Regulatory Affairs, MS

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

- 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
BTC 6210	Human Experimentation: Methodological Issues Fundamentals	4
RGA 6002	Introduction to Regulatory Compliance and Practice	2
RGA 6203	Pharmaceutical and Medical Device Law: Topics and Cases	5
or RGA 6204	Legal Issues in International Food, Drug, and Medical Device Regulation	
RGA 6212	Introduction to Safety Sciences	4
RGA 6463	Regulatory Strategy for Product Development and Life-Cycle Management	4

Capstone

Code	Title	Hours
RGA 6300	Practical Applications in Global Regulatory Affairs	4

The remaining quarter hours may be completed by selecting a combination of a concentration and additional electives or selecting any courses listed in the concentrations and electives lists.

Concentrations

- Biopharmaceutical Regulatory Affairs (p. 2)
- Clinical Research Regulatory Affairs (p. 2)
- Medical Device Regulatory Affairs (p. 2)
- Nonclinical Biomedical Product Regulation (p. 3)
- Quality Assurance Compliance (p.)

Program Credit/GPA Requirements

45 total quarter hours required
Minimum 3.000 GPA required

Elective Courses

Code	Title	Hours
General Electives		
COP 6940	Personal and Career Development	
EDU 6184	Interdisciplinary Foundations	
INT 6943	Integrative Experiential Learning	

RGA 6205	Emerging Trends and Issues in the Medical Device Industry
RGA 6210	Strategic Planning and Project Management for Regulatory Affairs
RGA 6215	Project Management in Early Drug Discovery and Development
RGA 6217	Biomedical Product Development: From Biotech to Boardroom to Market
RGA 6219	Advanced Topics in Advertising and Promotion of Drugs and Medical Devices
RGA 6255	Global Convergence of Regulatory Science and Reimbursement/Market Access
RGA 6461	Cybersecurity and Regulation of Digital Health Technologies by the FDA
Regulatory Affairs of Food	
GST 6350	Global Economics of Food and Agriculture
GST 6610	Sustainable Development
GST 6102	Global Corporate Social Responsibility
RFA 6220	Food Safety and Surveillance: Concepts and Applications
International Regulatory Affairs	
RGA 6221	European Union Compliance Process and Regulatory Affairs
RGA 6222	European Medical Device Regulations
RGA 6223	Introduction to Australian, Asian, and Latin American Regulatory Affairs
RGA 6224	Regulation of Biomedical Product Commercialization by Health Canada
RGA 6228	Managing International Clinical Trials
RGA 6228	Managing International Clinical Trials
RGA 6243	Medical Device Product Development in Canada
RGA 6244	Therapeutic Product Development in Canada

Concentrations

BIOPHARMACEUTICAL REGULATORY AFFAIRS

Code	Title	Hours
RGA 6000	Introduction to Food and Drug Administration (FDA) Pharmaceutical Regulation	2
RGA 6101	Therapeutic Product Development: A Regulatory Overview	4
RGA 6207	Global Impact of Electronic Common Technical Document (eCTD) Submissions	4
RGA 6380	Advanced Regulatory Writing: New Drug Applications	4
Complete one of the following:		4
RGA 6217	Biomedical Product Development: From Biotech to Boardroom to Market	
RGA 6235	Emerging Product Categories in the Regulation of Drugs and Biologics	

CLINICAL RESEARCH REGULATORY AFFAIRS

Code	Title	Hours
BTC 6211	Validation and Auditing of Clinical Trial Information	4
BTC 6213	Clinical Trial Design Optimization and Problem Solving	4
RGA 6101	Therapeutic Product Development: A Regulatory Overview	4
or RGA 6202	Medical Device Development: A Regulatory Overview	
Complete one of the following:		4
RGA 6217	Biomedical Product Development: From Biotech to Boardroom to Market	
RGA 6228	Managing International Clinical Trials	

MEDICAL DEVICE REGULATORY AFFAIRS

Code	Title	Hours
RGA 6001	Introduction to Food and Drug Administration (FDA) Medical Device Regulation	2
RGA 6202	Medical Device Development: A Regulatory Overview	4
RGA 6233	Application of Quality System Regulation in Medical Device Design and Manufacturing	4
Complete one of the following:		6
RGA 6205	Emerging Trends and Issues in the Medical Device Industry	
RGA 6222	European Medical Device Regulations	
RGA 6243	Medical Device Product Development in Canada	
RGA 6275	Product Development and Process Validation	
RGA 6370	Advanced Regulatory Writing: Medical Device Submissions	

NONCLINICAL BIOMEDICAL PRODUCT REGULATION

Code	Title	Hours
RGA 6207	Global Impact of Electronic Common Technical Document (eCTD) Submissions	4
RGA 6233	Application of Quality System Regulation in Medical Device Design and Manufacturing	4
RGA 6405	Nonclinical Regulations in Biomedical Product Commercialization	4
RGA 6420	Global IVD Regulations and Submissions	4

QUALITY ASSURANCE COMPLIANCE

Code	Title	Hours
Complete one of the following:		2
RGA 6000	Introduction to Food and Drug Administration (FDA) Pharmaceutical Regulation	
RGA 6001	Introduction to Food and Drug Administration (FDA) Medical Device Regulation	
RGA 6461	Cybersecurity and Regulation of Digital Health Technologies by the FDA	
Complete the following:		
RGA 6233	Application of Quality System Regulation in Medical Device Design and Manufacturing	4
RGA 6234	Risk Management: Compliance and Processes	4
RGA 6275	Product Development and Process Validation	2
Choose from the following to reach 16 quarter hours:		4
RGA 6221	European Union Compliance Process and Regulatory Affairs	
RGA 6410	Fundamentals of CMC Regulations and Methods	
RFA 6220	Food Safety and Surveillance: Concepts and Applications	