BIOMEDICAL ENGINEERING

UNIVERSITY of MICHIGAN ■ COLLEGE of ENGINEERING

BME 599.002: GRADUATE INNOVATIVE DESIGN IN BIOMEDICAL ENGINEERING

COURSE SYLLABUS - FALL 2016

LECTURES: TUESDAY/THURSDAY, 1:00 – 3:00 P.M., 1121 LBME

INSTRUCTOR: Jan Stegemann
E-MAIL: jpsteg@umich.edu
OFFICE HOURS: Tues/Thurs 3-4 p.m. or by appt.
OFFICE: 2146 LBME
PHONE: 734-474-2927 (cell)
734-764-8313 (office)

GSI: Biming Wu
E-MAIL: bimwu@umich.edu
OFFICE HOURS: Mon 2-4 p.m. or by appt
OFFICE: 2420 LBME (lab)
PHONE: 319-594-2827 (cell)

COURSE DESCRIPTION: Graduate Innovative Design is a two semester course that stimulates students to explore their own solutions to biomedical challenges. Students experience the entire spectrum of innovative design, from concept generation through design validation to prototype fabrication. The course challenges students to learn about the current state of the art, explore the technical needs and current challenges, and brainstorm new solutions with members of the medical community.

The first semester is dedicated to needs assessment through a series of lectures by practicing physicians who describe challenges they face in the clinic. Students formulate a set of possible solutions, evaluate each solution, and then assemble into design teams to work on selected solutions. The focus of the second semester is on product prototyping, validation, and commercialization strategy. Each team participates in a series of design reviews that highlight key aspects of product development. Guest lecturers in key areas of medical technology commercialization provide guidance. Students are encouraged to participate in national and local design and business competitions throughout the year. Successful designs compete to represent the University of Michigan in a national design competition at the end of the second semester.

DISCLOSURE: All information exchanged in this class should be considered confidential among the class participants, and not be disclosed publiclly unless the appropriate permissions are in place.

REQUIRED TEXT AND NOTEBOOK: Biodesign - The Process of Innovating Medical Technologies - Edited by Stefanos Zenios, Josh Makower, Paul Yock, Todd J. Brinton, Uday N. Kumar, Lyn Denend, Thomas M. Krummel and Christine Kurihara, Cambridge University Press, 2010.
→ available electronically from UM Library (link provided on Canvas)
→ Kindle e-book option is available through Amazon.com

Lab notebook: bound, lined, numbered pages
→ suitable notebooks are available from the UM Student Chapter of BMES

This course has a dedicated Canvas site which contains the information and materials needed for class.

EVALUATION RUBRIC FOR FIRST SEMESTER:

Participation	30%
Assignments	25%
Design Reviews	25%
Proposal	20%

Students are expected to actively participate in discussions and other exercises in class. Homework and reading assignments for each class are designed to help you prepare for in-class discussion. This is a team-based course and therefore some assignments (Design Reviews and Proposal) are a team effort.

Participation grades are based on:

Attendance and professionalism (10%).

In-class participation: demonstrated preparation and ability to build on comments of others (5%).

Peer evaluations (5%).

Design Review feedback: thoughtful, constructive criticism of peer presentations (5%).

Lab notebooks: accurate documentation of idea and design evolution (5%).

Assignments will be given throughout the semester:

Readings and Pre-class questions (5%): Students will be assigned readings prior to each clinical lecture. These readings are important as they serve as preparation for the discussion and brainstorming sessions that are held with the visiting clinicians. Readings will be posted on Canvas, and students should consider the following questions as they complete the readings:

What is the overall problem being addressed?

What are the current technologies being used to address these problems?

How are these technologies applied?

What are the advantages of the current technologies?

What are the limitations of the current technologies?

Based on these readings, students are required to generate at least five (5) thought-provoking or clarifying questions related to the clinical area in question. These questions must demonstrate that students have thought about the readings and will serve as a catalyst for discussion during the clinical session. Questions must be posted to the Forum area of Canvas by 11 am on the day of the clinical lecture.

Brainstorming/Wiki contributions (20%): After each clinical lecture and brainstorming session, students will work in instructor-assigned teams to generate a wiki that comprehensively covers the clinical area and results of the brainstorming discussions on that topic. These wikis are important for documenting and sharing the learning from each clinical session, and they are the basis on which projects are selected for further development. Each wiki will include the following topics:

Background of the clinical procedure (pathology, prevalence, etc)
Problems that are encountered (from lecture and outside research)
Current Solutions (e.g. procedures and devices)
Needs (broader view of gaps in care)
Solutions (preliminary brainstorming of solution space)

More information about the format and process for generating wikis will be provided in class.

