BME 451/452 Biomedical Design (2+3 credits)

Fall 2017 Schedule
Lecture: Tuesday & Thursday 12:30pm – 2:30pm 1024 FXB
Team Meetings: Tuesday & Thursday 2:30 – 5:30pm 1150 LBME

Winter 2017 Schedule
Lecture: Wednesday 1:30 – 3:30pm in 1014 Dow
Team Meetings: Monday & Wednesday 2:30 – 5:30pm in 1150 LBME

Course Syllabus and Outline

BME Instructors:
Rachael Schmedlen, Ph.D.
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Technical Communication Instructors:
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BME GSI:
Amrita Chaudhury
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Office Hours:
All instructors are willing to meet with any student or team by appointment. Often, appointments are made during the "lab time" of the course.

Required Materials:
Every student is required to obtain an account for an electronic lab notebook on LabArchives (labarchives.com) at a cost of $30. Information to sign up for the Classroom Edition (required for this course) will be provided in class and posted on Canvas.

Information helpful to the entire class (e.g., cheap local vendors, free interface software, safety and quality design documents, etc.) will be posted on the class Canvas site.

Course Description:
This course is the first part of a year-long, two course sequence that exposes students to the entire design process as currently covered by BME 450 in a single semester. The course is organized like a biomedical engineering company with projects sponsored by real clients from the Medical School, Dental School, College of Engineering research labs, and local industry. This course is comprised of seven main components, where items 1-3 will be covered during the fall term, 4-5 will be accomplished in the winter term, and 6-7 will be required both fall and winter terms:

1. Problem Definition – Students will be assigned a project and expected to decompose the problem, generate design specifications, and plan out the project.
2. Concept Generation and Evaluation – Students will use brainstorming and decision evaluation tools to generate and evaluate solutions to reach a design consensus.
3. Detailed Design – Students will generate a paper design of their proposed prototype including device specifications, key materials and components, detailed drawings, and principle of operation with all choices justified and supported through proof-of-concept.
4. Fabrication and Validation – Students will fabricate and conduct testing of their prototype, assess the degree to which the prototype meets the design specifications, and recommend design modifications to improve the prototype.
5. Prototype Redesign and Validation – Students will implement recommended changes to prototype, conduct testing, demonstrate improvement of redesign, and provide recommendations on next steps. Prototype, notebooks, and all documentation will be delivered to the client.
6. Project Management – Students will create and update a project timeline, budget, design history file, and maintain engineering notebooks throughout all phases of the project.
7. Technical Communications – Students will be required to describe, explain, and support the progress and solutions of their design project at all phases of the design process.

General outline of the course:
The structure of this course will probably be unlike any other course you have taken. The course will be structured to simulate activities of a small biomedical consulting company, with each 4 to 6 member design team assigned to consult on a different project. The group organization parallels a typical one in a small biomedical engineering company. The lead course instructor is the CEO of the company, your technical communications instructor is your marketing manager, and the instructor that meets weekly with your team is your engineering manager. Lectures can be considered company workshops, where basic concepts, tools, and related issues of the design process will be discussed. Weekly team meetings with your engineering manager will simulate real design team meetings in a company, where progress updates, key design issues, and proposed next steps are provided by the team.

You will be confronted with many of the technical and non-technical issues involved in successful design, such as basic research into the design problem, budget and scheduling issues, prioritization, and interpersonal communication. You will also confront issues unique to biomedical engineering, such as biohazard safety and tissue-instrumentation interfacing. You will also encounter the dynamics of the design review environment, documentation, integration and testing. The objective of the course is to provide you with as close to a real world industrial biomedical engineering design experience as is possible in an academic setting.

