Medical Device Regulatory Affairs, Graduate Certificate (Online)

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

This certificate is ideal for students already working in the regulatory industry, coming from bioengineering, quality control/assurance, intellectual property, business, marketing, and those just entering the profession.

Program Requirements

Complete all courses and requirements listed below unless otherwise indicated.

Required Courses

Code	Title	Hours
Required Courses		
RGA 6610	Introduction to Food and Drug Administration Medical Device Regulation	3
RGA 6620	Medical Device Development: A Regulatory Overview	3
RGA 6630	Medical Device Quality Management System: Principles and Applications	3
RGA 6640	Risk Management: Compliance and Processes	3

Program Credit/GPA Requirements

12 total semester hours required
Minimum 3.000 GPA required