Design Reviews are a key part of this course and allow students to present, evaluate, and share their progress in the course. These reviews will begin in the latter half of the semester, once projects have been selected and teams have been assembled. Each Design Review will cover a specific topic, and outlined in the class schedule. During each Design Review, every team will present for up to 15-20 minutes to update the class on their progress and any challenges they have encountered. The students in the audience will discuss each presentation as appropriate, and also will be required to provide written feedback to the presenting group. The feedback can cover a variety of topics, but advice and suggestions on addressing challenges is particularly encouraged. While all team members are not required to speak during a given design review, each team member is expected to present at least once during the semester. Presentations must be uploaded to Canvas by 11 am of the presentation day. In addition, each team must submit a two-page (single spaced) document that corresponds to each design review. These documents must also be uploaded to the Assignments area of Canvas by 11 am on the day of the review.

Proposal. At the end of the first semester, each team must submit a written proposal documenting their design goals for the next semester. This proposal will serve as a template and jumping-off point for the continued project development work in the second semester. The proposal is relatively short (10 pages maximum), but needs to be clear and concise. A complete proposal will include the following sections:

Description of the problem to be solved

The need in the market place

Proposed solution

Competing technologies and assessment

Clinical mentor

Technical mentor

Regulatory agency requirements to which the ultimate design would be subjected

Proposed budget

Materials and equipment to complete the first prototype and initial verification (initial order should be placed by end of finals upon approval by faculty)

Additional information about the content, format, and deadline for the proposal will be provided in class.

GENERAL CLASS POLICIES: The success of this class is ultimately dependent on the quality of in-class interaction between the students and speakers, and students themselves. It critical that everyone be engaged and prepared for each session, and to remember that speakers are taking time out of their schedules to come and share their experiences. The utmost respect is expected at all times. Students should be aware of the following:

- You are expected to attend every class session and to be on time. Late entries and early departures from class are a sign of disrespect to your fellow classmates and more importantly, the guest speakers that have taken time out of their valuable schedules to come and speak.
- Course readings are provided to help you prepare and become fully engaged in class discussions. You are expected to complete all reading assignments and assignments on time.
- You will NOT need your laptop during the first hour. Laptops, cell phones and any other electronics must be turned off and put away throughout the class unless otherwise indicated.

DESIGN TEAMS: This is a team-based course and students are required to assemble into design teams based on their choice of product concept, typically near the middle of the semester. The class is structured to provide many opportunities to get to know other students in the class throughout the semester and you

should be conscientious of how you select your team mates. After team formation, we will provide guidance on how to work in teams and how to deal with team-mates.

Option to "Hire in": BME599 is a year-long class. The only way a student can enroll in the class for the second term is to be "hired in" by a team. Throughout the first semester, teams should be cognizant of their project needs. Should you feel the need to add expertise to your team, you are encouraged to reach out to other students in the College, interview them and then "hire" them.

Note: You should actively recruit in November. If you decide to "hire in" – please make the instructor aware of this process so they can be given permission to enroll.

EXTERNAL COMPETITIONS: Teams are encouraged to participate in external competitions to increase funding streams for prototype development. Suggested competitions include:

BME Idea Prototype Stipend ($500, www.nciia.org/bmeidea/)
NCIIA Advanced Eteams (www.nciia.org)
Zell Lurie/Center for Entrepreneurship Dare to Dream Grants ($500, www.zli.bus.umich.edu/events_programs/dream_grant.asp)
MPowered 1000 pitches Competition

More information on local and national competitions can be found by signing up for e-newsletters from:

Zell Lurie Institute (www.zli.bus.umich.edu/news_publications)
MPowered (mpowered.studentorgs.umich.edu)

LAB NOTEBOOKS: A laboratory notebook is a vital record of events leading to a patentable invention. The recorded information can establish dates of conception and reduction to practice of a technology as well as the inventorship of a patent claiming the technology. Students in this class are expected to keep a design notebook for both semesters. Lab notebooks can be purchased through the Biomedical Engineering Society or elsewhere. Lab notebooks must be bound notebooks with numbered pages. Rules for managing a lab notebook will be provided.

PROJECT ROOM: LBME 1150 is designated as the BME Design Project Room and is available to students in BME 599, BME 450, and BME 451/452. Students will be given access to the room via keycode once they have read and signed off on the BME Student Design Project Room Safety Manual. Access to the room is a privilege and can be revoked for inappropriate conduct. The following rules must be followed:

Sign in on the signup sheet whenever you use the room.

Clean up after yourself. If your group has left a mess, make sure it gets cleaned up.

Department supplies and equipment are not to leave the room.

If you need to use the soldering iron and hand drill, you must FIRST notify Prof. Stegemann and Dana Jackson for training and approval. These items cannot be used without proper training and documentation.