Course Policies:
You should all feel like members of the same company with your own careers intimately linked to the success of the ENTIRE company (i.e., you have significant stock options as part of your employment contract). If one client is unhappy with a team, it lowers the positive perception of your company. Therefore, always try to help each other - there should be no competition between groups other than the natural competition of trying to do a good job. Other conduct to keep in mind:

1. Show the utmost respect for each other, the course instructors, guest speakers, and your client at all times throughout the course. Please remember that speakers are taking time out of their schedules to come and share their knowledge. See "Guidelines for Client and Technical Expert Interactions" at the end of the syllabus for expectations.

2. Handle interactions with your client in a professional manner. Treat these people as customers first and a resource second. Many customers are willing to help, but in the end, it's your project – they hired YOU to solve their problem.

3. Attendance, advance preparation and full attention at lectures are required. In order to receive full points on participation, you must comply with the following policies throughout the course
    a. Coming to class more than 15 minutes late will be considered an absence.

    b. Focusing on anything other than the current work of the class will be considered an absence, as will the use during lecture of electronic devices (e.g. laptops, tablets, and cell phones) for anything other than note-taking. (Such behavior is particularly unacceptable during guest lectures.)

    c. Demonstrated unfamiliarity with assigned readings and/or lack of engagement during class exercises will be reflected in a lower participation score.

    d. One unexcused absence per semester is permitted. Absences for training or meetings related to your project must receive prior approval to be excused.

4. Attendance, advance preparation, and engagement at manager meetings are mandatory. Just as if you were a member of a design team in a company, each team member is expected to attend all meetings, provide updates on his/her progress, and be engaged in the discussion unless prevented from doing so by illness. During design group meetings, each student will be expected to be aware of his/her team's project status and familiar with the material from previous lectures. Demonstrated unfamiliarity with team's status and/or lecture materials during a meeting will be reflected in the student's participation grade. **Only one unexcused absence per term is allowed.**

5. Absences or tardiness for lectures and manager meetings may be excused under limited circumstances (e.g. illness, family emergency, and medical school/graduate school interviews); to be considered, a request must be made at least **24 hours** in advance, and

requests are not guaranteed to be granted. In case of a sudden emergency or illness, contact Dr. Schmedlen as soon as possible to make appropriate accommodations. You may be asked to provide verification. For medical school/graduate school interviews, please contact Dr. Schmedlen at least one week prior to the absence. For all absences/tardiness, you will be held responsible for all materials and assignments covered during that period.

Performance:
Students will be individually graded, based on their performance in design group meetings, design reviews, completion of their design tasks, and overall ability to help the group meet its goal of successfully completing the project. Projects are not given just a 'group' grade. Each individual will be graded on their contribution to the project, their demonstrated effort during design group meetings, as well as their use of the information presented during lectures in the design process. Essentially, the grade will include factors that are used by employers to evaluate engineers and will be broken down as follows:

Fall Term (BME 451)

Participation		**10%**
Engineering notebook		**10%**
Drafts		**4%**
Project Brief		**2%**
Requirements Review		**17%**
Paper Design Review		**55%**
• Oral Presentation	25%	
• Written Report	30%	

Winter Term (BME 452) - tentative

Participation		**10%**
Drafts		**3%**
Project Briefs		**2%**
Engineering Notebook		**10%**
First Gen Prototype Review		**20%**
• Oral Presentation	18%	
• Prototype	2%	
Final Design Review		**55%**
• Oral Presentation	20%	
• CoE Design Expo	2%	
• Written Report	25%	
• Prototype and Project Notebook	5%	
• User Manual	3%	

Students often request a detailed explanation of the participation grade, thus participation grades will be determined by the following factors:

1. Attendance, participation, and professionalism during lectures and manager meetings
2. Completion of Student IP and Legal Agreement modules
3. Perusall Annotation of reading materials in preparation for lecture

4. Attendance at one Medical Device Sandbox (MDS) session
5. Completion of peer evaluations (CATME and Canvas)
6. Completion of HIPAA and PEERRS modules
7. Attendance at two UM Responsible Conduct of Research and Scholarship workshops

The course is graded on a straight scale (i.e. A = 100-90%, B = 89-80%, C = 79-70%, etc.) to foster cooperation between design teams. The lead instructor, however, reserves the right to increase or decrease the average grade for this course in accordance with student performance over the duration of the course.

