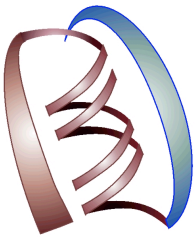

BIOMEDICAL ENGINEERING

Carnegie Mellon University

42-401/51-441: Foundations of Biomedical Engineering Design
Fall 2013

42-402/51-442: Biomedical Engineering Design Project
Spring 2014

Instructors:

	Conrad M. Zapanta
Title:	Teaching Professor and Associate Head of Biomedical Engineering
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Office hours:	Wednesday: 11:00 AM to 12:00 PM Other meeting times available by appointment via the following link: TinyURL.com/bmescheduling
	Wayne Chung
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Teaching Assistants

Name	E-mail
Melissa Delgado	medelgad@andrew.cmu.edu
Krista Rochussen	kristaroch@cmu.edu
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Each team will have a teaching assistant "embedded" within their team. The roles of this teaching assistant are to observe the interactions between the team members, provide guidance to the team as needed, and to serve as a liaison between each team and the instructor. The teaching assistant will meet with each team **at least** once every week (at the discretion of the teaching assistant and instructor).

Class Time and Location:

MM 103 (Breed Hall)
Tuesday and Thursday, 3:00 to 4:20 PM

Textbook and Resources:
Required:

Zenios S, Krummel TM, Makower J, Yock P, and TJ Brinton. *Biodesign: The Process of Innovating Medical Technologies.* Cambridge University Press: New York, 2009.
ISBN: 0521517427
ISBN-13: 9780521517423

Website for textbook: http://www.stanford.edu/group/biodesign/cgi-bin/ebiodesign/

This textbook is available at the Carnegie Mellon Bookstore, as well as other fine bookstores.

Relevant articles and references (such as those that follow) will be posted on class the website on Blackboard.

1. Design Control Guidance for Medical Device Manufacturers, FDA 21 CFR 820.30 (& ISO 9001-4.4), March 11, 1997 – aka "QSR"
2. Sawyer, D., Do It By Design: An Introduction in Human Factors in Medical Design, CDRH, Dec. 1996, US Department of Health and Human Services – aka DIBD

In addition, the following *recommended* reference books are available at the Bookstore, and may be helpful throughout the entire semester… and your careers for that matter.

1. any Medical Dictionary
2. any Anatomy Textbook, e.g. Gray's, Netter, others
3. any Physiology Textbook, e.g. Guyton, others
4. Kucklick, TR. The *Medical Device R&D Handbook.* Taylor and Francis: Boca Raton, 2006.
5. Ratner B, Hoffman A, Schoen F, and Lemons J (eds). *Biomaterials Science: An Introduction to Materials in Medicine, 2nd Edition.* Elsevier: San Diego, 2004.
6. 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.
7. Baura, G. *Medical Device Technologies: A Systems Based Overview Using Engineering Standards.* Elsevier: San Diego, 2011.

Web Resources/Links:

1. bmesource.org – potpourri of valuable biomedical design reference links
2. US Patent and Trademark Office - uspto.gov
3. US Food and Drug Administration – fda.gov
    a. Quality System Regulation

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

Pre- and co-requisite:

42-401: 42-101, priority given to BME seniors
42-402: 42-401

Course Description: This course sequence introduces Biomedical Engineering students to the design of useful biomedical products. Students will learn to identify product needs, how to specify problem definitions and to use project management tools. Methods to develop creativity in design will be introduced.

The course sequence is comprised of two parts:

42-401 is offered in the Fall semester and meets once/week. It also provides the students opportunity to form project teams, and select and define a project.

