

TOPICS IN BME: INDUSTRIAL APPLICATIONS OF MEDICAL DEVICES

Course Number: 16:125:575

Index Number: 13852

Course Time and Location: Thursdays, 5 – 8 PM in BME-116

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:

Kristen Labazzo, Ph.D., MBA

Assoc. Teaching Professor

Rutgers University, BME

kristen.labazzo@rutgers.edu

Carlos E. Caicedo-Carvajal, Ph.D.

Innovation Leader, Diagnostic Films

Ashland

ccaicedo@soe.rutgers.edu

Major Textbooks and Other Reference Materials:

Relevant reading material will be provided by each lecturer and posted on Canvas.

Criteria for student grading:

Component	Percent
Class Participation/Pre-Class Work	20%
Module Essays	35%
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 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. Please use complete sentences, references, and provide thoughtful answers.
- 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

Grading: This is a graduate class. As such, most students receive As and Bs. Cs are not considered good grades in graduate courses, and anything less would be a failing grade.

Topics and Speakers, Spring 2025 (topics could change):

23-Jan	A) Introduction and Roadmap B) Historical FDA Perspective for Medical Device Development	<i>Carlos Caicedo, Kristen Labazzo Jordan Katz</i>	Ashland Rutgers University Orthobond Corporation
30-Jan	Medical Devices: An Overview of Generally Used Standards & Guidances	<i>Rosemarie Logan</i>	Rlogan Consulting (Regulatory Science)
6-Feb	Five Tools for Medical Device Development	<i>David Dalessandro</i>	Retired Johnson & Johnson MedTech
13-Feb	Making “Magic” to Guide your Product Innovation	<i>John Crombie</i>	UpStart Product Development
20-Feb	Health Digital Twins	<i>Lance Ladic</i>	Siemens Healthineers
27-Feb	Wound Closure Products	<i>Carlos Caicedo</i>	Ashland
6-Mar	Development of a Percutaneous Transcatheter Mitral Valve Repair Solution for the Treatment of Congestive Heart Failure	<i>Natalie Macon</i>	
13-Mar	Prep for final project	<i>Carlos Caicedo, Kristen Labazzo</i>	
20-Mar	Spring Break		NO CLASS
27-Mar	Dental Applications for Medical Devices	<i>Josh Simon</i>	
3-Apr	Animal Welfare and Ethics alongside Preclinical research strategies (may change topic?)	<i>Amardeep Hoonjan</i>	Abbvie
10-Apr	Managing Quality	<i>Meg Smith</i>	Retired, Stryker
17-Apr	Combination Products through Launch and Post-Market Surveillance	<i>Theresa Scheuble</i>	Johnson & Johnson
24-Apr	Panel Discussion (physician, patient, clinical, researcher, engineer, etc all at one table!)	<i>variety TBD</i>	variety
1-May	Medical Device Presentations	<i>Guest judges</i>	

Medical Device Proposal (this will be discussed in more detail later in the semester):

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: Are you going to license your device? Partner? Sell to a larger company?
- 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.

Other Important Information

Support Services: Students of **all abilities are welcome** in the BME educational program!
<https://ods.rutgers.edu/faculty/syllabus-statement>

CAPS (Counseling, Alcohol and Other Drug Assistance Program & Psychiatric Services):
 Ms. Fanteema Barnes-Watson, LCSW: <http://www.health.rutgers.edu/dropin>.

Academic Integrity:

Rutgers University takes academic integrity very seriously. By enrolling in this course, you assume responsibility for familiarizing yourself with the [Academic Integrity Policy](#) and the possible penalties, including suspension and expulsion, for violating the policy.

As per the policy, all suspected violations will be reported to the Office of Student Conduct.

Academic dishonesty includes (but is not limited to):

- Cheating
- Plagiarism (using the work of others as your own)
- Aiding other students in committing a violation or allowing other students to use your work
- Failure to cite sources correctly
- Fabrication
- Using another person's ideas or words without attribution
- Reusing previous assignments
- Unauthorized collaboration
- Sabotaging another student's work

If you are in doubt about what does and does not constitute academic dishonesty, please consult Dr. Labazzo.

Adherence to academic integrity principles is important to ensure that:

- All student work is fairly evaluated and no student has an inappropriate advantage over others.
- The academic and ethical development of all students is fostered.
- The reputation of the University for integrity, ethics, scholarship, and professionalism is maintained and enhanced.

Key points for this course:

All work submitted in this course must be your own, unless instructed. In some cases, students can work together on homework, but in these cases, everyone must contribute, and you must list who worked on the assignment. In no instance should a student copy another student's work verbatim, and submit it as their own. All work must be appropriately cited and referenced. There are no exams, and the final project is a group assignment.

Honor pledge:

On each assessment you will be required to re-affirm the university honor pledge: "*On my honor, I have neither received nor given any unauthorized assistance on this examination / assignment*".

The academic integrity policy also states that "*Students are also encouraged to help educate fellow students about academic integrity and to bring all alleged violations of academic integrity they encounter to the attention of the appropriate authorities*". i.e. if you are aware of or suspect that other students are violating the academic integrity policy, you should inform the instructor, anonymously if you prefer.

Disclaimer:

Drs. Labazzo and Caicedo reserve the right to change the syllabus or any course policies at any time, in order to achieve the learning objectives for the course. Students will be informed of any changes to the syllabus prior to their implementation.