

42-444/744: Medical Devices
Carnegie Mellon University
Department of Biomedical Engineering
Carnegie Institute of Technology
Spring 2014

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Office hours: Monday: 3:30 PM to 4:30 PM
Wednesday: 10:00 AM to 11:00 AM
Other times by appointment

Class Time and Locations:

1:30 PM to 2:50 PM, Monday and Wednesday
Porter Hall, room A18B

Textbook: The main textbook for this course is *Medical Device Technologies: A System Based Overview Using Engineering Standards* by Gail Baura.

Relevant articles and references will be posted on Blackboard. The Carnegie Mellon copyright policy can be found at
<http://www.cmu.edu/policies/documents/Copyright.html>

The following textbooks can be found in the Engineering and Science Library. They may be helpful throughout the entire semester.

1. Ratner B, Hoffman A, Schoen F, and Lemons J (eds). *Biomaterials Science: An Introduction to Materials in Medicine, 2nd Edition*. Elsevier: San Diego, 2004.
2. Kucklick, TR. *The Medical Device R&D Handbook*. Taylor and Francis: Boca Raton, 2006.
3. Helmus MN (ed). *Biomaterials in the Design and Reliability of Medical Devices*. Landes Bioscience/Eurekah.com: Georgetown, TX; Kluwer Academic/Plenum Publishers: New York, 2003.

Class Website: All registered students will have access to the class website via Blackboard (<http://www.cmu.edu/blackboard>). Class announcements, course information, instructor information, course documents, and assignments are contained on this website. This website will be constantly updated with relevant information throughout the semester.

Prerequisites: The level of technical content will require junior standing for MCS and CIT students, a degree in science or engineering for non-MCS or non-CIT graduate students, or permission of the instructor for all other students.

Cross listing: 42-744 (12 units)

Course Description: (As stated in the Carnegie Mellon 2014 Spring Course Catalog)

This course is an introduction to the engineering, clinical, legal and regulatory aspects of medical device performance and failure. Topics covered include a broad survey of the thousands of successful medical devices in clinical use, as well as historical case studies of devices that were withdrawn from the market. In-depth study of specific medical devices will include: cardiovascular medicine, orthopedics, and general medicine. We will study the principles of operation (with hands-on examples), design evolution, and modes of failure. Additional lectures will provide basic information concerning biomaterials used for implantable medical devices (metals, polymers, ceramics) and their biocompatibility, mechanisms of failure (wear, corrosion, fatigue, fretting, etc.).

Course Objectives:

By the end of this course, the students should have met the following objectives:

1. Be familiar with medical devices in the four high-growth areas of cardiovascular device, neural devices, orthopedics and combination products as preparation for work in the medical device industry
2. Understand basic engineering design and problem solving techniques
3. Be familiar with the engineering issues surrounding the design of medical devices
4. Understand the process of obtaining regulatory approval for medical devices
5. Gain hands-on experience with medical devices through in-class demonstrations

Class Procedures

Grading

The final grade for students registered for **42-444** (9 units) will be computed by combining homework, quizzes, and the final exam in the following manner:

Quizzes (49 points)

- Nine (9) 7-point quizzes based on Chapter reading assignments
- End of class (following student lecture on Chapters)
- 7 Multiple Choice / FITB questions
- Closed Book, Open Note
- Drop the lowest 2 scores

Homework (21 points)

- 2-pg report including a 1 pg summary of the guest lecture and a 1 pg response to the 'question of the week' (due \geq 1 week following the lecture)
- 7 guest lectures, max 3 points per summary
- Single spaced, 1" margins, 12pt font, written paragraph format (i.e, not just bullet points)... may include figures.

Final Exam (30 points)

- Comprehensive exam covering all course lectures
- 60 Multiple Choice / FITB questions
- Open Book, Open Note

Total

100 points

The following scale will be used to assign final letter grade for **42-444** students:

90 to 100%	A
80 to 89.9%	B
70 to 79.9%	C
60 to 69.9%	D
0 to 59.9%	R

The final grade for students registered for **42-744** (12 units) will be computed by combining homework, quizzes, in-class chapter presentation, and the final exam in the following manner:

Quizzes (49 points)

- Nine (9) 7-point quizzes based on Chapter reading assignments
- End of class (following student lecture on Chapters)
- 7 Multiple Choice / FITB questions
- Closed Book, Open Note
- Drop the lowest 2 scores

Homework (21 points)

- 2-pg report including a 1 pg summary of the guest lecture and a 1 pg response to the 'question of the week' (due one week following the lecture)
- 7 guest lectures, max 3 points per summary
- Single spaced, 1" margins, 12pt font, written paragraph format (i.e, not just bullet points)... may include figures

In-class Chapter Presentation (30 points)

- Work with partner(s) to give a 60-minute presentation based on assigned material in the 'Medical Devices' textbook. (**15** points total)
- The presentation is to be equally divided between/among group members
- Each presenter will create a (signed) handout summarizing the material covered in their portion of the presentation (worth **15** points—one half of the total grade). Handouts are to be distributed in class prior to the presentation.
- All presenters will get automatic 7 points for the quiz that week

Presentation Guidelines: (IMPORTANT!)

