



BIOMEDICAL ENGINEERING

Carnegie Mellon University

**42-401: Foundations of
Biomedical Engineering Design
Fall 2012**

**42-401: Biomedical Engineering
Design Project
Spring 2013**

Instructor:

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Office hours: Wednesday: 12:00 PM to 1:00 PM
Other times by appointment

Teaching Assistants

Name	E-mail
Molly Blank	mollyblank@cmu.edu
Kevin Fok	kehfok@gmail.com
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Each team will also 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 instructors. The teaching assistant will meet with each team every one to two weeks (at the discretion of the teaching assistant and instructor).

Class Time and Location:

Erwin R. Steinbrenner Auditorium, Baker Hall A53
Tuesday, 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. Geigy Scientific Tables – super convenient source of physiological meta-data (unfortunately out of print, but available used.)
5. Geddes, Medical Device Accidents and Illus. Cases ISBN: 9781930056367 (appx \$79)
6. Casey, Set Phasers on Stun and Other True Tales..., ISBN: 9780963617880, (appx \$28)
7. Kucklick, TR. *The Medical Device R&D Handbook*. Taylor and Francis: Boca Raton, 2006.
8. Ratner B, Hoffman A, Schoen F, and Lemons J (eds). *Biomaterials Science: An Introduction to Materials in Medicine, 2nd Edition*. Elsevier: San Diego, 2004.
9. 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.
10. 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

<i>Program Outcome</i>	<i>Relation to Program Outcome</i>	<i>Mechanism</i>
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 using 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”

Selection of Topic and Proposed Scope of Work:

Projects will be selected from actual real-world problems from a recognized field of medicine. The final design topics for each of the teams will be selected in one of the following methods:

1. Instructor provides selection of pre-screened projects to entire class, which are selected by a team based on their interests and skill sets. If necessary, a student may be assigned to a team to fill a specific need in order to complete a project.
2. Teams are charged with discovery and definition of their own project topic, according to prescribed guidelines, and subject to approval of the course instructor and teaching assistants.

There could be as many topics as there are teams, or there could be multiple teams working in tandem on the same project.

Deliverables at the End of the Fall Semester (42-401):

At the completion of this course, the teams will be required to present the following:

1. Oral presentation: This 10 to 15 minute presentation will give a description of the project that will be completed in 42-402 in the Spring Semester. The presentation will be given during the assigned time during finals.
2. Final written report: This report will give a more detailed description of the project presented in the oral presentation. More details will follow at a later date.

Grading

The final grade will be computed by combining homework, lab reports, lab notebook, class participation, and the final project in the following manner:

Peer Grading	20%
Project Updates	10%
Final Report	25%
Oral Presentation	20%
Homework	15%
Attendance (lectures and group meetings)	10%
Total	100%

Peer grading will be performed using the CATME (Comprehensive Assessment for Team-Member Effectiveness) system. This system gathers peer evaluation data and self evaluations to assess how effectively each team member contributes to the team and gives feedback to team members and to the person administering the teams. Detailed instructions on how to use this system will be reviewed in class.

The following scale will be used to assign a final letter grade:

90 to 100%	A
80 to 89%	B
70 to 79%	C
60 to 69%	D
0 to 59%	R

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, lab reports, and laboratory notebooks are to be submitted by the beginning of class on the day it is due. This can be done via Blackboard.

Homework solutions (as appropriate) will be posted on the class website after the graded homework is returned. 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

Presentations: The final presentations 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.

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>.

In order to deter and detect plagiarism, online tools (Turnitin) and other resources are used in this class. The mission of the Office of Technology for Education is to support faculty in the selection, implementation and evaluation of educational technologies. As part of this mission, we continually monitor and assess the use of educational technologies on

campus so that we can understand and better meet the needs of our faculty and students. Periodically, we may ask for information on the usability and value of the Turnitin tool. Your comments are vital to the evaluation of the tool and will help determine the future role that Turnitin will play at Carnegie Mellon.

If at any time you would like to provide comments or suggestions, or need assistance, please contact the Eberly Center for Teaching Excellence at <http://www.cmu.edu/teaching/eberly/>.

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, final presentation, 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. report, homework, etc) when applicable. 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.

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 on time and will be prepared for the lecture or the class activity.
2. Students will turn in assignments on time (see policy on assignment due dates).
3. Students will immediately inform the instructor or the teaching assistants 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 design groups to successfully complete the assigned tasks.
7. Students will be flexible and willing to perform design tasks outside of the allocated class time.
8. 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 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 2012)

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 2012 and Spring 2013)

3. Stage III: Concept Generation (Fall 2012)
 - 3.1 Ideation and Brainstorming
 - 3.2 Concept Screening

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

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 10/29/12, Changes in Yellow

	Date	Topic/Class Exercise	Assigned Readings	Homework/Assignment Due
1	8/28/12	<ul style="list-style-type: none"> Welcome to Class CATME Self Inventory Demonstration Review projects from previous years 		
2	9/4/12	<ul style="list-style-type: none"> Potential final project formats CATME Peer Review Demonstration 		<ul style="list-style-type: none"> CATME Self Inventory Group preferences Resume and cover letter
3	9/11/12	NO CLASS – TOC and Dr. Z messed up the groups so he had to fix them before anyone complained about them		<ul style="list-style-type: none"> CATME Peer Review HW
4	9/18/12	Presentations of pre-screened projects 1.1 Strategic Focus 1.2 Observation and Problem Identification	Biodesign: Chapters 1.1 & 1.2	<ul style="list-style-type: none">
5	9/25/12	1.3 Need Statement Development 2.1 Disease State Fundamentals 2.2 Treatment Options	Biodesign: Chapters 1.3, 2.1, & 2.2	<ul style="list-style-type: none"> List of five (5) potential topics Final group adjustments due
6	10/2/12	2.3 Stakeholder Analysis 2.4 Market Analysis	Biodesign: Chapters 2.3 & 2.4	<ul style="list-style-type: none"> Final topic chosen Report addressing 1.1, 1.2, 1.3, 2.1, & 2.2
7	10/9/12	2.5 Needs Filtering	Biodesign: Chapter 2.5	<ul style="list-style-type: none"> Report addressing 2.3 & 2.4 CATME peer review #1
8	10/16/12 or 10/18/12	<i>Dr. Zapanta and TAs meet with groups to review status of project</i>		<ul style="list-style-type: none"> Report addressing 2.5 Project update #1
9	10/23/12	Meet with TAs		
10	10/30/12	3.1 Ideation and Brainstorming 3.2 Concept Screening	Biodesign: Chapters 3.1 & 3.2	
11	11/6/12 or 11/8/12	<i>Dr. Zapanta and TAs meet with groups to review status of project</i>		<ul style="list-style-type: none"> <li style="background-color: yellow;">Report addressing 3.1 & 3.2
12	11/13/12	Meet with TAs OR Project management		<ul style="list-style-type: none"> <li style="background-color: yellow;">Project update #2
	11/20/10	No Class-Thanksgiving		
13	11/27/12 or 11/29/12	<i>Dr. Zapanta and TAs meet with groups to review status of project</i>		<ul style="list-style-type: none"> Project update #3
14	12/4/12 or 12/6/12	<i>Dr. Zapanta and TAs meet with groups to review draft of final presentation and outline of written presentation</i>		<ul style="list-style-type: none"> Draft of oral presentation Outline of written presentation
15	Finals	Final Concept Presentation		<ul style="list-style-type: none"> Oral presentation Written report <li style="background-color: yellow;">CATME peer review #2