Your final paper design must be approved by the course faculty and your client in order for your team to continue the project into the Winter 2017 semester. If the faculty and/or client does NOT approve a design teams' final paper design and/or performance during the Fall 2016 semester, the design team will receive a failing grade and will NOT be permitted to enroll in BME 451/452 during the Winter 2017 term. This policy ensures that clients receive something of value and protects the clients' time and financial resources.

Medical Device Sandbox (MDS)
Students will attend at least one session of MDS to gain a better understanding of medical device user errors, design flaws, and the clinical perspective. In addition, teams will be encouraged to use the MDS to stage usability tests of their prototypes throughout the course. The MDS was developed to promote interprofessional collaboration and learning between biomedical engineering students and medical learners that is critical to the design, development, use, and commercialization of safe and effective medical equipment. It consists of a simulated clinical space within the Center for Experiential Learning and Assessment (CELA, Taubman Health Sciences Library) equipped with medical devices and accessories used in home, clinical and, hospital settings. Dr. John Gosbee will facilitate these sessions and present teams of BMEs and medical learners with a realistic patient safety scenario involving the use of a medical device, ask them to identify problems associated with use, and brainstorm solutions on-the-spot.

Responsible Conduct of Research and Scholarship (RCRS Workshops)
Students are required to attend two of four RCRS workshops offered by the College of Engineering before the end of the course. Attendance will be included as part of the course participation grade. To view the workshop descriptions and schedules and register for a workshop, go to the website: http://rcrs.engin.umich.edu/workshops. These workshops are a requirement of an NIH (R25-EB019898) grant, which funds some of the guest lectures and design projects. The NIH asks all students benefitting from the grant to undergo this training, as well as complete the PEERRS, HIPAA, Student IP, and Legal Agreement modules.

PEERRS and HIPAA Modules
As mentioned above, students are required to complete two online training modules, PEERRS "Human Subjects – Biomedical and Health" and HIPAA, as part of the NIH R25 grant requirement. Completion of these modules will be part of the participation course grade. The HIPAA module can be accessed on the Canvas course website and the PEERRS module at: http://my.research.umich.edu/peerrs/?_ga=1.177126113.553218121.1426970481. To receive credit, download and submit the certificate that is issued upon completion of each module.

Re-grade Requests (For Student/Team Work and Course Grades):
If a student or team believes that portions of an assignment are incorrectly graded or that a course grade has been calculated incorrectly, a brief formal memo requesting a re-grade may be submitted, along with any relevant evidence to Dr. Schmedlen within two weeks of receiving the grade. The memo must include a description of the grading error and explanation of why the grade is believed to be incorrect. If a re-grade is requested for an assignment, the entire assignment will be re-graded, not just the portion of the assignment in question.

Late Assignment Submissions:
All assignments in this course are to be submitted both electronically on Canvas and in hard copy. Failure to turn in both a hard copy and electronic copy on time will result in a 10% penalty per day (any portion of a 24 hr. period after the due date issued on Canvas). This penalty applies equally to individual as well as team assignments.

Project Teams:
Teams will be formed to provide a balance of skills and experience in each group from the information provided by the Student Questionnaire and CATME online program. For example, each group will ideally be made up of students with some subset of electrical, software, and machining skills, lab experience, industry experience, project interests, career goals.

Once formed, each team will have the opportunity request to trade a teammate from another team with one of their own. Management will review the requests before making a final decision. Please see the course schedule for the trade deadline.

