Global Clinical and Pharmacovigilance Regulations MS

SCHOOL OF PHARMACY

Learn more about the Master of Science in Global Clinical and Pharmacovigilance Regulations.

About the Program

The MS in Global Clinical and Pharmacovigilance Regulations addresses the career needs of individuals involved in domestic and global clinical trials and pharmacovigilance activities within the pharmaceutical industry, including managing and assisting in clinical trials, supervising record keeping of clinical trials, reviewing safety data of clinical trials or post-marketing reports of healthcare products, and other related activities. In recent years, pharmacovigilance activities have been conducted alongside clinical trials to determine the benefits and risk factors of products both under development and on the market.

Pharmacovigilance, or drug safety, relates to the myriad of activities the pharmaceutical and related industries use in monitoring, assessing and compiling the benefits and risks involved with their products. Whereas pharmacovigilance studies used to be undertaken once products were already on the market, the latest trend is to conduct these studies with "first in human" studies, which are generally done on healthy volunteer subjects to ascertain how a new product affects an individual without the known disease state. Clinical trials are highly regulated research studies of pharmaceutical and related products, treatment options, or medical devices in human beings. Their goal is to find new or better ways to prevent, detect, diagnose, or treat disease or disease states. In order to accomplish this, clinical trials must rigorously follow certain protocols, study designs, and data collection and monitoring methods defined by regulatory authorities.

The MS in Global Clinical and Pharmacovigilance Regulations degree program is primarily designed for PharmD students who already possess extensive experience in clinical settings, but would benefit from specific knowledge of domestic and global regulations to be more marketable for careers in the pharmaceutical industry. This MS degree combining clinical practices with global pharmacovigilance empowers PharmD graduates with knowledge of:

- the need for pharmacovigilance and clinical regulations;
- the evolution of global pharmacovigilance and clinical regulations;
- domestic and international pharmacovigilance and clinical requirements and regulations for healthcare products;
- differences in regulations between product types and regions;
- current utilization of pharmacovigilance data throughout the lifespan of all products;
- the ability to contextualize and interpret safety data; and
- the paramount importance of data collection, statistics and data mining in the industry.

Time Limit for Degree Completion: 5 years

Campus Location: Online or at Fort Washington on evenings and weekends

Full-Time/Part-Time Status: The degree program can be completed on a full- or part-time basis.

Interdisciplinary Study: The program fosters interdisciplinary study between the pharmaceutical sciences and technology.

Job Prospects: The program prepares graduates for positions in the global marketplace related to drug safety and human clinical trials.

Non-Matriculated Student Policy: Non-matriculated students are able to take up to 9 credits before formal application must be made to the program.

Financing Opportunities: Master's students are generally not considered for financial support.

Admission Requirements and Deadlines

Application Deadline:

Fall: March 1; December 15 international
Spring: November 1; September 1 international
Summer I: March 1; January 15 international

Applications are processed throughout the year. Late applications may be considered for admission. However, the entire application packet must be received by the Regulatory Affairs and Quality Assurance Office before it is reviewed by the Admissions Committee. Applicants are responsible for making sure that all materials have been received.

APPLY ONLINE to this graduate program.

Letters of Reference:
Number Required: 2

From Whom: Letters of recommendation should be obtained from college/university faculty members familiar with academic competence.

Coursework Required for Admission Consideration: It is expected that applicants are PharmD students or graduates.

Bachelor's Degree in Discipline/Related Discipline: A BS degree in Biochemistry, Biology, Chemistry, Physics or a health-related discipline is required.

Applicants who earned a degree at a non-U.S. institution must submit an equivalency evaluation of their transcript(s) through a third-party provider, either World Education Services (WES) or Educational Credential Evaluators (ECE).

Statement of Goals: Describe your experience in the pharmaceutical or related industries, indicating how the Global Clinical and Pharmacovigilance Regulations MS program will help you achieve your career objectives.

Standardized Test Scores:
Applicants who earned their baccalaureate degree from an institution where the language of instruction was other than English, with the exception of those who subsequently earned a master's degree at a U.S. institution, must report scores for a standardized test of English that meet these minimums:

- TOEFL iBT: 85
- IELTS Academic: 6.5
- PTE Academic: 58

Resume: Current resume or CV required.

Transfer Credit: Temple University PharmD students may apply a maximum of 15 credits toward this MS degree. The following courses are applicable:

Code	Title	Credit Hours
Ethics course		2
PP P254	Bio Stat/Med Lit Eval	2
PP P312	ADRS Organ Systems Appr	2
PP P313	Clin Pharmacokinetics	3
QARA 5459	Drug Development	3
QARA 5536	Good Clinical Practices	3
QARA 5537	Clinical Trial Management	3

Students in and graduates of PharmD programs at other accredited schools of pharmacy may apply for transfer credits. Such requests are decided on a case-by-case basis. A maximum of 6 transfer credits are permitted for this group of prospective students.

Program Requirements

General Program Requirements:
Number of Credits Required Beyond the Baccalaureate: 30

Required Courses:

Code	Title	Credit Hours
Core Courses		
QARA 5459	Drug Development	3
QARA 5508	Good Pharmacovigilance Operations	3
QARA 5536	Good Clinical Practices	3
QARA 5537	Clinical Trial Management	3
QARA 5538	Clinical Drug Safety and Pharmacovigilance	3
or QARA 5571	Post-Marketing Safety Surveillance	
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

Electives		
Select from the following approved courses:		6
PP P312	ADRS Organ Systems Appr	
PP P313	Clin Pharmacokinetics	
QARA 5497	Statistics for Clinical Trials [1]	
QARA 5539	Global Clinical Drug Development	
QARA 5547	Project Management for Clinical Trials	
QARA 5612	Bioethics for Pharmaceutical Professionals	
QARA 5618	Clinical Data Management (CDM)	
Total Credit Hours		**30**

[1] Alternately, students may take PP P254 Bio Stat/Med Lit Eval.

Culminating Event: Successful completion of coursework is required to earn the MS in Global Clinical and Pharmacovigilance Regulations.

Contacts

Program Web Address:

https://pharmacy.temple.edu/academics/regulatory-affairs-quality-assurance-ms-programs-non-thesis-certificates/about-programs/degree-programs-raqa/master-science-global-clinical-pharmacovigilance-regulations-gcpr-raqa

Department Information:

Global Clinical and Pharmacovigilance Regulations Graduate Program
425 Commerce Drive, Suite 175
Fort Washington, PA 19034-2728
qara@temple.edu
267-468-8560

Submission Address for Application:

QARA2@temple.edu

Mailing Address for Application Materials:

Temple University
Global Clinical and Pharmacovigilance Regulations Graduate Program
425 Commerce Drive, Suite 175
Fort Washington, PA 19034-2728

Department Contacts:

Admissions:
Wendy Lebing, MALD, MS
Assistant Dean
qara@temple.edu
267-468-8560

Graduate Chairperson:
Swati Nagar, PhD
phscgrad@temple.edu

Assistant Dean:
Wendy Lebing, MALD, MS
wlebing@temple.edu
267-468-8560