Clinical Research Regulatory Affairs, Graduate Certificate (Online)

The Graduate Certificate in Clinical Research Regulatory Affairs offers students an opportunity to develop a comprehensive understanding of continuously and rapidly evolving clinical research global biomedical product regulatory standards and processes. Credits earned in this certificate may be used to satisfy some of the degree requirements of the Master of Science in Regulatory Affairs program, which develops the professional competencies required to ensure regulatory processes for new biomedical products are conducted in compliance with global standards and regulatory agency requirements. Such clinical global standards and regulatory processes are separate and distinct from those applicable to the indirect, non-patient-facing development of biomedical products, including in vitro design work, in vivo animal testing, in silico testing, and manufacturing process validation.

Program Requirements

Complete all courses and requirements listed below unless otherwise indicated.

Required Courses

Code	Title	Hours
RGA 6600	Introduction to Food and Drug Administration Pharmaceutical Regulation	3
or RGA 6610	Introduction to Food and Drug Administration Medical Device Regulation	
RGA 6285	Validation and Auditing of Clinical Trial Information	3
RGA 6290	Clinical Trial Design Optimization and Problem Solving	3
RGA 6295	Managing International Clinical Trials	3

Program Credit/GPA Requirements

12 total semester hours required
Minimum 3.000 GPA required