Report any type of damage to supplies and equipment to Dr. Stegemann and/or Dana Jackson.

Clearly label all group items placed in the refrigerator.

Students that are found to be neglecting these rules will not be able to use the facility.

LOCKERS: Lockers are available in the project room. Locker keys are available through Dana Jackson (2117 LBME, 647-9828, dmjackso@umich.edu).

Guidelines for Working with Faculty and Clinical Mentors

Please keep in mind that faculty and clinicians participating in this class were asked to come and describe the current needs in their field. Faculty/clinicians who agree to mentor BME 599 projects are *NOT SPONSORS*. They have generously volunteered their time to mentor you. They are not responsible for defining your project. They are there to help identify a clinical need and offer feedback and guidance from a clinical perspective.

Communications:
One person from each team should be designated as the "clinical faculty liaison." This person will be responsible for the majority of email/phone communication with the faculty mentor. This will 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 mentor and that Dr. Stegemann is cc'd on all correspondence.
Ask the faculty mentor how they prefer to be contacted – email, through administrator, by phone etc?

Email Etiquette:
Email should be professional
Please refer to the mentor as Dr. [Last name] unless otherwise instructed.
Try to maximize the quality vs quantity ratio – in other words, please make sure that your emails to the faculty are substantive and less frequent, as opposed to frequent with little value. Basically, do no spam.
TAKE SOME TIME TO MAKE YOUR MESSAGE/QUESTION CLEAR AND CONCISE; don't ramble on or be too cryptic.

In-person meetings:
If you would like to meet with your faculty mentor in person, please request a meeting. Please do not treat it like an expectation – they are not required to meet with you at your convenience.
Be respectful of their time.
Act professionally.
Be punctual.
Be prepared. Make sure that you have a plan with regard to what you want to discuss.
Treat them as a "consultant". Their role is to provide feedback, hence you must go to them with a plan/idea/contingency plan etc.
Mentors should sign lab notebooks in instances where they are contributing to the technical content of the conversation.

Grading:
Mentors will be asked to comment on interactions with teams for grading purposes. Some specific points measured will be: timeliness, professionalism, and organization.

Guidelines for Lab Notebooks

Lab Notebooks are used as documentation of project development: a complete record of what each individual does as a member of the project team at each step of the design, construction, and testing of the project. It is updated whenever project work is done. Most research and development work in industry will require keeping a similar log. It enables you and/or others to pick up the thread of your past work and carry it forward and serves as a legal record supporting patent claims. The book should show entries made at or shortly after every working session.

In the context of this course, the notebook additionally serves as documentation of progress. It is often referred to when project demos are not successful. The notebook can be requested by the instructor to resolve disagreements among the team members about how much effort each member put into the project. Finally, students that attempt to obtain patents may find that this notebook is a crucial piece of information for proving their work.

The notebook should prove that each partner is individually carrying an important part of the design effort. **Each group member must keep his or her own lab notebook.** Freely referring to the work of teammates is encouraged (e.g. "Fred derived the full equations for harmonic detection in his notebook. The basic idea is to look for peaks at integer fractions of the highest peak..."), but the notebooks submitted at the end of the semester should not be identical.

To stress the importance of keeping track of your progress, the instructor and GSI may conduct occasional spot checks of your notebooks, and your notebook will contribute to your final course grade.

Any notebook with permanent bindings designed for laboratory record keeping is acceptable. Those with pre-numbered pages are preferred. Ideally, it should have graph rulings on alternate pages, or else quarter-inch square grid on all pages.

Each notebook entry should include:

• the date

• a brief statement of the objectives for that session

• a record of what was discussed / done

• any relevant equations, diagrams, and figures, numbered for reference in the narrative portion of the book

• drawn figures, diagrams, and photocopies extracted from published sources

• references to books, papers, or websites

All separate documents should be permanently attached to the notebook. Sign and date across the document edge after attaching to your notebook.

Overall, the book should contain a record that is clear and complete, so that someone else can follow progress, understand problems, and understand decisions that were made in designing and executing the project.

What to include (at a minimum):

- A copy of your project proposal.

- Bibliographic references for any materials that are used as sources. Many of these references will be needed later in the written report.

- Diagrams, schematic and/or block, for any hardware that is to be tested. There should be an accompanying discussion explaining the principal design problems and decisions. Proposed tests should be mentioned here, too.

- Equations and formulas used in the design process, along with a reference to their sources. If derived by you, sketch enough of the development so that someone can follow the idea from your notes.

- Documentation of the testing and debugging process. This may include notes of what is being checked, test set-up diagrams, and non-routine results. Difficulties should be noted with particular care. It is wise to note anything of any conceivable importance when dealing with debugging problems.