42-402 is offered in the Spring semester is a full semester course, meeting twice/week to implement and complete the plan that was developed in the fall semester. This course culminates in the completion of **preliminary and final prototypes, a poster presentation, and a written report.**

Course Objectives:

By the end of this course, the students should be able to do the following:

- Develop and exercise skills to apply engineering knowledge to problems that are ill-defined and open ended.
- Develop skills and techniques of locating and evaluating information.
- Develop an appreciation of the design process. These include, but are not limited to: the ability of recognizing, and defining engineering problems, creating conceptual solutions, and evaluation of alternatives.
- Develop skills for professional communication including both formally and informal written and oral presentation.
- Develop skills for documenting your work, including proposal writing and patenting.
- Develop appreciation of social responsibility, the needs of society, and the ethical principles necessary for determining professional and personal conduct.

Relation of Class to ABET (Accreditation Board for Engineering and Technology) Criteria

Program Outcome	***Relation to Program Outcome***	***Mechanism***
Ability to apply knowledge of mathematics, science, and engineering	Primary	Homework, presentations, final project
Ability to design a system, component, or process to meet desired needs within realistic constraints such as economic, environmental, social, political, ethical, health and safety, manufacturability, and sustainability	Primary	Homework, presentations, final project
Ability to function on multidisciplinary teams	Primary	Homework, presentations, final project
Ability to identify, formulate, and solve engineering problems	Primary	Presentations and final project
Understanding of professional and ethical responsibility	Secondary	Homework and final project
Ability to communicate effectively	Secondary	Homework, presentations, final project
Recognition of the need for, and an ability to engage in life-long learning	Secondary	Homework, presentations, final project
Knowledge of contemporary issues	Secondary	Homework, presentations, final project
Ability to use the techniques, skills, and modern engineering tools necessary for engineering practice	Primary	Homework, presentations, final project
Capability to apply advanced mathematics (including differential equations and statistics), science, and engineering to solve the problems at the interface of engineering and biology	Primary	Homework, presentations, final project
Ability to address problems associated with the interaction between living and non-living materials and systems	Secondary	Final project

Class Procedures

Organization of Teams:

The teams will be organized into teams of four to six students. Teams will be selected by user input, project interest, and the Comprehensive Assessment for Team-Member Effectiveness (CATME) system. This system uses class schedule, major, software skills, leadership styles, big-pictures/detail oriented preferences, and other criteria to create diverse teams. This diversity promotes multi-disciplinary collaboration and cooperative learning.

Each team is expected to meet at least once a week **outside of class**. Team members may be re-assigned to other teams if a specific need is required for another team.

Each team will be led by a Project Leader who is vested with the authority and accountability for the team. These responsibilities include the following:

- assure communication with client and advisors
- generate time table, identify milestones and deliverables of the overall project and of team members.
- monitor status of project & recognize slippage and take corrective action
- documentation
- other duties as needed to "fill in the gaps"

Deliverables at the End of the Spring Semester (42-402):

At the completion of 42-402, the teams will be required to present the following:

1. Working prototype
2. Final written report based on BMEStart format (http://nciia.org/bmestart/guidelines#rules)
3. Poster that summarizes the written report

In addition, student teams are **strongly encouraged** to enter their project to either one (or both) of these competitions:

1. BMEStart competition (http://nciia.org/bmestart/guidelines#rules)
2. National Institute of of Biomedical Imaging and Bioengineering (NIBIB) Design by Biomedical Undergraduate Teams (DEBUT) Challenge (https://contests.dobt.co/debut2014/)

Grading

The final grade will be computed in the following manner:

Peer Grading	30%
Prototype #1	15%
Prototype #2	15%
Final Prototype (including poster and report)	20%
Homework and Project Updates	10%
Attendance (lectures and group meetings)	10%
Total	**100%**

Peer grading will be performed using the CATME (Comprehensive Assessment for Team-Member Effectiveness) system.

Class Policies

Attendance: *Attendance at lectures and group meetings is required*. 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 (including project updates), peer reviews, and the final report are to be submitted by the beginning of class on the day it is due. This can be done via Blackboard or CATME (as appropriate). Any assignment turned in after the due date will be deducted 15 percentage points for every day it is late. Please note that that weekends count as late days!

