Regulatory Affairs, MS (Toronto)

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 post-marketing 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 post-market 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

Required Courses

Code	Title	Hours
BTC 6210	Human Experimentation: Methodological Issues Fundamentals	4
RGA 6002	Introduction to Regulatory Compliance and Practice	2
RGA 6300	Practical Applications in Global Regulatory Affairs	4
RGA 6212	Introduction to Safety Sciences	4
RGA 6463	Regulatory Strategy for Product Development and Life-Cycle Management	4
Complete one of the following:		5
RGA 6203	Pharmaceutical and Medical Device Law: Topics and Cases	
RGA 6204	Legal Issues in International Food, Drug, and Medical Device Regulation	

Concentrations

A concentration is not required. The remaining required quarter hours for this program may be completed by selecting a combination of a concentration and electives or selecting any courses listed in the concentrations and electives.

- Biopharmaceutical Regulatory Affairs (p. 1)
- Clinical Research Regulatory Affairs (p. 1)
- Medical Device Regulatory Affairs (p. 2)
- Nonclinical Biomedical Product Regulation (p. 2)
- Quality Assurance and Compliance (p. 2)

PROGRAM CREDIT/GPA REQUIREMENTS

45 total quarter hours required
Minimum 3.000 GPA required

CONCENTRATION IN 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
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	

CONCENTRATION IN 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
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	
Complete one of the following:		4

RGA 6101	Therapeutic Product Development: A Regulatory Overview
RGA 6202	Medical Device Development: A Regulatory Overview
RGA 6228	Managing International Clinical Trials

CONCENTRATION IN 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:		2-4
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	

CONCENTRATION IN NONCLINICAL BIOMEDICAL PRODUCT REGULATION

Code	Title	Hours
RGA 6207	Global Impact of Electronic Common Technical Document (eCTD) Submissions	4
RGA 6405	Nonclinical Regulations in Biomedical Product Commercialization	4
Choose 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	

CONCENTRATION IN QUALITY ASSURANCE AND COMPLIANCE

Code	Title	Hours
RGA 6233	Application of Quality System Regulation in Medical Device Design and Manufacturing	4
RGA 6234	Risk Management: Compliance and Processes	4
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 one of the following:		4
RGA 6221	European Union Compliance Process and Regulatory Affairs	
RGA 6410	Fundamentals of CMC Regulations and Methods	

Electives

Code	Title	Hours
INT 6200	Experiential Project Preparation	
RGA 6219	Advanced Topics in Advertising and Promotion of Drugs and Medical Devices	
RGA 6244	Therapeutic Product Development in Canada	