- Analysis of, and proposed solutions for, any debugging problems. Include all revisions of diagrams and test setups and any new equations, etc.

- Documentation of the new tests, as before.

- Documentation of final performance tests and design verification.

- Topic outlines for oral and/or written reports can reasonably be included.

There is always something to record. Suppose you are only "kicking around" design ideas for the project with someone, or scanning library sources. Your objective is what you're hoping to find. The record shows what you found or what you decided and why, even if it isn't final. One of the most common errors is to fail to record these seemingly "unimportant" activities.

BME 599.002 GRADUATE INNOVATIVE DESIGN IN BIOMEDICAL ENGINEERING

FALL 2016 CLASS SCHEDULE

Updated: September 29, 2016

NOTE: *This schedule is subject to change depending on the availability of guest lecturers, etc. Check the course Canvas site regularly for announcements about schedule changes and other course information.*

SEMESTER AT A GLANCE: Classes are Tuesdays and Thursdays from 1:00 pm – 3:00 pm in 1121 LBME

Wk	Date	Tuesday (2 hr)	Date	Thursday (2 hr)
1	9/6	Course Introduction: *Overview, Goals, and Expectations*	9/8	Clinical Lecture 1: *Emergency Medicine* *Dr. Robert Neumar, UM/Emergency Med.*
2	9/13	Teams and Teaming 1 *Brian Tolle, UMHS*	9/15	Clinical Lecture 2: *Dermatology* *Dr. Jennifer Reeve, UM/Dermatology*
3	9/20	Review and Course Discussion	9/22	Clinical Lecture 3: *Ophthalmology* *Dr. Yanni Paulus, UM Kellogg Eye Center*
4	9/27	Clinical Lecture 4: *Neuroradiology* *Dr. Joseph Gemmete, UM/Neurosurgery*	9/29	Clinical Lecture 5: *Gastroenterology* *Dr. Ryan Law, UM/Internal Medicine*
5	10/4	Clinical Lecture 6: *General Surgery, Trauma* *Dr. Mark Hemmila, UM/Surgery*	10/6	Review Session – Project Vetting (Clinical Lecture 7: *Neurosurgery)*
6	10/11	Choose Projects and Teams	10/13	Biomedical Engineers in Industry *Scott Merz, MC3 Cardiopulmonary*
7	10/18	Fall Break (No Class)	10/20	Design Review 1: *(Bruns)* Problem Description and Current Solutions
8	10/25	Translating User Needs into Design Inputs *Richard Griewski, Terumo CVS*	10/27	Teams and Teaming 2 *Brian Tolle, UMHS*
9	11/1	Design Heuristics *Jin Woo Lee, Mechanical Engineering*	11/3	Design Review 2: Requirements and Specifications
10	11/8	Design Review 3: Potential Solutions	11/10	The Patent Process *Victoria Schumate, USPTO*
11	11/15	Design Review 4: Intellectual Property	11/17	Medical Device Regulatory Process *Gael Tisack, Wichita State U.*
12	11/22	In-Class Work Session	11/24	Thanksgiving (No Class)
13	11/29	Design Review 5: Downselect	12/1	Case Study
14	12/6	Team Meetings	12/8	Design Review 6: Propose Solution
15	12/13	Study Days: Work on Proposals		

FINAL WRITTEN REPORTS are due on December 17, 2016.

BIOMEDICAL ENGINEERING

UNIVERSITY of MICHIGAN ■ COLLEGE of ENGINEERING

BME 599.004: GRADUATE INNOVATIVE DESIGN IN BIOMEDICAL ENGINEERING

COURSE SYLLABUS - WINTER 2017

LECTURES: MONDAY/WEDNESDAY, 10:00 AM – 12:00 PM, 1311 EECS

INSTRUCTOR: Jan Stegemann
E-MAIL: jpsteg@umich.edu
OFFICE HOURS: Mon/Wed 12-1 pm or by appt.
OFFICE: 2146 LBME
PHONE: 734-474-2927 (cell)
734-764-8313 (office)

GSI: Biming Wu
E-MAIL: bimwu@umich.edu
OFFICE HOURS: By appointment
OFFICE: 2420 LBME (lab)
PHONE: 319-594-2827 (cell)

COURSE DESCRIPTION: Graduate Innovative Design is a two term course that stimulates students to explore their own solutions to biomedical challenges. Students experience the entire spectrum of innovative design, from concept generation through design validation to prototype fabrication. The course challenges students to learn about the current state of the art, explore the technical needs and current challenges, and brainstorm new solutions with members of the medical community.

