1. Course Number and Name

ENME413 Medical Device Development

2. Credits and Contact Hours

3 credits, 3x50 minutes/week

3. Instructor

Dr. Neil Rothman, nrothman@umbc.edu
Please include the course number (ENME489) in the subject line of your emails.

Office: ENGR225C
Office Hours: As posted on Blackboard or by appointment
Open Door Policy:

- If my door is open, come on in.
- If my door is ajar, please knock softly so I know you're there. You may have to wait a few minutes if I'm meeting with someone.
- If my door is closed, I'm occupied or away. Please come back at another time.

Telephone:
410-455-5507 (UMBC campus)
Before you call or email me, check the course Blackboard site.

4. Textbook or Material

Instructor will provide in-class handouts and information

5. Specific Course Information

This course will examine the multidimensional aspects of medical device development and manufacturing and provide students with the entrepreneurship skills necessary to understand how devices are developed and brought to market. Students will specifically learn how to assess a device's clinical effectiveness, to evaluate its core function/technology, and to identify the appropriate path and requirements to obtain regulatory clearance/approval. The course will use a combination of lectures and case studies to explore the complex environment and challenges associated with medical device development and provide students with a foundation to work in that industry. Selected devices will be analyzed from technical, regulatory, and medical perspectives, including the evaluation of alternative technologies. Guest lectures will be used to provide first hand exposure to medical device organizations and development.

Prerequisites: Senior standing in Mechanical Engineering with a 2.0 or better GPA. This is an elective course.

6. Specific Goals for the Course

Students will learn to research and analyze case studies about specific devices from technical, medical/clinical, and regulatory perspectives. These three aspects of medical device development will provide students with the perspective to quantify

the market need for the device, understand its core technology, and identify the regulatory pathway for bringing the device to market. These entrepreneurial skills are critical for building a business around a new medical device, but are also of significant importance for a member of a development team in an established medical device manufacturer. Further, these skills readily transfer to the assessment of market opportunities and development of new products in any industry.

Students will demonstrate their understanding and acquisition of these skills in a semester project consisting of in-depth research and reporting on an existing or new medical device.

Upon completion of the course, students will demonstrate the following entrepreneurship skills, specifically focused on the medical device industry:

- Assessing the market need for a medical device
- Evaluating a medical device's core technology for reliability and robustness
- Understanding the regulatory pathway to clearance/approval of a medical device.

After completing this course, students will also demonstrate the following ABET learning outcomes:

1. An ability to identify, formulate, and solve engineering problems by applying principles of engineering, science, and mathematics

4. An ability to communicate effectively with a range of audiences

5. An ability to recognize ethical and professional responsibilities in engineering situations and make informed judgments, which must consider the impact of engineering solutions in global, economic, environmental, and societal contexts

6. An ability to recognize the ongoing need for additional knowledge and locate, evaluate, integrate, and apply this knowledge appropriately

7. An ability to function effectively on teams that establish goals, plan tasks, meet deadlines, and analyze risk and uncertainty

7. Course Content

- Regulatory environment/Design requirements
    - FDA Quality system regulations/Medical Device Directives
    - Design controls
    - Device classification and approval/clearance paths
    - Consensus standards/HIPAA
    - US vs. European device regulations
    - Human factors/ergonomics
    - Risk management
        - Risk/hazard analysis
        - FMEA/FTA

    - Manufacturing
        - Design transfer and process validation
        - Shelf life
        - Supply chain and vendor qualification

- Case study topics
    - Orthopedic devices (knee replacement, prosthetics, surgical tools)
    - Implantable electronic devices (pacemaker, artificial retina, pain management, heart valve, PFO closure)
    - Diagnostics (ECG, glucometer, smart phone applications)
    - Therapeutic devices (resuscitation, diabetes, neonatal microenvironments)
    - Skin closure devices (sutures, Zip)

8. Case Studies

Case studies provide the opportunity to critically review different devices and understand their development, clearance, and use from many different perspectives. Each assignment will require independent research and a written assignment about a specific device. Class periods will be used to provide more in depth background for each device with a majority of the time devoted to discussing the clinical/market need, core technology, and regulatory requirements for each device. Therefore class attendance is critical for your understanding of medical device development.

Case studies should examine the following aspects of medical devices and diagnostics:

- Indications for use (user/market need)
- Core technology/operating principles
- Competing technologies/alternative devices or approaches (where appropriate)
- Risk/benefit analysis
- Regulatory classification and rationale
- Validation requirements and methods
- Suppliers/manufacturers

For each assigned case study, you must research the specified device and prepare a 1-2 page case study that addresses the above topics. All references for your information must be included. Case studies must be submitted as PDF files via email prior to the associated class period as shown on the course schedule. You should also bring a copy of your study to class since we will use this information as the basis for the class discussion of the device.

You should also look for information from device manufacturer websites, industry publications, etc. Remember that Wikipedia is NOT a reference, but may be helpful in pointing your toward actual sources for information. Case studies will be evaluated based on how well they cover the above topics and present the information.

Semester Project

Students will also work with a partner to complete a semester project consisting of an in-depth case study of an existing or new medical device. Students will prepare and deliver a class presentation and submit a written report covering indications for use, regulatory classification and requirements, clinical validation, technical details (technologies, manufacturing, etc.), existing manufacturers (if any), and projected future developments. Details about the project will be posted on Blackboard. Rubrics for evaluating the presentation and report are attached to the syllabus.

9. Course Calendar

Meeting time: TBD

A detailed class schedule with assignments and due dates is provided on Blackboard and at the end of this syllabus.

10. Policies and Procedures

Work is due on time. Not an hour late or the next day. No homework passes, no "graduate style homework", no "within two weeks", no "it's in my apartment". On time!

Everything Counts: Writing style, grammar, typing, word usage, font selection, everything counts in everything you write or deliver, including presentations.

Mobile Phones: This class will require participation and discussion and phones ringing is disruptive for everyone. The best solution is to put your phone on vibrate and in your backpack.

11. Grading

Grading will follow the usual weighted scoring:

Weighted sum ≥ 90 = A

$90 >$ Weighted sum ≥ 80 = B

$80 >$ Weighted sum ≥ 70 = C

$70 >$ Weighted sum ≥ 60 = D

Weighted sum <60 = F

The following weights will be applied for final grades:

Attendance – 20% (attendance will be taken in each class period)

Case studies/homework – 60%

Project (20%) – 5% presentation, 15% report

12. Academic Integrity

By enrolling in ENME413, each student assumes the responsibilities of an active participant in UMBC's scholarly community, in which everyone's academic work and behavior are held to the highest standards of honesty. Cheating, fabrication, plagiarism, and helping others to commit these acts are all forms of academic dishonesty, and they are wrong. Note that lack of contribution to team activities/projects may be considered a violation of the UMBC Student Academic

Conduct Policy since you are essentially submitting work and attempting to get credit for work done by others.

Academic misconduct could result in disciplinary action that may include, but is not limited to, suspension or dismissal. The full Student Academic Conduct Policy is available in the UMBC Student Handbook, the Faculty Handbook, or the UMBC Policies section of the UMBC Directory. Students will not be required to sign a confirmation of compliance with these policies, but will be held to this standard in all effort associated with the course.

Failure to comply with the requirements of the Student Academic Conduct Policy may result in failure of this course.

Neil S. Rothman, PhD