International Biopharmaceutical Regulatory Affairs, Graduate Certificate

To work in today's global biopharmaceutical industry, there is a strong need to understand international regulations that impact the development, marketing, and manufacturing of pharmaceutical and biotechnology products.

The Graduate Certificate in Biopharmaceutical International Regulatory Affairs curriculum focuses on factors that facilitate the safety, performance, and efficacy of biomedical goods. Program training covers the assessment of international regulations and interpretation of their likely impact on a company's global commercialization strategies. Through participation in the program, students will have an opportunity to gain an understanding of international regulatory requirements necessary to implement such strategies.

Course work covers biotechnology and pharmaceutical product approval processes, regulatory analysis, and liability laws as they exist across different regulatory systems. The graduate certificate will provide core regulatory knowledge to students entering into the field from bench research, clinical studies, quality control/assurance, pharmacy, bioengineering, business, and legal analysis. The curriculum covers regulatory environments in Europe, Latin America, Australia, Japan, and other emerging economies. Courses from this certificate may be applied toward the Master of Science in Regulatory Affairs for Drugs, Biologics, and Medical Devices.

Program Requirements

- Concentrations and course offerings may vary by campus and/or by program modality. Please consult with your advisor or admissions coach for the course availability each term at your campus or within your program modality.
- Certain options within the program may be *required* at certain campuses or for certain program modalities. Please consult with your advisor or admissions coach for requirements at your campus or for your program modality.

Complete all courses and requirements listed below unless otherwise indicated.

Required Courses

Code	Title	Hours
RGA 6221	European Union Compliance Process and Regulatory Affairs	4
Complete a minimum of 12 quarter hours		12
RGA 6204	Legal Issues in International Food, Drug, and Medical Device Regulation	
RGA 6207	Global Impact of Electronic Common Technical Document (eCTD) Submissions	
RGA 6210	Strategic Planning and Project Management for Regulatory Affairs	
RGA 6212	Introduction to Safety Sciences	
RGA 6223	Introduction to Australian, Asian, and Latin American Regulatory Affairs	
RGA 6224	Regulation of Biomedical Product Commercialization by Health Canada	
RGA 6244	Therapeutic Product Development in Canada	
RGA 6245	Regulation of Generic Pharmaceutical and Biosimilar Products	

Program Credit/GPA Requirements

16 total quarter hours required
Minimum 3.000 GPA required