This first term is dedicated to needs assessment through a series of lectures by practicing physicians who describe challenges they face in the clinic. Students formulate a set of possible solutions, evaluate each solution, and then assemble into design teams to work on selected solutions. The focus of the second term is on product prototyping, validation, and commercialization strategy. Each team participates in a series of design reviews and workshops that highlight key aspects of product development. Guest lecturers in key areas of medical technology commercialization provide guidance. Students are encouraged to participate in national and local design and business competitions throughout the year. Successful designs compete to represent the University of Michigan in a national design competition at the end of the second semester.

The main components of the Winter term are:

1) Product Design and Development: Student teams will design, manufacture, and validate the prototype of the product proposed at the end of the Fall term.

2) Critical Review and Teamwork: Students will work within their own teams, as well as together as a class to move all projects forward. Regular design reviews provide the opportunity to critically review other teams, as well as to offer support and resources, with the goal of value creation for all teams.

3) Guest Lectures and Workshops: Guest experts will come to class during the term to address relevant product development topics, including: prototyping, risk analysis, IP strategy, regulatory strategy, entrepreneurship, manufacturing, reimbursement and pricing. These experts will also work directly with teams to address specific questions and needs for their projects.

Teams will present their products at a final design showcase, and the top team will have the opportunity to represent UM BME in the national BMEidea competition (more information below).

DISCLOSURE: All information exchanged in this class should be considered confidential among the class participants, and not be disclosed publically unless the appropriate permissions are in place.

REQUIRED TEXT AND NOTEBOOK: Biodesign - The Process of Innovating Medical Technologies - Edited by Stefanos Zenios, Josh Makower, Paul Yock, Todd J. Brinton, Uday N. Kumar, Lyn Denend, Thomas M. Krummel and Christine Kurihara, Cambridge University Press, 2010.
→ available from UM Library (link provided on Canvas)
→ a Kindle e-book option is available through Amazon.com

Lab notebook: students should continue to use the notebook they started in the Fall term.

This course has a dedicated Canvas site which contains the information and materials needed for class.

GENERAL CLASS POLICIES: The success of this class is ultimately dependent on the quality of interaction between the participants: students, instructors, and guest experts. It critical that everyone be engaged and prepared for each session, and to remember that speakers are taking time out of their schedules to come and share their experiences. Professionalism and respect are expected at all times. Students should be aware of the following:

- You are expected to attend every class session and to be on time. Late entries and early departures from class are a sign of disrespect to your fellow classmates and more importantly, the guest speakers that have taken time out of their valuable schedules to come and speak.
- Course readings are provided to help you prepare and become fully engaged in class discussions. You are expected to complete all reading assignments and assignments on time.
- You will NOT need your laptop during guest lectures, unless explicitly asked to use them. Laptops, cell phones and any other electronics must be turned off and put away throughout the class unless otherwise indicated.

EVALUATION RUBRIC FOR WINTER TERM:

Participation	25%
Design Reviews	25%
Final Report	40%
Final Presentation	10%

Students are expected to actively participate in discussions and other exercises in class. Homework and reading assignments for each class are designed to help you prepare for in-class discussion. This is a team-based course and therefore some assignments are a team effort.

Participation grades are based on:
Attendance and professionalism (5%).
In-class participation: good preparation and ability to build on contributions of others (5%).
Peer evaluations (5%).
Design Review feedback: thoughtful, constructive criticism of peer presentations (5%).
Lab notebooks: accurate documentation of idea and design evolution (5%).

Design Reviews are a key part of this course and allow student teams to present, evaluate, and share their progress and challenges. Each Design Review will cover a specific topic, as outlined in the class schedule. During each review, every team will present for up to 15-20 minutes to update the class on their progress

and any challenges they have encountered. The students in the audience will discuss each presentation as appropriate, and also will be required to provide written feedback to the presenting group. The feedback can cover a variety of topics, but advice and suggestions on addressing challenges is particularly encouraged. Each Design Review should cover:

1) The assigned topic (see class schedule). These topics reflect the topics covered in lectures and workshops, as well as the content of the final report.

2) The progress over the previous week, including any validation testing or other results.

3) Current challenges. Feel free to ask for input from your classmates.

4) Goals for the next week. As appropriate, provide task assignments and individuals responsible.

5) Current Budget Status: amount spent vs amount projected

Teams are encouraged to include demonstrations and/or videos of their prototypes to demonstrate their results and challenges. While all team members are not required to present during a given design review, each team member is expected to present at least once during the semester. Presentations must be uploaded to Canvas by 9 am of the presentation day. In addition, each team must submit a two-page (single spaced) document that corresponds to each design review. The written document should focus on the assigned topic area (i.e. numbers 2-5 above are not required in the write-up). These documents must also be uploaded to the Assignments area of Canvas by 9 am on the day of the review.

