



Medical Product Development II

BIOMEDE 5902

Credit Hours:

3.00 - 3.00

Course Levels:

Graduate (5000-8000 level)

Course Components:

Lecture

Course Description:

Second course in a two-course sequence, focused on taking a medical product or device from concept/prototype to commercialization. Topics include medical product or device testing, IP protection, business models, manufacturability, FDA approvals, and commercialization.

Prerequisites and Co-requisites:

Prereq: 5901, or permission of instructor.

Course Goals / Objectives:

- Identify and apply elements of lean-design process (1.2)
 - Utilize the primary elements of human-centered, usability design (2)
 - Describe the methods, strategy and process of protecting intellectual property
 - Analyze the impacts of healthcare costs and reimbursements for a medical product
 - Produce documentation that meets industrial product requirements and standards
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Course Topics:

- Business planning and commercialization strategies
 - Professional documentation and communication
 - Project management and leadership
 - Verification and validation of medical product in healthcare market
 - Time management
 - Professional ethics and practice
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Designation:

Elective