Being Fired
Students are expected to participate wholly on their team for the benefit of the entire team. In cases of demonstrated lack of commitment on the part of a team member, that member may be "fired" from their design team by the majority vote of the remaining members. The process is as follows:

- The concerned team members should inform course faculty of the existence of an issue as early in the course as possible, and take whatever intermediate steps suggested by faculty to address and hopefully resolve the issue.
- If the issue remains two (2) weeks or more after implementing the actions suggested by faculty, the team sends a gentle warning of a risk of firing in email or hardcopy to the team member in question, copied to the entire team and class faculty. The warning must specify the work required for the team member to remain on the team.
- Three (3) calendar days elapse to allow time for compliance.
- If the student does not comply, the team sends a statement of firing in email or hardcopy, copied to the entire team and class faculty.

Fired team members receive a zero on the current team assignment. Fired team members must actively pursue and obtain membership on another team. The entire class faculty must receive documentation from the entire new team stating that student has been hired by that team. Students that do not belong to a team do not receive a grade on the appropriate portions of the

team project and may be asked to drop BME 451 (if fired during the Fall Term) and take BME 450 in the winter instead.

Intellectual Property/Non-Disclosure (IP/NDA) Agreements:
Please note that the sponsors of some design projects require all students working on that project to sign an IP/NDA agreement. The terms of this agreement can vary from just allowing the client to continue work on the project after the course is over to signing away all rights to royalties and use of any patent. It is each student's responsibility to read these agreements and ask questions *prior* to selecting a project. Non-disclosure agreements may require you to keep the information you obtain about the client's products and the design project confidential for a specified period of time. By selecting one of these projects, you are agreeing to the terms of the IP/NDA contract, even before signing the contract. Students that do not wish to give up their IP rights will be assigned a project that does not require an agreement to be signed.

You are strongly encouraged to read the IP/NDA agreements posted on the Canvas site prior to ranking your projects. If you have questions about the agreements, please talk to the project sponsor or Chris Fick, UM Office of Technology Transfer (cafick@umich.edu).

IP and/or NDA agreements must be signed and returned to Dr. Schmedlen by **Thursday, September 15th, 2016.** Failure to do so will result in the team being reassigned to another project.

Intellectual Property Disclosure:
All information exchanged in class is in the context of the course itself. All information should be kept confidential amongst the participants and nothing discussed is for public disclosure.

Engineering Notebooks:
Each student will be required throughout both semesters to maintain an engineering notebook, a crucial record of all design activity by an engineer that leads to a patentable invention. This record can be used to establish dates of conception and the inventorship of a patent during patent litigation. A complete list of engineering notebook requirements can be found on the Canvas site.

Design Reviews:
Each design team will be required to undergo four design reviews over the academic year, set up to emulate actual design reviews that take place in industry. Each design review will include both a team presentation, in which every team member participates, and a report, due approximately one week after the presentation. The audience will consist of management (i.e. course instructors), the client(s), peers, and invited guests in the medical, engineering, and regulatory fields. The purpose of the design reviews is for the design team to effectively communicate their design approach and to receive feedback and advice from the audience. Furthermore, the design reviews serve as a checkpoint in the design process, to keep the project on schedule. Instructions for the content and the format of the design reviews will be discussed in class and will be posted on the Canvas site approximately two weeks prior to the review.

Project Room:
LBME 1150 has been designated as the BME Design Project Room, with access granted to students enrolled in BME 599, 450, and 451/452 who have signed off on reading the BME Student Design Project Room Safety Manual. Access to the room should be considered a privilege. Students using the project room are expected to:

1. Sign in on the signup sheet whenever you use the room.
2. Clean up after yourself.
3. Keep all department supplies inside the project room.
4. Training must be obtained to use the soldering iron and hand drill. These items cannot be used without proper training and documentation.
5. Report immediately any type of damage to supplies and equipment.
6. Clearly label all group items placed in the refrigerator.

Students found neglecting these rules will lose access to the facility. Entrance code is **2118.**

Lockers in the project room are available for use by teams (1 locker/team). Locker keys are available through Dana Jackson (1134 LBME, 647-9828, dmjackso@umich.edu). All keys must be returned by the end of April in order to receive a grade for the course.

