Fall and *Spring* admissions are on a rolling basis. Interested students should contact the School of Pharmacy for permission to enroll in coursework.

APPLY HERE to the post-baccalaureate certificate program.

Bachelor's Degree in Discipline/Related Discipline: Applicants must hold a bachelor's degree from an accredited institution. While no specific major is required, most applicants should have a background in biological sciences, engineering, healthcare, natural sciences or related discipline.

Certificate Requirements

Number of Credits Required to Complete the Certificate: 15

*Required Courses:*¹

Code	Title	Credit Hours
QARA 5508	Good Pharmacovigilance Operations	3
QARA 5538 or QARA 5571	Clinical Drug Safety and Pharmacovigilance Post-Marketing Safety Surveillance	3
QARA 5573	Pharmacoepidemiology	3
QARA 5578	Benefit Risk Management and Safety Signaling of Healthcare Products	3
QARA 5579	Regulatory and Legal Basis of Pharmacovigilance	3
Total Credit Hours		15

1

For their first course, it is suggested that students take QARA 5538 Clinical Drug Safety and Pharmacovigilance or QARA 5571 Post-Marketing Safety Surveillance. Both courses provide an overview of pharmacovigilance practices, but with a slightly different focus. QARA 5538 focuses on preclinical and clinical applications, while QARA 5571 focuses primarily on pharmacovigilance practices after a product is created. Alternately, students may begin the program with QARA 5573 Pharmacoepidemiology. Finally, those with prior educational or professional experience in regulatory affairs, clinical research or clinical drug safety may start with QARA 5579 Regulatory and Legal Basis of Pharmacovigilance.

GPA Required to be Awarded the Certificate: 3.0 minimum

Contacts

Certificate Program Web Address:

<https://pharmacy.temple.edu/raqa/certificate-programs/pre-masters-certificates/global-pharmacovigilance-benefit-risk-management-certificate>

Department Information:

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425 Commerce Drive, Suite 175
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Mailing Address for Application Materials:

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