

# Quality Assurance Compliance, Graduate Certificate (Boston)

Global regulatory requirements and compliance standards for development, marketing approval, and clinical utilization of new biomedical products continue to evolve rapidly in today's dynamic healthcare environment. The professional practice of quality assurance involves ensuring compliance to appropriate industry-specific regulatory standards throughout a biomedical product's life cycle.

## Program Requirements

Complete all courses and requirements listed below unless otherwise indicated.

## Required Courses

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 courses:		
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		

## Program Credit/GPA Requirements

16 total quarter hours required

Minimum 3.000 GPA required