Regulatory Affairs, MS (Online)

The rapid advancement of technology within healthcare and other sectors has driven the evolution of a complex global regulatory landscape and concurrently created the need for professionals with the skills necessary to facilitate the commercialization of products used therein. In response to this demand, Northeastern University's College of Professional Studies offers the Master of Science in Regulatory Affairs degree.

This unique graduate degree is designed to both broaden and deepen the student's understanding of current global compliance requirements and their practical application in the design, development, approval, and postmarketing of products utilized within regulated industries. Courses within this degree program offer students an opportunity to integrate scientific and technical knowledge and engineering and regulatory perspectives within the larger context of global product commercialization. From research and discovery through the postmarket phase of product utilization, the Master of Science in Regulatory Affairs degree examines the processes required for stakeholders to maintain compliance to product standards and regulations throughout the global marketplace.

Program Requirements

Complete all courses and requirements listed below unless otherwise indicated.

Required Courses

Code	Title	Hours
RGA 6105	Introduction to Regulatory Compliance and Practice	3
RGA 6150	Regulatory Strategy for Product Development and Life-Cycle Management	3
RGA 6208	Introduction to Safety Sciences	3
RGA 6238	Human Experimentation Methodological Issues Fundamentals	3
RGA 6308	Pharmaceutical and Medical Device Law: Topics and Cases	3
or RGA 6350	Legal Issues in International Food, Drug, and Medical Device Regulation	
Restricted Electives		
Complete 4 semester hours from the following:		4
RGA 6400	Medical Device Product Development and Process Validation	
RGA 6415	Fundamentals of CMC Regulations and Methods	
RGA 6435	Medical Device Cybersecurity and Digital Health	
RGA 6440	Advanced Topics in Advertising and Promotion of Drugs and Medical Devices	
RGA 6450	Financing and Reimbursement in Biomedical Product Development	
RGA 6465	Nonclinical Regulations in Biomedical Product Commercialization	
RGA 6475	Strategic Planning and Project Management for Regulatory Affairs	
RGA 6480	Real-World Evidence and Patient-Reported Outcomes in Regulatory Decision Making	
RGA 6490	Emerging Trends and Challenges in Regulatory Affairs	
RGA 6500	Biomedical Product Development: Regulatory Affairs in a Market-Based Setting	
Capstone		
RGA 6980	Capstone: Practical Applications in Global Regulatory Affairs	3

Concentration or Electives Option

A concentration is not required. Students may complete the electives option in lieu of a concentration.

- Biopharmaceutical Regulatory Affairs (p. 1)
- Clinical Research Regulatory Affairs (p. 2)
- Global Regulatory Affairs (p. 2)
- Medical Device Regulatory Affairs (p. 2)
- Electives Option (p. 2)

Program Credit/GPA Requirements

34 total semester hours required
Minimum 3.000 GPA required

BIOPHARMACEUTICAL REGULATORY AFFAIRS CONCENTRATION

Code	Title	Hours
RGA 6600	Introduction to Food and Drug Administration Pharmaceutical Regulation	3
RGA 6660	Therapeutic Product Development: A Regulatory Overview	3

RGA 6670	Global Impact of Electronic Common Technical Document (eCTD) Submissions	3
RGA 6680	Project Management in Early Drug Discovery and Development	3

CLINICAL RESEARCH REGULATORY AFFAIRS CONCENTRATION

Code	Title	Hours
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
RGA 6600	Introduction to Food and Drug Administration Pharmaceutical Regulation	3
or RGA 6610	Introduction to Food and Drug Administration Medical Device Regulation	

GLOBAL REGULATORY AFFAIRS CONCENTRATION

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

MEDICAL DEVICE REGULATORY AFFAIRS CONCENTRATION

Code	Title	Hours
RGA 6610	Introduction to Food and Drug Administration Medical Device Regulation	3
RGA 6620	Medical Device Development: A Regulatory Overview	3
RGA 6630	Medical Device Quality Management System: Principles and Applications	3
RGA 6640	Risk Management: Compliance and Processes	3

ELECTIVES OPTION

Code	Title	Hours
Complete courses from concentrations above or from the unused electives options in the restricted electives of the major.		12