Class Schedule:
The activities during the term will approximate the following schedule, once design projects have been assigned to the teams:

- Project teams will formally meet each week with their Engineering Manager
- Project teams will formally meet with sponsor a minimum of 3-4 times per term
- Project teams will informally meet each week as a team

Weeks 1-6
Introduction - Form design groups
Create team letterhead, choose project name
Research technical background and competing technologies
Define motivation and problem statement
Formulate design requirements and specifications
Determine rough budget & timeline

Week 6: Requirements Review – 10/4/16 and 10/6/16

Weeks 7-15
Brainstorm, generate concept solutions
Evaluate design concepts
Construct mock ups and conduct usability testing
Arrive at design consensus
Conduct engineering analysis
Determine design details – component specifications and detailed drawings
Construct detailed budget & timeline
Order parts for prototype

Week 14: Paper Design Review – 12/6/16 and 12/8/16 (Report due 12/13/16)

Weeks 16-22
Fabricate and assemble alpha prototype
Generate a DFMEA
Conduct verification and validation testing
Propose modifications for beta prototype

Week 22: First Generation Prototype Design Review – 2/6/17 and 2/8/17

Weeks 22-31
Fabricate and assemble beta prototype
Validate beta prototype
Propose recommendations for next steps
Complete design documentation (drawings, user manuals, report, design history file, engineering notebook)

Weeks 29-31: Final Design Review – 4/3/17 and 4/5/17
College of Engineering Design Expo – 4/13/17
(Report due 4/17/17)

Strategy for getting the most from this course:

- Focus on following the design process instead of, "What do I need to do to get an 'A'?"
- Prepare to fail early to come to a strong solution sooner.
- Use the course scheduled "lab" time to meet as a team and work on the project.
- Identify all available resources early (e.g. fabrication and testing facilities, faculty experts, etc.)
- Immerse yourself in the intended user environment, observe and talk to users.
- Start tinkering with mocks ups as soon you as you begin generating concept solutions.
- Spend time each day thinking about your design project.
- Conduct formal meetings with your team on a regular basis and take a break together once in a while (e.g. get pizza, ice cream, or cupcakes).
- Keep detailed notes (in your notebook) of everything related to the project.
- Cultivate the attitude that you will do a little more than your fair share on the project.
- Keep the intangibles in mind (communication skills, creativity, open-mindedness).
- Get involved in areas of the design outside of your area of expertise.

Guidelines for Client and Technical Expert Interactions

1. One person from each team should be designated as the "client/tech expert liaison". This person will be responsible for the majority of email/phone communication and ensure that the faculty mentors are not bombarded with items from each team member. The liaison will be responsible for ensuring that all team members see communication with the client.

2. Ask the faculty mentor how they prefer to be contacted – email, through administrator, by phone etc?
3. Email Etiquette
    a. Email should be professional
    b. Please address the client/technical expert as Dr. or Mr./Ms. [Last name] unless otherwise instructed.
    c. Try to maximize the quality vs. quantity ratio – in other words, please make sure that your emails are substantive and less frequent, as opposed to frequent with little value. Basically, do not spam.
4. In-person meetings
    a. If you would like to meet with your client, technical expert, etc. in person, please request a meeting. Please schedule a meeting that accommodates his/her time – they are not required to meet with you at your convenience.
    b. Be respectful of their time.
    c. Dress appropriately (business casual is recommended for first meeting, then follow client's dress or cue for future meetings).
    d. Be punctual.
    e. Act professionally.
    f. Be prepared. Plan what you want to discuss and make a meeting agenda.
    g. Treat them as a "consultant." Their role is to provide feedback, hence you must go to them with a plan/idea/contingency plan etc.
    h. Clients, technical experts, etc. should sign engineering notebooks in instances where they contribute to the technical content of the conversation.

