Medical Device Regulatory Affairs, Graduate Certificate

The national and regional medical device industries have continued to experience significant market growth, despite the fluctuations in the overall global economy. There are more than 7,000 medical device companies in the United States alone, and nearly 1,000 of these are based in Massachusetts. In total, the medical device sector in Massachusetts employs 36,000 workers, has a payroll of over $1.8 billion, and annual product shipments of $7.3 billion.

The Graduate Certificate in Medical Device Regulatory Affairs provides students with an opportunity to gain a detailed knowledge of the regulations influencing the commercialization of new and existing medical devices. The intensely practical curriculum spans the entire life cycle of product development and introduces students to the salient features governing both pre- and postapproval stages. The program content also examines the relationship between regulatory agencies and the medical device industry. Students have the opportunity to take specialized courses on regulatory systems outside the United States.

The certificate will help advance the careers of students coming from such fields as bioengineering, quality control/assurance, intellectual property, business, and marketing. The choice of several courses makes this certificate ideal for students already working in the regulatory world as well as those just entering into the profession.

Courses from this certificate may be applied toward the Master of Science in Regulatory Affairs.

Program Requirements

Complete all courses and requirements listed below unless otherwise indicated.

Core Requirement

Code	Title	Hours
Required Courses		
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
Electives		
Choose from the following:		6
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	

Program Credit/GPA Requirements

16 total quarter hours required
Minimum 3.000 GPA required