Final Report. The main deliverable for each team is a written final report that comprehensively describes their product. These reports will be prepared in the format prescribed by the BMEidea competition sponsored by VentureWell (formerly the National Collegiate Inventors and Innovators Alliance, or NCIIA). Details on the content and format are also provided in Appendix A. The topics to be covered are:

Description of the problem to be solved
Project objective statement
Documentation of the final design
Prototype of the final design
Proof that the design is functional and will solve the problem
Results of a patent search and/or search for prior art, assessment and patentability
Anticipated regulatory pathway
Reimbursement
Estimated manufacturing costs
Potential market

Final Presentation: Teams will present their final projects in a design showcase near the end of the semester. Guests who have participated in the class over the year will be invited to attend, as will others in the BME community. A panel of guest reviewers will judge and score each of the final presentations.

Note: All students will be required to evaluate the presentations and reports of the other teams in the class. This will require a significant time commitment during the week before project presentations.

BMEidea Competition: The team with the highest score in the final presentation will be given the opportunity to submit their final written report to the national BMEidea competition. Teams are NOT required to participate in this competition. If the top scoring team chooses not to participate, then the runner up will be given the option.

More information about the BMEidea competition and submission deadlines will be provided in class.

OTHER KEY COMPONENTS OF CLASS IN WINTER TERM:

Workshops: Teams will have an opportunity to meet with industry guest experts during class to get feedback on their projects. This experience is extremely valuable and should be taken seriously. Teams should come prepared with questions related to the guest's area of expertise. Meetings will be either 15 or 30 minutes, depending on the expert's availability. In cases where availability is 30 minutes, students may need to be prepared to meet outside out of the typical class time. Teams will be asked to sign up based on their availability.

Mentor Meetings: Teams should ensure that they meet regularly with their clinical mentors. In the first two weeks of the semester, teams should create a schedule of mentor meetings for the semester. It is recommended that these meetings occur at least every 2-3 weeks, however extra meetings are welcomed and encouraged based on your mentors' availability. Meetings with technical mentors should be scheduled as needed.

Project Budgets: Each team has been allocated a budget of $1000 for prototype development. Teams are responsible for monitoring their budget and reporting spending during Design Reviews. Budgeting information should be kept up to date in an electronic spreadsheet that documents actual expenses versus projected expenses. These spreadsheets should be made available for the course instructors on the class website (use the shared Google Drive folder).

Budgeted funds are meant for expenses of prototyping, including materials, supplies, equipment, and services required to fabricate and test prototypes. It is suggested that purchases larger than $250 be cleared by Dr. Stegemann, since the materials or equipment in question may already be available on campus, or may be available at a lower cost.

In addition, teams may exceed their initial budget allocation if they have pre-approved and justified expenses that will significantly enhance their project and product. Teams can apply for additional funds up to a maximum of $1000 by supplying a written justification and itemized list of purchases to be made to Dr. Stegemann for approval before the purchase is made.

Purchasing: All purchasing should go through Ms. Kathy McCrumb, Senior Secretary in BME, in 1107 Gerstacker Bldg (734/764-9588, kmccrumb@umich.edu). All requests for purchasing through Kathy should be via email and must include the full information to specify the purchase, as well as clear explanation that this is for a BME599 project, and your group name.

Reimbursement for small expenditures by team members can be arranged through the petty cash process. Petty cash reimbursement requests require and itemized receipt and must be submitted within 30 days of the purchase. Kathy McCrumb will process these requests, and they are to be counted as part of the total allotted budget.

CoE Design Expo: All teams are expected to participate in the CoE Design Expo (end of semester, date TBA) unless there are extenuating circumstances (e.g. intellectual property disclosure). Funds for poster printing can be obtained through the department with advance notice. Posters must adhere to the Design Expo guidelines, and a template for BME posters is available through the department.

External Competitions: Teams are encouraged to participate in external competitions to increase funding streams for prototype development. Information on these opportunities will be provided as they arise, and students are encouraged to seek out new ones. Some suggested competitions include:

VentureWell E-Teams
Dare to Dream, Mayleben, and TechArb Grants
MPowered 1000 pitches Competition

LAB NOTEBOOKS: A laboratory notebook is a vital record of events leading to a patentable invention. The recorded information can establish dates of conception and reduction to practice of a technology as well as the inventorship of a patent claiming the technology. Students in this class are expected to keep a design notebook for both terms. Lab notebooks can be purchased through the Biomedical Engineering Society or elsewhere. Lab notebooks must be bound notebooks with numbered pages. Rules for managing a lab notebook will be provided.