Assignments can be turned in after one week (7 days) for corrections, but will count as a zero.

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

The use of cell phones (including texting!) and laptops during class is prohibited and will not be tolerated.

Eating is permitted in the lecture room, but please remember to clean up your trash after class!

Classroom activities may be recorded by a student for the personal, educational use of that student or for all students presently enrolled in the class only, and may not be further copied, distributed, published or otherwise used for any other purpose without the express written consent of Dr. Zapanta. All students are advised that classroom activities may be taped by students for this purpose.

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

Exams: None

Final Presentation: The final presentation will be given during the final exam period on the day determined by Carnegie Mellon University. **The final presentation 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. Zapanta 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.

The Carnegie Mellon Code (http://www.cmu.edu/student-affairs/theword/code.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.

As members of the Carnegie Mellon community, individuals are expected to uphold the standards of the community in addition to holding others accountable for said standards. It is rare that the life of a student in an academic community can be so private that it will not affect the community as a whole or that the above standards 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 (http://www.cmu.edu/academic-integrity/defining/cheating.html)

Cheating "occurs when a student avails her/himself of an unfair or disallowed advantage which includes but is not limited to:

1. Theft of or unauthorized access to an exam, answer key or other graded work from previous course offerings.
2. Use of an alternate, stand-in or proxy during an examination.
3. Copying from the examination or work of another person or source.
4. Submission or use of falsified data.
5. Using false statements to obtain additional time or other accommodation.
6. Falsification of academic credentials."

Examples of cheating in academic life include the following:

- Copying another student's work
- Having a student complete an assignment or take an exam for another student
- Stealing an exam or paper
- Paying a student do to the work for another student or buying papers
- Submitting or using falsified data
- Lying to obtain additional time or other accommodation to complete an assignment
- Falsifying academic credentials including (but not limited to) internship documentation, letters of recommendation, transcripts, and diplomas

Plagiarism (http://www.cmu.edu/academic-integrity/defining/plagiarism.html)

Plagiarism "is defined as the use of work or concepts contributed by other individuals without proper attribution or citation. Unique ideas or materials taken from another source for either written or oral use must be fully acknowledged in academic work to be graded. Examples of sources expected to be referenced include but are not limited to:

1. Text, either written or spoken, quoted directly or paraphrased.
2. Graphic elements.
3. Passages of music, existing either as sound or as notation.
4. Mathematical proofs.
5. Scientific data.

6. Concepts or material derived from the work, published or unpublished, of another person."

In academic life, plagiarism can include the following:

- Failing to cite references or not attributing ideas to the original source of ideas
- Cutting and pasting material from a web resource (including sample graphic or music files) directly into a assignments without attribution
- Putting someone else's ideas into a student's own words without the appropriate citation

In order to deter and detect plagiarism, online tools (Turnitin and SafeAssign) are used in this class.

Unauthorized Assistance
(http://www.cmu.edu/academic-integrity/collaboration/index.html)

Unauthorized assistance "refers to the use of sources of support that have not been specifically authorized in this policy statement or by the course instructor(s) in the completion of academic work to be graded. Such sources of support may include but are not limited to advice or help provided by another individual, published or unpublished written sources, and electronic sources. Examples of unauthorized assistance include but are not limited to:

1. Collaboration on any assignment beyond the standards authorized by this policy statement and the course instructor(s).
2. Submission of work completed or edited in whole or in part by another person.
3. Supplying or communicating unauthorized information or materials, including graded work and answer keys from previous course offerings, in any way to another student.
4. Use of unauthorized information or materials, including graded work and answer keys from previous course offerings.
5. Use of unauthorized devices.
6. Submission for credit of previously completed graded work in a second course without first obtaining permission from the instructor(s) of the second course. In the case of concurrent courses, permission to submit the same work for credit in two courses must be obtained from the instructors of both courses"

