The rapid growth of the biomedical product industries and the ever-evolving regulatory landscape have driven high demand for trained regulatory affairs professionals in both the public and private sectors. In response to this demand, Northeastern University’s College of Professional Studies offers the Master of Science in Regulatory Affairs for Drugs, Biologics, and Medical Devices.

This unique graduate degree is designed to both broaden and deepen the student’s understanding of current regulations and their practical application in the development of biomedical products. Courses within this program provide students with the opportunity to integrate both scientific knowledge and regulatory perspectives, within the larger context of global commercialization. From discovery through the postmarket phase of product development, this master’s degree covers the regulatory and market access requirements to bring a medical product to—and maintain its presence in—the global marketplace.

Program Requirements
Complete all courses and requirements listed below unless otherwise indicated.

Required Courses
- RGA 6000 Introduction to Food and Drug Administration (FDA) Pharmaceutical Regulation
- RGA 6001 Introduction to Food and Drug Administration Medical Device Regulation
- RGA 6101 Therapeutic Product Development: A Regulatory Overview
- RGA 6202 Medical Device Development: A Regulatory Overview
- RGA 6207 FDA and the Electronic Common Technical Document (eCTD)
- RGA 6220 Global Biotechnology Product Registration: E.U., U.S. Product Regulation
- RGA 6223 Introduction to Canadian, Asian, and Latin American Regulatory Affairs
- RGA 6300 Practical Applications in Biomedical Product Global Regulatory Affairs

Required Electives
Students must earn a minimum of 16 quarter hours by choosing at least one course from each elective category.

REGULATORY AND CLINICAL OPERATIONS
Complete at least one of the following: 3-4
- BTC 6211 Validation and Auditing of Clinical Trial Information
- BTC 6213 Clinical Trial Design Optimization and Problem Solving
- RGA 6208 Introduction to Safety Sciences
- RGA 6370 Regulatory Writing: Medical Device Submissions
- RGA 6380 Regulatory Writing: New Drug Applications
- RGA 6280 Advanced Writing on International Biomedical Topics

REGULATORY PERSPECTIVE
Complete at least one of the following: 2-5
- RGA 6203 Food, Drug, and Medical Device Law: Topics and Cases
- BTC 6260 The Business of Medicine and Biotechnology
- RGA 6217 Biomedical Product Development: From Biotech to Boardroom to Market
- RGA 6235 Emerging Product Categories in the Regulation of Drugs and Biologics
- RGA 6205 Emerging Trends and Issues in the Medical Device Industry
- RGA 6210 Strategic Planning and Project Management for Regulatory Affairs
- RGA 6245 Regulation of Generic Pharmaceutical and Biosimilar Products
- RGA 6211 Combination Products and Convergence
- COP 6940 Personal and Career Development (Enrollment in COP 6940 requires participation in the cooperative education program (subject to availability). Students must complete two of the following four courses prior to enrolling in COP 6940: RGA 6100, RGA 6201, RGA 6202, or BTC 6210.)
- INPS 5184 Interdisciplinary Professional Foundations
  or EDU 6184 Interdisciplinary Foundations
- INT 6943 and RGA 6920 Integrative Experiential Learning and Internship Reflection

INTERNATIONAL
Complete at least one of the following: 4
- RGA 6221 European Union Compliance Process and Regulatory Affairs
- RGA 6222 European Medical Device Regulations
- RGA 6224 Regulation of Biomedical Product Commercialization by Health Canada
- RGA 6225 Japanese Medical Device Regulations and Registration
- RGA 6226 Canadian and Australian Medical Device Regulations
- RGA 6227 Emerging Medical Device Markets
- RGA 6228 Managing International Clinical Trials
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<tr>
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<tr>
<td>RGA 6229</td>
<td>Biomedical Product Regulatory Affairs in Emerging Markets: Russia and Kazakhstan</td>
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<tr>
<td>RGA 6211</td>
<td>Combination Products and Convergence</td>
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**Program Credit/GPA Requirements**

45 total quarter hours required  
Minimum 3.000 GPA required