Global Regulatory Affairs, Graduate Certificate (Online)

The professional practice of regulatory affairs is becoming increasingly harmonized; regulatory intelligence, submissions, operations, and strategy are evolving into globally based endeavors. Organizations, including the International Conference on Harmonization, are setting common guidelines and standards for these and other regulatory practices, such that marketing approval and postmarket surveillance requirements are geographically converging. The Graduate Certificate in Global Regulatory Affairs is designed to allow students to study convergent regulatory requirements in Canada, the European Union, the EMEA countries, and the ASEAN nations. By examining specific biomedical regulatory requirements in these countries, students can efficiently utilize their knowledge of such requirements through global, rather than geographically based, regulatory practice.

Program Requirements

Complete all courses and requirements listed below unless otherwise indicated.

Required Courses

Code	Title	Hours
RGA 6650	Medical Device Product Development in Canada	3
RGA 6675	Therapeutic Product Development in Canada	3
RGA 6685	European Medical Device Regulations	3
RGA 6690	Global In Vitro Diagnostic Regulations and Submissions	3

Program Credit/GPA Requirements

12 total semester hours required
Minimum 3.000 GPA required