Welcome to

BE 467
Product Design and Innovation

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Contact Information

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• Blackboard BE 467 website
Why are you here?

• You have chosen BME to learn about design product solutions for unique clinical problems
• To learn the process of medical product development
• To prepare you for a professional biomedical engineering career (interview)
• Get a competitive advantage
Course Organization

• Innovation Knowledge Base
  • 11 lectures (~1/week)
  • 11 Application Workshops
  • 4 Case Study Reviews
  • Prereading Assignments
  • Written Team Assignments
  • Midterm/Final Written Exams - individual
  • Final Team Presentation

• Team Projects (knowledge application & teamwork)
  – Prepare a Development Plan for a Medical Version of a Common Device (Grab Bag)
Grading

• Deliverables
  – 20% for each Written Assignments
    • All team members will receive the same grade
  – 25% Midterm (individual)
  – 30% Final (individual)
  – 20% Final Presentation (team)
  – 5% Class Participation (individual + one team meeting with one Prof.)

• Exams will cover lecture and case study material
• Exams will cover interval lectures/case studies
Miscellaneous

• To minimize distractions during our tightly packed classes, please:
  • During class, close your laptops and turn off your phones.
  • If you must take a call, do it outside the classroom.
  • Lecture slides will be available on our Blackboard website.
Schedule (Lectures in PHO205)

• 9/3 - Course Structure, logistics and objectives
• AS1  What makes this a medical device? Describe career goals & course expectations. Due Sept. 8 Hard copy & pdf by class time
• 9/8 Introduction to Product Development Process and Regulations
• 9/10 Project Team Discussions and Project Grab Bag in SCI 113
• AS2 Meet with team to discuss the medical device for your project and email your selection to us by 9/14 midnight. Select team and sign up individually under the same group number on Blackboard Learn (BB) by 9/14 midnight.
• 9/15 Problem Identification and Need Statements
• AS3  Prepare Project Draft Problem and Need Statement - hard copy and PDF to Blackboard and by Sept. 17
• 9/17 Problem Identification and Need Statements Workshop
Schedule (Lectures in PHO205)

- **AS4** Prepare Final Project Problem and Need Statement - hard copy and PDF to Blackboard by Sept. 29
- **9/22** Industry (Saunders) Introduction to Intellectual Property (Part 1)
- **9/29** Industry (Saunders) Introduction to Intellectual Property (Part 2)
- **10/1** IP Workshop - Assignment Reviews
- **AS6** Written Assignment - Blue Book October 1
- **10/6** Exam 1
- **10/8** FDA Regulatory Requirements
- **AS7** Draft Project Product Classification and Identify Predicate Devices - hard copy and PDF; FDA Case Questions - Blue Book by Oct 14
- **10/14** Product Classification Workshop - FDA Case 1 Review
- **AS8** Prepare Final Classification and Predicate Identification by Oct 22
Schedule (Lectures in PHO205)

• 10/15 Design Controls
  • AS9  Draft Project Product Functional and Performance Specifications by October 27
• 10/20 Risk Management- Process
  • AS10  Draft Project Product Risk Assessment ; FDA Case Study Questions - Blue Book by October 22
• BME((Szabo) -  Risk Management Workshop - Review FDA Case 2
  • Wednesday October 22
  • AS11  Prepare Final Risk Assessment Matrix Draft by October 27
• 10/27 Risk Management - FMEA tool
  • AS12  Draft FMEA for Project Product - hard copy and PDF by Oct. 29
• 10/29 FMEA Workshop
  • AS13  Prepare Final Project Prodcut FMEA - hard copy and PDF by November 5
• 11/3  Pre Market Approval Process and Requirements
  • AS14  FDA Case 3 - Homework Questions - Blue Book by Nov. 5
Schedule (Lectures in PHO205)

- 11/5  Pre Market Approval Workshop - Case 3 Rw Case
- 11/10 Pre Market Notification Process - 510K
- AS15    FDA Case 4 - Homework Questions - Blue Book
- 11/12 Pre Market Notification Workshop - FDA Case Rw
- AS16    FDA Regulatory Pathway & Outline Submission for Project Product by 12/1
- 11/17 Course Material Review
- 11/19 Exam 2
- 11/24 No class
- 11/26- 11/30 Thanksgiving Recess
- 12/1,12/3, 12/8, 12/10 Project Presentations
Meanwhile in room 205....
If you feel like a sardine...

- There are 58 students in BE 467 A1
- There are 59 students in BE 467 A2
- There are 58 seats in PHO 205!
Forming Teams (Groups)

• The ideal team size is 5
• The boundary condition is 58 or 59 in a section
• Means 10 groups of 5 and 2 groups of 4 in a section of 58
• Means 11 groups of 5 and 1 group of 4 in a section of 59
• Total number of groups = 24
Finalizing Teams

• To finalize the selection of your team members,

• Choose an untaken group number for your team on Blackboard then

• Each prospective team member follows the directions for group signup on Blackboard

• Do so by 9/14 midnight
Team **Medical Device** Selection

Grab Bag of names of hardware store items

Imagination! & resources

Meet with team to discuss the medical device (9/10 or before) for your project and email your selection to us by 9/14 midnight

Draw your team’s item on Wednesday September 10
WHAT MAKES THIS A MEDICAL DEVICE?

SHOP TOOL

SURGICAL TOOL
First Assignments

- 9/8 Assignment 1 –
- (Hard Copy (hand in at class) and post pdf copy on Blackboard by class time:
  - Your Career Goal(s)
  - Your Course Expectations
  - What Makes this a Medical Device?
- Form teams (groups) (usually 5)
- 9/10 Grab bag for devices, team meetings & discussion (NOTE THIS WILL BE IN SCI 113)
- 9/14 midnight: select team and sign up as a group on Blackboard
- 9/14 midnight: select & signup on BB for team device