Fall Term Detailed Schedule (Subject to Change):				
Date		**Lecture Topic**	**Team Meeting Topics ("Lab Time")**	**Action Items**
Week 1				
6-Sep	Tu	Intro to the Design Process - Dr. Schmedlen	Survey, Student IP, and Legal Agreements modules	CATME surveys, Student IP and Agreement modules due
8-Sep	Th	Problem Definition - Dr. Schmedlen	IP Agreements - Chris Fick, OTT; Project Fair	Perusall annotations #1 due at 00:00am
Week 2				Team Project Preference surveys due Fri (9/9)
13-Sep	Tu	Marketing Workshop: Representing Your Work and Your Team - Dr. Sheffield, Task Analysis - Dr. Gosbee	First Engineering Manager Meeting	Projects assigned
15-Sep	Th	Design Documentation - Amrita Chaudhury, Market Analysis - Doug Rimatzki, EntreMentor LLC	First Engineering Manager Meeting	Signed IP/NDA agreements due; Teammate trade deadline
Week 3				
20-Sep	Tu	Intellectual Property - Tara Hartman, UM General Counsel		Problem Definition draft due (on team letterhead)
22-Sep	Th	Design Requirements & Specifications - Dr. Schmedlen		Perusall annotations #2 due at 00:00am
Week 4				
27-Sep	Tu	Marketing Workshop: Design Requirements - Dr. Sheffield	Library Workshop; Consults with Aaron Kehrer, In2Being Inc.	Market and Patentability Analysis draft due
29-Sep	Th	No lecture - Rehearsals		Sign up for 1 MDS session
Week 5				
4-Oct	Tu	***Design Requirements Review (2203 LBME)***		Slides due
6-Oct	Th	***Design Requirements Review (2203 LBME)***		Slides due
Week 6				
11-Oct	Tu	Concept Generation I - Jin Lee, Mechanical Engineering	TRIZ workshop - Dr. Gosbee (optional)	Design Rqmnts Approval draft; CATME peer evals due
13-Oct	Th	Concept Generation II - Disher	ME CAD Workshop (4-5:30pm, optional), MDS session	Engineering notebooks due
Week 7				
18-Oct	Tu	**FALL BREAK**		
20-Oct	Th	Human Factors Engineering - Dr. Gosbee	MDS session; Low-fidelity Prototyping Workshop (optional)	
Week 8				
25-Oct	Tu	Concept Evaluation - Dr. Schmedlen	Project Rm training (1150 LBME); MDS session	Perusall annotations #3 due at 00:00am
27-Oct	Th	Prototyping - Michael Deininger	MDS session	
Week 9				
1-Nov	Tu	Detailed Design - Dr. Schmedlen	MDS session	Perusall annotations #4 due at 00:00am
3-Nov	Th	FDA Design Control - Kay Fuller, MRDS	3D Printing Workshop (3D Lab, optional); MDS session	
Week 10				
8-Nov	Tu	Manufacturing - Lara Brown, MC3	MDS session, Material Selection Workshop (optional)	
10-Nov	Th	Hazard Risk Management – Kay Fuller, MRDS	MDS session	
Week 11				
15-Nov	Tu	Project Briefs - BME Design Teams		Prepared Presentation
17-Nov	Th	Project Briefs - BME Design Teams		Prepared Presentation
Week 12				
22-Nov	Tu	Failure Effect Mode Analysis Workshop - Dr. Gosbee (optional)		Detailed Design & Engineering Analysis draft due
24-Nov	Th	**THANKSGIVING**		
Week 13				
29-Nov	Tu	No lecture - Rehearsals		
1-Dec	Th	No lecture - Rehearsals		
Week 14				
6-Dec	Tu	***Paper Design Review Presentations (2203 LBME)***		Slides due
8-Dec	Th	***Paper Design Review Presentations (2203 LBME)***		Slides due
Week 15				
13-Dec	Tu	Mid-project Reflection		**Paper Design Report, peer evaluations, engineering notebooks due; Components ordered**