PROJECT ROOM: LBME 1150 is designated as the BME Design Project Room and is available to students in BME 599, BME 450, and BME 451/452. Students will be given access to the room via keycode once they have read and signed off on the BME Student Design Project Room Safety Manual and performed basic safety training with Mr. Dana Jackson (Facilities Manager for BME). Access to the room is a privilege and can be revoked for inappropriate conduct. The following rules must be followed:

Safety is the priority. You will be given basic safety training before using the Project Room, but you are responsible for maintaining a safe environment for yourself and your fellow students.

Sign in on the signup sheet whenever you use the room.

Clean up after yourself. If your group has left a mess, make sure it gets cleaned up.

Department supplies and equipment are not to leave the room.

If you need to use the soldering iron, hand drill, or Dremel tool, you must first notify Dana Jackson for training and approval.

Report any type of damage to supplies and equipment to Dr. Stegemann and/or Dana Jackson.

Clearly label all group items placed in the refrigerator.

Students who neglect these rules will be denied access to the facility.

LOCKERS: Lockers are available in the project room. Locker keys are available through Mr. Dana Jackson (2117 LBME, 647-9828, dmjackso@umich.edu). **Grades WILL NOT be posted until your key has been returned at the end of the semester.** Students will be charged $25 for keys not returned.

APPENDIX A: Format and Content of Final Reports

Final reports for this class are to be prepared in the format of a submission to the VentureWell BMEidea competition. The guidelines below are modified slightly from the BMEidea website. The team(s) entering the BMEidea competition should consult the VentureWell website before preparing their proposals to ensure that they strictly meet the content and formatting criteria, and to ensure that they understand the rules of the competition.

The proposal: Required and optional components

Required components: The following documents are required as part of your BMEidea application and must be included in the following order, combined together in a single PDF:

1. Narrative (no more than 10 pages)
2. Key team member resumes (limit of three pages per resume)

Narrative description guidelines: The narrative may not exceed 10 pages in length (double-spaced, 12 point font). Please include any images referenced in your narrative in the body of the narrative, NOT as appendices. Please prepare a narrative description that includes the following:

- **Executive summary** (two pages). An outline of the strategy for commercialization and opportunity statement. See below for additional details.
- **Description of the problem to be solved** (no more than 1/2 page). What is the problem you have solved? What is the market and/or industry needs that you intend to address?
- **Project objective statement** (no more than 1/2 page). How does your team intend to address the problem? How does your final design solve the problem?
- **Documentation of the final design** (one page). Be sure to include applicable standards and a risk analysis.
- **Prototype of the final design** (one page). Paste graphical representations and photographs in the document and, if available, provide a link to a video.
- **Proof that the design is functional and will solve the problem** (one page). Include test data, market research or pre-clinical/clinical trials.
- **Results of a patent search and/or search for prior art, assessment and patentability** (one page). Two excellent resources for this search are www.uspto.gov and your institution's technology transfer office. Regarding marketplace competition, what is currently being used to solve the problem and/or what are the anticipated alternate methods that could be in competition with you in the future?
- **Anticipated regulatory pathway (510(k) vs. PMA, etc.)** (1/2 page). Consider researching how the FDA has treated analogous devices.
- **Reimbursement** (1/2 page). Do you expect your device to be reimbursable by Medicare/Medicaid? Why or why not?
- **Estimated manufacturing costs** (one page). Provide detailed per unit cost breakdown, including volume discount, for components, final assembly, quality assurance, etc.
- **Potential market** (one page). Who would your customers be (i.e., who will be purchasing the product) and who would the end users be (i.e., who would be using the product)? If possible, quantify the number of potential users and the benefit they would receive from use of the product. Define the potential market size, selling price, and distribution channels.

What's in an Executive Summary? An executive summary summarizes all of the above and serves as a stand-alone justification for why this idea should be pursued. Be sure to address the essentials:

- *Problem*: What is the problem you aim to solve?
- *Solution*: How will you solve it?

- *Competition*: What are alternate methods of solving the problem or anticipated methods that could be in competition with you in the future?
- *Differentiation*: Why will people choose your solution over others?
- *Technical Feasibility*: Have you done it and can it be done?
- *Regulatory and Reimbursement*: What FDA approvals will be required? What Medicare/Medicaid strategy is needed?
- *Sales and Marketing*: What is the estimated size of the market (with rationale)? Who is the buyer/customer/user? Who will they buy it from? At what pricing?

Required key team member resumes should be no more than three pages each, and are only required for key team members.