1. Presentation will cover all the material in the assigned Chapter(s), including clinical need, historic devices, system descriptions, and key features from Engineering Standards. PowerPoint slides of Chapter illustrations will be provided by the instructor; students should substantially expand upon these (5 points);
2. Presentations will include at least one historical case study (not covered in the book chapter) of a device that was either the subject of a safety alert or was withdrawn from the market altogether. An analysis of possible failure modes must also be included (5 points);
3. Presentations must also include a discussion of the biomaterials used to manufacture the device and the criteria for choosing those materials (5 points).

Final Exam (30 points)

- Comprehensive exam covering all course lectures
- 60 Multiple Choice / FITB questions
- Open Book, Open Note

Total

130 points

*The following scale will be used to assign a final letter grade to all **42-744** students:*

93 to 100%	A
90 to 92.9%	A-
87 to 89.9%	B+
83 to 86.9%	B
80 to 82.9%	B-
77 to 79.9%	C+
73 to 76.9%	C
70 to 72.9%	C-
60 to 69.9%	D
0 to 59.9%	R

Class Policies

Attendance: Attendance at lectures is *highly recommended*. The concepts and techniques covered during the lectures will most likely not be repeated. As a result, consistent attendance will help you learn, understand, and apply the concepts and techniques being presented.

Assignment Due Dates: Homework assignments (guest lecture summaries) are to be submitted *at the beginning of class* on the day it is due (that is, *one week following the lecture* unless otherwise instructed). This is to be done by hardcopy only. Any assignment turned in after the due date will be deducted one point for every day it is late. Please note that that weekends count as late days!

Class Decorum: Lectures will start and end on time. If you are late, please enter the class without disruptions. If you need to leave early, please inform the instructor before class and exit as quickly and quietly as possible.

The use of cell phones and pagers during class lectures is **strictly prohibited**.

Please keep in mind that these guidelines are necessary to maintain an environment that is safe and conducive for learning.

Exams:

Quizzes will consist of multiple choice and fill-in-the-blank questions covering specific points of information, basic concepts, and problems taken from the chapter material to be covered that day (to ensure that everyone comes to class prepared to participate). The exams will be **closed book, open notes**. Students are therefore encouraged to take notes as they read the assigned chapters and bring them to class for the quizzes (the volume of notes allowed is unlimited, so there will be no need to memorize).

The final exam will be given during the final exam period on the day determined by Carnegie Mellon University. **The final cannot be missed.** Any conflicts will be resolved by abiding with the Carnegie Mellon University Policies on Examinations (<http://www.cmu.edu/policies/documents/Exams.htm>).

Accommodations due to Disabilities: If you wish to request an accommodation due to a documented disability, please inform Dr. Trumble and contact Disability Resources (102 Whitfield Hall, 8-2013, lpowell@andrew.cmu.edu) as soon as possible. For ongoing documented classroom accommodations, a one-week notice is required. Accommodations for finals require three weeks notice.

Academic Integrity: (Excerpted from the Student Handbook and found at http://www.studentaffairs.cmu.edu/acad_integ/acad_integ_text.html)

Students at Carnegie Mellon, because they are members of an academic community dedicated to the achievement of excellence, are expected to meet the highest standards of personal, ethical, and moral conduct possible.

These standards require personal integrity, a commitment to honesty without compromise, as well as truth without equivocation, and a willingness to place the good of the community above the good of the self. Obligations once undertaken must be met, commitments kept.

Rarely can the life of a student in an academic community be so private that it will not affect the community as a whole or that the standards above do not apply.

The discovery, advancement and communication of knowledge are not possible without a commitment to these standards. Creativity cannot exist without acknowledgment of the creativity of others. New knowledge cannot be developed without credit for prior knowledge. Without the ability to trust that these principles will be observed, an academic community cannot exist.

The commitment of its faculty, staff, and students to these standards contributes to the high respect in which the Carnegie Mellon degree is held. Students must not destroy that respect by their failure to meet these standards. Students who cannot meet them should voluntarily withdraw from the university.

Cheating and Plagiarism: (Reproduced from <http://www.cmu.edu/policies/documents/Cheating.html>)

Students at Carnegie Mellon are engaged in preparation for professional activity of the highest standards. Each profession constrains its members with both ethical responsibilities and disciplinary limits. To assure the validity of the learning experience a university establishes clear standards for student work.

In any presentation, creative, artistic, or research, it is the ethical responsibility of each student to identify the conceptual sources of the work submitted. Failure to do so is dishonest and is the basis for a charge of cheating or plagiarism, which is subject to disciplinary action.

