

TOPICS IN BME: APPLICATIONS IN MEDICAL DEVICES

Course Number: 16:125:575

Index Number: 21374

Course Time: Thursdays, 5 – 8 PM

Remote instruction via Zoom:

for students only

Description and Objectives:

This course will provide students insight into the practical aspects of medical device applications, and introduce business concepts as they relate to medical devices from a realistic industrial perspective. Representative fields including but not limited to cardiovascular, preclinical testing, diagnostics, imaging, rehabilitation, and wound healing will be covered. Within each field, topics such as market and design considerations, FDA pathway, clinical trial requirements, manufacturing/QA/QC, and post-market considerations will be touched on. Industrial practitioners provide lectures and facilitate discussions highlighting problems such as manufacturing issues or project management challenges that engineers and scientists may encounter when dealing with the medical device industry.

After taking this course, students should have a better understanding of the challenges that engineers and scientists face in the medical device industry and gain an appreciation for the practical applications of their academic studies.

Course Directors:

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Major Textbooks and Other Reference Materials:

Relevant reading material will be provided by each lecturer.

Criteria for student grading:

Component	Percent
Class Participation	25%
Homework	30%
New Device Executive Summary	35%
Presentation	10%
Total	100%

Participation:

This class was kept small to encourage interaction with our guest speakers and each other. Please speak up in class, don't be shy! There will also be a lot of group work using Zoom breakout rooms, and presenting back to the class. Our speakers enjoy hearing your ideas!

Homework:

- Assignments and materials will be provided by the speakers to prepare you for the class topic.
- Answers should be submitted in essay format.
- Due at the beginning of class to ensure preparedness for the lecture and active participation.

Class Preparation: Reading material for each session can be found on the course Canvas page:

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- Course NOT recommended if you expect to miss > 1 class
- **You must notify** the course directors in advance if you will miss a session, and you must submit answers to questions on that session's reading assignment

Topics and Speakers, Spring 2021:

21-Jan	A) Introduction to Course Objectives B) Historical FDA Perspective for Medical Device Development	<i>Kristen Labazzo, Natalie Macon Jordan Katz</i>	Rutgers Orthobond
28-Jan	Medical Devices: An Overview of Generally Used Standards & Guidances	<i>Rosemarie Logan</i>	Rlogan Consulting (Regulatory Science)
4-Feb	Personalized Medicine, Consumer Products	<i>David Dalessandro</i>	Johnson & Johnson
11-Feb	Animal Welfare and Ethics alongside Preclinical research strategies	<i>Amardeep Hoonjan</i>	Abbvie
18-Feb	Wound Closure Products	<i>Carlos Caicedo</i>	Orthobond
25-Feb	Mistakes and Failures	<i>Meg Smith</i>	Stryker
4-Mar	Process for Scouting and Evaluating New Technologies for Medical Diagnostics	<i>Lance Ladic</i>	Siemens
11-Mar	Wheelchairs and seating: Promoting abilities through understanding and innovation	<i>John Reck</i>	Matheny Medical and Educational Center
18-Mar	SPRING BREAK-NO CLASS		
25-Mar	Topic TBD	<i>Natalie Macon</i>	Rutgers
1-Apr	Product Management Across Life of a Medical Device from Innovation to Life Cycle Management	<i>Nasir Uddin</i>	Abbott
8-Apr	"CellScope" Case Study	<i>Lance Ladic</i>	Siemens Healthineers
15-Apr	Combination Products through Launch and Post-Market Surveillance	<i>Theresa Scheuble</i>	Johnson & Johnson
22-Apr	Panel Discussion (physician, patient, clinical, researcher, engineer, etc all at one table!)	<i>variety TBD</i>	variety
29-Apr	Medical Device Presentations	<i>Guest judges</i>	

Medical Device Proposal:

Students will form groups and have the opportunity to propose a novel medical device. The idea does not have to be realistic, so long as it can be appropriately justified and a convincing argument can be made.

Students are to prepare an executive summary for their medical device which should include the following elements:

- Opportunity: what is the unmet need that your device fulfills?
- Value Proposition: how will your device be better? What value does it bring to the community you are serving?
- Market Size: who are your customers and how large is the population? If there are comparable products, how many are sold a year?
- Development: What are your big design hurdles? User Needs, Design Inputs, Performance Requirements??
- Investment Opportunity: how much money are you looking to generate? Can the product be reimbursed through health insurance to make it more attractable to physicians?
- Competition and Barriers to Entry: what are some competitive products? Are there other barriers such as FDA issues or clinical trial difficulties?
- Exit Strategy:
- Freedom to Operate: are there patents which may prevent you from making this product?
- Regulatory: what FDA classification will your device have? What will your clinical trials look like? Enrollment size?

The executive summary should be no more than 2 pages.

Presentation:

Groups will have the opportunity to present their medical device concept to the class. Each presentation should contain 7-10 powerpoint slides. Presentations will be graded on relevance, novelty, justification of idea, attention to detail, and how well the presentation is organized and delivered. Previous industrial speakers will be invited back to serve as guest judges.

Academic Integrity:

Students are expected to familiarize themselves with and adhere to the University policy on academic integrity at: <http://academicintegrity.rutgers.edu/academic-integrity-policy/>