



THE OHIO STATE UNIVERSITY
COLLEGE OF ENGINEERING

Medical Device Development and Regulation

BIOMEDE 5639

Credit Hours:

3.00 - 3.00

Course Levels:

Undergraduate (1000-5000 level)

Graduate (5000-8000 level)

Course Components:

Lecture

Course Description:

Basic principles and essential steps for medical device design and commercialization.

Prerequisites and Co-requisites:

Prereq: Sr or Grad standing in Engineering, or permission of instructor.

Course Goals / Objectives:

- Distinguish between primary and secondary market research, to identify marketing resources in medical device industry, and to convert clinical needs into engineering specifications
 - Identify methods for intellectual property protection and to carry out the patent search for medical devices
 - Utilize engineering and management tools for medical device design, project management, progress reporting, and documentation
 - Itemize the essential components for medical device regulation, to differentiate between PMA and 510k pathways for FDA approval, and to emphasize safety, human factor, and research ethics in medical device development
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Course Topics:

- Clinical needs and market analysis
 - Product definition and QFD analysis
 - Computer-Aided Design and Manufacturing
 - Design and fabrication of biomedical devices and micro devices
 - Design management and project plan
 - Human factors, safety and ergonomics
 - Prototyping, testing and quality control
 - Software programming, verification, and validation
 - Benchtop, animal, and clinical testing
 - Regulation and FDA
 - Research ethics
 - Funding and business plan
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Designation:

Elective