Cheating includes but is not necessarily limited to:

1. Plagiarism, explained below.
2. Submission of work that is not the student's own for papers, assignments or exams.
3. Submission or use of falsified data.
4. Theft of or unauthorized access to an exam.
5. Use of an alternate, stand-in or proxy during an examination.
6. Use of unauthorized material including textbooks, notes or computer programs in the preparation of an assignment or during an examination.
7. Supplying or communicating in any way unauthorized information to another student for the preparation of an assignment or during an examination.
8. Collaboration in the preparation of an assignment. Unless specifically permitted or required by the instructor, collaboration will usually be viewed by the university as cheating. Each student, therefore, is responsible for understanding the policies of the department offering any course as they refer to the amount of help and collaboration permitted in preparation of assignments.
9. Submission of the same work for credit in two courses without obtaining the permission of the instructors beforehand.

Plagiarism includes, but is not limited to, failure to indicate the source with quotation marks or footnotes where appropriate if any of the following are reproduced in the work submitted by a student:

1. A phrase, written or musical.
2. A graphic element.
3. A proof.
4. Specific language.
5. An idea derived from the work, published or unpublished, of another person.

Any disciplinary actions regarding charges of cheating or plagiarism will follow the procedures described in the “Carnegie Mellon University Undergraduate Academic Disciplinary Actions Overview” that can be found at <http://www.cmu.edu/policies/documents/AcadRegs.html>.

Collaboration vs. Cheating: Collaboration is defined by Merriam-Webster's Collegiate Dictionary (10th edition) as "to work jointly with others or together, especially in an intellectual endeavor." Much of the work that is performed in this laboratory (and in biomedical engineering as a whole) is collaborative in nature. Therefore, collaboration in this class is encouraged during the execution of the labs. In addition, discussions regarding the content of homework assignments, lab reports, and the final project are also encouraged.

You are encouraged to discuss the course material, concepts, and assignments with other students in the class. **However, each student must eventually submit his/her own unique work (i.e. laboratory report, homework, etc).** If any collaboration was used to complete an assignment, record the names of the collaborators and the nature of the collaboration. Any attempt to submit work that is not the student's own work will be considered to be an act of cheating and will be subject to prosecution.

If you have any questions regarding this policy, please contact Dr. Trumble.

Expectations of Students and Instructors:

The instructor has the right to expect the following of students:

1. Students will arrive to class on time and will be prepared for the lecture.
2. Students will turn in assignments on time (see policy on assignment due dates).
3. Students will immediately inform the instructor if extenuating circumstances prevent the student from attending a lecture.
4. Students will follow the code of conduct regarding academic integrity, cheating, plagiarism, and collaboration as outlined in the syllabus.
5. Students will seek assistance when they need it.
6. Students will work together effectively in groups (if applicable) to successfully complete the assigned tasks.
7. If contacted by the instructor by phone or e-mail, students will respond within 24 hours during the week and 48 hours on weekends.

The students have the right to expect the following of the instructor and teaching assistants:

1. A syllabus that describes class procedures, policies, and a course description will be provided.
2. Class sessions that will start and end on time.
3. Any changes to the course schedule will be provided to the students within 48 hours of the change.
4. The instructor will be available outside class either during their posted office hours or during other pre-arranged times.
5. Assignments will be returned within two weeks after the due date.
6. Emails to the instructor from students will be returned within 24 hours during weekdays and 48 hours on weekends.

These expectations were adapted and modified from those developed by Howard Culbertson at Southern Nazarene University. The original list of expectations can be accessed at <http://home.snu.edu/~HCULBERT/contract.htm>.

Course Outline

1. Introduction to Medical Devices
2. Specific Engineering Issues regarding Medical Devices
 - a. Biomaterials and Biocompatibility
 - i. Mechanical Properties and Testing
 - ii. Types of Materials
 - iii. Structure/Function Relationships in Biomaterials
 - iv. Failure Mechanisms in Biomaterials
 - v. Surface Properties and Host Response (Biocompatibility)
 - vi. Design Principles for Tissue and Blood Contact
 - b. Power Systems for Implanted Systems
 - c. Control of Medical Devices
3. Obtaining Regulatory Approval and Funding
 - a. Codes and Regulations
 - b. Reliability and Device Testing
 - c. Medical Device Industry
 - d. Commercialization
4. Examples of Medical Devices
 - a. Surgical Instruments
 - b. EKGs and Pacemakers
 - c. Robotic Surgery (daVinci)
 - d. External and Internal Defibrillators
 - e. Heart Valves
 - f. Circulatory Support Devices
 - g. Blood Pressure Monitors
 - h. Extra-corporeal Membrane Oxygenators
 - i. Catheters, Stents, and Grafts
 - j. EEGs and Deep Brain Stimulators
 - k. Cochlear implants
 - l. Intraocular Lens Implants
 - m. Total Hip Prostheses
 - n. Radiation Therapy