

MEDICAL DEVICE MANAGEMENT AND REGULATION, CERTIFICATE

Certificate in Medical Device Management and Regulation (480008C)

Medical Device Management and Regulation Certificate prepares students with knowledge and skills required to work in medical device industry. Specifically, students will be able to demonstrate knowledge of medical devices and how they are regulated by ISO standards, U.S. Food and Drug Administration (FDA), and European Union, risk management standards related to medical device regulatory pathway, good manufacturing practices of medical devices and operations and process improvements in production settings, 510(k) submissions, quality systems, and different stages of project management.

The following information has official approval of **The Department of Biomedical Engineering** and **The College of Engineering and Polymer Science**, but is intended only as a guide. Completion of this minor is contingent upon many factors, including but not limited to: class availability, total number of required credits, work schedule, finances, family, course drops/withdrawals, successfully passing courses, prerequisites, among others.

Summary

Code	Title	Hours
Required Courses		15
Total Hours		15

Required Courses

Code	Title	Hours
BMEN 391	Biomedical Engineering Regulatory Process	1
BMEN 394		1
BMEN 395		1
BMEN 300	Biomaterials	3
BMEN 325	Design of Medical Devices	3
BMEN 493		3
BMEN 494		3
Total Hours		15