Regulatory Affairs for Drugs, Biologics, and Medical Devices with Concentration in Medical Devices, MS

The medical devices regulation concentration within the master's degree for drugs, biologics, and medical devices program enables students to focus specifically on regulatory issues associated with global commercialization of medical device products and services. Medical device regulation, in many aspects, differs substantially from regulation of drug and biologic product commercialization. In addition to significant geographic variability between these product groups from a regulatory perspective, most of the regulatory operational functions associated with commercializing medical device products and services are unique to that product category. Moreover, these differences extend to both the preapproval and postapproval aspects of compliance reporting between the two sets of product groups. Given this variability, the medical devices regulation concentration gives students the opportunity to study the global regulatory marketing approval processes, compliance issues, and operational details specific to this product group. The concentration also enables students to compare and contrast both the similarities and differences between global medical device product and service regulations and those of drug and biologic product regulation.

Program Requirements

Complete all courses and requirements listed below unless otherwise indicated.

Required Courses

Code	Title	Hours
RGA 6001	Introduction to Food and Drug Administration Medical Device Regulation	2
BTC 6210	Human Experimentation: Methodological Issues Fundamentals	4
RGA 6202	Medical Device Development: A Regulatory Overview	4
RGA 6203	Pharmaceutical and Medical Device Law: Topics and Cases	5
RGA 6370	Advanced Regulatory Writing: Medical Device Submissions	4
RGA 6300	Practical Applications in Biomedical Product Global Regulatory Affairs	4

Electives

Code	Title	Hours
Complete 22 quarter hours from the following. At least one elective must be taken from each of the categories below.		22
Regulatory and Clinical Operations		
RGA 6233	Application of Quality System Regulation in Medical Device Design and Manufacturing	
RGA 6234	Drug and Device Supplier Risk Management: Compliance and Processes	
Regulatory Perspective: Product Development, Business, and Strategy		
RGA 6219	Advanced Topics in Advertising and Promotion of Drugs and Medical Devices	
RGA 6112	Biomedical Intellectual Property Management Strategy: Patents and Trade Secrets	
RGA 6205	Emerging Trends and Issues in the Medical Device Industry	
RGA 6210	Strategic Planning and Project Management for Regulatory Affairs	
RGA 6211	Combination Products and Convergence	
COP 6940	Personal and Career Development (Enrollment in COP 6940 requires participation in the cooperative education program, subject to availability)	
INT 6943	Integrative Experiential Learning	
EDU 6184	Interdisciplinary Foundations	
International		
RGA 6222	European Medical Device Regulations	
RGA 6225	Japanese Medical Device Regulations and Registration	
RGA 6226	Canadian and Australian Medical Device Regulations	
RGA 6227	Emerging Medical Device Markets	
RGA 6241	Working in Multicultural Environments: Challenges and Opportunities	
RGA 6247	Medicines Regulatory Harmonization in Africa	
Special Topics		
RGA 6243	Medical Device Product Development in Canada	
RGA 6460	Intellectual Property in the Life Sciences	
RGA 6420	Global IVD Regulations and Submissions	
RGA 6242	Preparing EU Medical Device Clinical Evaluations	

Program Credit/GPA Requirements

45 total quarter hours required
Minimum 3.000 GPA required