Nonclinical Biomedical Product Regulation, Graduate Certificate

The professional practice of nonclinical regulatory affairs involves understanding, developing, and applying global compliance standards to the biomedical product commercialization process in several cross-functional areas that are separate and distinct from direct clinical patient care. This includes, but is not limited to, design and preclinical development processes, including *in vitro* and *in vivo* animal testing, *in silico* testing, small-scale/large-scale manufacturing process development and validation, development and maintenance of supply chains, as well as product handling and distribution. The Graduate Certificate in Nonclinical Biomedical Product Regulation introduces students to the practice of understanding, developing, and effectively applying global nonclinical compliance standards to new healthcare technologies. Students in the certificate program have the opportunity to:

- Differentiate between the nonclinical vs. clinical aspects of the global biomedical product commercialization process from a regulatory compliance perspective
- Explain the compliance-associated requirements needed to successfully practice professional nonclinical work within the global biomedical products industry
- Describe the nonclinical regulatory standards utilized by the United States Food and Drug Administration (FDA) and other global regulatory agencies to evaluate the safety and efficacy of new and existing biomedical products employed by healthcare practitioners in various patient settings
- Apply fundamental global nonclinical regulations to the biomedical product commercialization process, including therapy design, manufacturing process development and validation, cybersecurity, and supply chain risk management

Students that successfully complete this certificate may apply their courses toward the Master of Science in Regulatory Affairs (http://catalog.northeastern.edu/graduate/professional-studies/masters-degree-programs/regulatory-affairs-ms/).

Program Requirements

Complete all courses and requirements listed below unless otherwise indicated.

Required Courses

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
Complete one of the following:		4
RGA 6385	Operational Aspects of Electronic Common Technical Document (eCTD) Submissions	
RGA 6420	Global IVD Regulations and Submissions	

Program Credit/GPA Requirements

16 total quarter hours required
Minimum 3.000 GPA required