Additional (optional) supporting documents: Up to five additional appendices may be included in your proposal and must be uploaded as one merged PDF. Appendices may include but are not limited to:

1. Images demonstrating design and/or technical feasibility (drawings, photographs, etc.)
2. A summary of prior art
3. Literature review
4. Any data collected as part of testing your technology
5. Any other relevant supporting materials
6. *[Only for entrant(s) to BMEidea Competition]* Letter(s) of support. Applicants are strongly encouraged to include at least one letter of support from an industry mentor and/or faculty advisor, if applicable, who has worked with the team, attesting to the quality of the work they have done.

Note: Sheer volume of material is not an asset. Reviewers are directed to use supporting materials only to supplement the 10-page narrative. Therefore, key information should be included in the narrative.

Optional videos and/or links — In addition to the appendices mentioned above, teams may upload up to four links, which may include online articles, videos and/or other relevant online data.

Recommended video — Teams are encouraged to submit a brief video (up to two minutes) about your innovation. The video should address the following:

Technical feasibility: demonstrate that the prototype works or otherwise describe the function of the device

Product pitch: make a compelling case that the device is innovative and impactful. State the problem that's being solved, why your device/solution is better than what currently exists, and the impact of your team's solution.

How are entries evaluated?

BMEidea competition entries will be judged on the following criteria:

1. Technical feasibility
2. Clinical utility
3. Economic feasibility and market potential
4. Novelty and patentability
5. Potential for commercialization

***[for entrant(s) to BMEidea competition]* Proposal review process and notification**

- Submitted applications are reviewed by external panels of reviewers made up of individuals from academia, industry, nonprofits & NGOs, and venture capital with experience in the technology areas and in the commercialization of early stage innovations.

- VentureWell notifies applicants of the status of their submissions via email within 90 days of the submission deadline.
- All prizes are awarded to the winners' universities and are considered unrestricted gifts for the purpose of research and educational initiatives related to the winning projects. There is no expectation for services rendered and no reporting required. Funds are disbursed to each of the winning teams' departments to be allocated at the discretion of the Faculty Advisor.

BME 599.004: GRADUATE INNOVATIVE DESIGN IN BIOMEDICAL ENGINEERING

WINTER 2017 CLASS SCHEDULE

UPDATED: JAN 10, 2017

NOTE: *This schedule is subject to change depending on the availability of guest lecturers, etc. Check the course CTools site regularly for announcements about schedule changes and other course information.*

SEMESTER AT A GLANCE: Classes are Mondays and Wednesdays from 10:00 am – 12:00 pm in 3150 DOW.

Wk	Date	Monday (2 h)	Date	Wednesday (2 h)
1	1/2	No Class	1/4	Winter Term Kick-Off and Discussions
2	1/9	New Venture Creation Adrienne Harris, *Alum of UM Med Inn Cent*	1/11	Risk Analysis *Bill Hansen, Terumo Heart*
3	1/16	No Class (MLK Day)	1/18	Workshop - Risk Analysis *[DL3 in Dude]* *Bill Hansen, Terumo CVS, and Brian Tolle*
4	1/23	Design Science and Prototyping *Michael Deininger, UM Design Science*	1/25	DR7: Prototype 1.0
5	1/30	DR8: Evaluation Plan	2/1	Workshop - IP Strategy *[DL3 in Dude]* *TBA, OTT;*
6	2/6	State of the Medical Device Industry 2017 *Jan Stegemann, BME*	2/8	Workshop - Regulatory Strategy *[DL3 in Dude]* *TBA;*
7	2/13	Manufacturing *TBA*	2/15	DR9: IP and Regulatory Revisited
8	2/20	Standards in Medical Device Design *TBA*	2/22	DR10: Prototype 2.0
9	2/27	No Class (Spring Break)	3/1	No Class (Spring Break)
10	3/6	Teams and Teaming *Brian Tolle*	3/8	DR11: Manufacturing Plan
11	3/13	Medical Device Pricing *TBA*	3/15	DR12: Verification Results
12	3/20	Reimbursement ***[9am-1pm, Phoenix Lab]*** *Susan Rowinski, Rowinski Group LLC*	3/22 ^^^	DR13: Pricing and Reimbursement
13	3/27	Team Meetings *(*Teams need to critique all reports*)*	3/29 ***	Final Presentations at Design Showcase 2017 [Johnson Rooms in LEC from 9-12]
14	4/3	No Class JPS OUT	4/5	Venture 101 JPS OUT *Biming Wu*; ***BMEIdea Deadline
15	4/10	Professional Development *Brian Tolle*	4/12 ###	Class visit to Xoran Technologies TBA, [***9-11:30***]
16	4/17	Recap and Discussion		

^^^ FINAL WRITTEN REPORTS ARE DUE ON SAT MARCH 25 AT 11 PM

***** BMEIDEA DEADLINE IS WEDNESDAY APRIL 5**

COE DESIGN EXPO IS ON THURSDAY APRIL 13