



**THE OHIO STATE UNIVERSITY**  
COLLEGE OF ENGINEERING

# Medical Product Development I

## BIOMEDE 5901

**Credit Hours:**

3.00 - 3.00

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**Course Levels:**

Graduate (5000-8000 level)

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**Course Components:**

Lecture

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**Course Description:**

First 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.

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**Prerequisites and Co-requisites:**

Prereq: 4902, Engr 5902.02H, or equiv.; and permission of instructor.

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**Course Goals / Objectives:**

- make design decisions based on basic design-for-manufacturability principals
  - understand the financials of a manufacturing company, including cost structure and ROI requirements for new product developments
  - design, implement, and document testing plans to verify and validate a medical device or product with respect to user needs, design requirements, standards, national and international regulatory pathways, and FDA approvals
  - collaborate effectively in multidisciplinary teams that include integration between clinical professionals, patients, and product manufacturer
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**Course Topics:**

- Concept screening, or taking an initial design concept through to final concept selection
  - Professional documentation and communication
  - Project management and leadership
  - Teamwork
  - Time management
  - Professional ethics and practice
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**Designation:**

Elective