Since the University Policy on Academic Integrity gives each instructor the ability to determine what is appropriate in each of their courses, it is possible that what is permitted or even required in one course may be prohibited in another. **Thus, it is absolutely crucial for students to know the expectations for each of their courses and to ask before they act in instances where the expectations are unclear.**

In academic life, inappropriate collaboration can include the following:

- Talking to friends about an assignment outside of class or working on homework with other students on assignments that the instructor has designated to be individual
- Dividing up problem sets or parts of a paper or lab among a group
- Sharing a student's code or essay with another student or sharing notes from previous semesters with students currently taking the class
- Accessing unauthorized information during an exam (including from a cell phone)
- Looking at another student's exam
- Reusing a student's work from another class without the permission of all of the instructors

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 is 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. Zapanta.

Consequences:

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.

Expectations of Students and Instructors:

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

1. Students will arrive to class or team meetings on time
2. Students will be prepared for the lecture or group meeting by reviewing the lecture notes, readings, agenda, etc. beforehand.
3. Students will turn in assignments on time (see policy on assignment due dates).
4. Students will immediately inform the instructor or the teaching assistants if extenuating circumstances prevent the student from attending a lecture or team meeting.
5. Students will follow the code of conduct regarding academic integrity, cheating, plagiarism, and collaboration as outlined in the syllabus.
6. Students will seek assistance when they need it.
7. Students will work together effectively in design groups to successfully complete the assigned tasks.
8. Students will be flexible and willing to perform design tasks outside of the allocated class time.
9. If contacted by the instructor or teaching assistant 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 and team meetings 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 and teaching assistants will be available outside class either during their posted office hours or during other pre-arranged times.
5. Lecture notes will be posted in a timely manner before the lecture begins.
6. Reports, homework assignments, and other items that are turned in to be graded will be returned within two weeks after the due date.
7. Phone calls or e-mails to the instructor or teaching assistants 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

***Identify* (Fall 2013)**

1. Stage I: Needs Finding
   - 1.1 Strategic Focus
   - 1.2 Observation and Problem Identification
   - 1.3 Need Statement Development

2. Stage II: Needs Screening
   - 2.1 Disease State Fundamentals
   - 2.2 Treatment Options
   - 2.3 Stakeholder Analysis
   - 2.4 Market Analysis
   - 2.5 Needs Filtering

***Invent* (Fall 2013 and Spring 2014)**

3. Stage III: Concept Generation (Fall 2013)
   - 3.1 Ideation and Brainstorming
   - 3.2 Concept Screening

4. Stage IV: Concept Selection (Fall 2013/Spring 2014)
   - 4.1 Intellectual Property Basics (Spring 2014)
   - 4.2 Regulatory Basics (Spring 2014)
   - 4.3 Reimbursement Basics (Spring 2014)
   - 4.4 Business Models (Spring 2014)
   - 4.5 Prototyping (Spring 2014)
   - 4.6 Final Concept Selection (Fall 2013)

***Implement* (Not Covered in 42-401/402)**

5. Stage V: Development Strategy and Planning
   - 5.1 Intellectual Property Strategy
   - 5.2 Research and Development Strategy
   - 5.3 Clinical Strategy
   - 5.4 Regulatory Strategy
   - 5.5 Quality and Process Management
   - 5.6 Reimbursement Strategy
   - 5.7 Market and Stakeholder Strategy
   - 5.8 Sales and Distribution Strategy
   - 5.9 Competitive Advantage and Business Strategy

6. Stage VI: Integration
   - 6.1 Operating Plan and Financial Model
   - 6.2 Business Plan Development
   - 6.3 Funding Sources
   - 6.4 Licensing and Alternate Pathways

