Ever-changing laws and regulations are driving demand for regulatory affairs professionals who can help companies effectively bring medical products to market. To prepare you to effectively manage regulatory activities, 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 deepen your understanding of current regulations and their practical application in the development and commercialization of drugs, biologics, and medical device products. Regulatory affairs courses within this program will provide you with the integrated knowledge and broad perspectives you need to effectively manage the regulatory process.

Program Objectives:
- Gain the essential knowledge and skills required to help companies navigate an increasingly complex regulatory environment
- Acquire the foundation necessary to work within a variety of fields, including medical product development, pharmaceutical sales, strategic marketing, and clinical investigations
- Examine every step of the drug development and regulation process
- Sharpen your understanding of the laws that govern the development, manufacturing, and commercial distribution of drugs, biologics, and medical devices
- Analyze how emerging developments and trends are reshaping medical device regulations
MASTER OF SCIENCE
IN REGULATORY AFFAIRS FOR DRUGS,
BIOLOGICS, AND MEDICAL DEVICES

Development and Strategy  4 q.h.
Choose one of the following courses:
BTC 6213  Clinical Trial Design Optimization and
          Problem Solving  4 q.h.
PMC 6212  Clinical Drug Development Data Analysis:
          Concepts and Applications  4 q.h.
RGA 6112  Biomedical Intellectual Property Management:  4 q.h.
          Patents, Trademarks, Copyrights, Trade Secrets,
          and Technology Licensing
RGA 6205  Emerging Trends and Issues in the
          Medical Devices Industry  4 q.h.
RGA 6210  Strategic Planning and Project Management
          for Regulatory Affairs Professionals in Domestic
          and International Markets  4 q.h.
RGA 6211  Combination Products and Convergence
          4 q.h.
RGA 6215  Project Management in Early Drug Discovery
          and Development  4 q.h.
RGA 6245  Regulation of Generic Pharmaceutical
          and Biosimilar Products  4 q.h.
RGA 6250  Financing and Reimbursement in
          Biomedical Product Development  4 q.h.

International  4 q.h.
Choose one of the following courses:
RGA 6220  Global Biotechnology Product Registration:
          E.U., U.S. Product Regulation  4 q.h.
RGA 6221  European Union Compliance Process and
          Regulatory Affairs  4 q.h.
RGA 6222  Global Awareness: European Medical Device
          Regulations  4 q.h.
RGA 6223  Global Awareness: Introduction to Canadian,
          Asian, and Latin American Regulatory Affairs
          4 q.h.
RGA 6225  Global Awareness: Japan Medical Device
          Regulations and Registrations  4 q.h.
RGA 6226  Canadian and Australian Medical
          Device Regulations  4 q.h.
RGA 6227  Global Awareness: Emerging Medical
          Device Markets  4 q.h.
RGA 6228  Managing International Clinical Trials
          4 q.h.
RGA 6240  The Evolving Indian Regulatory Landscape
          3 q.h.

Open Elective  4 q.h.
Choose one of the following courses or one course from
any other category.
COP 6940  Personal and Career Development:
Leadership in Practice  3 q.h.
          Enrollment into this course requires participation in
          the cooperative education program (subject to
          availability). Students must also take RGA 6920 (1 q.h.)
          to meet the 4 q.h. elective course requirement.
          Effective spring 2012, all students in this program
          are required to complete both RGA 6100 and
          BTC 6210 before enrolling in COP 6940.
RGA 6206  Practical Aspects of Regulatory Compliance  4 q.h.

Total Quarter Hours:  45 q.h.

Information about tuition rates for the 2013-2014 academic year is available on
northeastern.edu/cps/tuition-financial-aid.
Tuition and fees are subject to revision by the
President and the Board of Trustees at any time.