Course Schedule
Revised 2/12/14

Week	Date	Topic/Class Exercise	Lecturer	Readings/ *Assignment Due*
1	1/14/14	1. Welcome (Back) to Class 2. Review BMEStart Format 3. Prototyping	Conrad Zapanta	4.5 (pp. 340-366)
	1/16/14	Group Meetings/ Walk-in Advising		
2	1/21/14	Intellectual Property Basics	David Radack, Esq. Eckert Seamans Cherin Millot	4.1 (pp. 210-272)
	1/23/14	Group Meetings/ Walk-in Advising		1. *Individual Response to CATME #2 from Fall 2013* 2. *Group Response to Comments from Fall 2013* 3. *Progress Report #1 (include plan for prototype #1)* 4. *Project Website*
3	1/28/14	Medical Reimbursement	Debbie Parrish, Esq. Parrish Law Offices	4.3 (pp. 299-318)
	1/30/14	Group Meetings/ Walk-in Advising		*Progress Report #2*
4	**2/4/14**	**Prototype Demo #1 (Rangos 3)** **Groups #2, 3, 4, 5, 7, 10, 13, and 15**		
	2/6/14	**Prototype Demo #1 (Connan Room)** **Groups #6, 8, 9, 11, 12, 14, and 16**		*Progress Report #3*
5	2/11/14	Group Meetings with Dr. Z: Melissa's Groups		
	2/13/14	Group Meetings with Dr. Z: Krista's Groups		*Progress Report #4*
6	2/18/14	Group Meetings with Dr. Z: Kenny's Groups		
	2/20/14	Group Meetings with Dr. Z: Trent's Groups		1. *Progress Report #5* 2. *Group Response to Comments on Prototype Demo #1*
7	2/25/14	Manufacturing	James Antaki, Ph.D. CMU Biomedical Engineering	TBD
	2/27/14	Group Meetings/ Walk-in Advising		*Progress Report #6*

Week	Date	Topic/Class Exercise	Lecturer	Readings/ ***Assignment Due***
8	3/4/14	Regulatory Issues	Conrad Zapanta	4.2 (pp. 273-298)
	3/6/14	**No Class- Mid-Semester Break**		*1. Mid-Semester CATME* *2. Progress Report #7*
9	**3/11/14**	**No Class - Spring Break**		
	3/13/14	**No Class - Spring Break**		
10	3/18/14	Group Meetings with Dr. Z: Melissa's Groups		
	3/20/14	Group Meetings with Dr. Z: Krista's Groups		*Progress Report #8 (include plan for prototype #2)*
11	3/25/14	Group Meetings with Dr. Z: Kenny's Groups		
	3/27/14	Group Meetings with Dr. Z: Trent's Groups		*1. Progress Report #9* ***2.*** *Individual Response to Mid-Semester CATME from Spring 2014*
12	**4/1/14**	**Prototype Demo #2 (Rangos 1)** **Groups #6, 8, 9, 11, 12, 14, and 16**		
	4/3/14	**Prototype Demo #2 (Connan Room)** **Groups #2, 3, 4, 5, 7, 10, 13, and 15**		*Progress Report #10*
13	4/8/14	Group Meetings/ Walk-in Advising		
	4/10/14	**No Class – Spring Carnival**		
14	4/15/14	What to do with your BME Design project after graduation	Kelly Collier CEO, ActivAided Orthotics	
	4/17/14	Group Meetings with Dr. Z: Melissa's Groups		*1. Progress Report #11* *2. Response to Prototype Demo #2 Comments*
15	4/22/14	Group Meetings with Dr. Z: Krista's Groups		
	4/24/14	Group Meetings with Dr. Z: Trent's Groups		*1. Draft of Final Report* *2. Draft of Poster* 3. *Progress Report #12*
16	4/29/14	Group Meetings with Dr. Z: Kenny's Groups		
	5/1/14	Group Meetings/ Walk-in Advising		*Progress Report #13*
Finals	5/6/14	Poster to Dr. Zapanta for Free Printing		*Poster*
	5/9/14	**Project Fair** **UC Rangos 1 and 2** **1:00 to 4:00 PM**		*1. Final Paper* *2. CATME #2*