



# BME 498Y: Biomedical Engineering Capstone Design

## 1. Calendar Information

In this project-based design course teams of students from diverse engineering disciplines (enrolled in the biomedical engineering minor) will engage in the bio-medical technology design process to identify, invent and implement a solution to a unmet clinical need. The students will learn about medical technology development and will engage in the process through lectures, guest lectures delivered by medical technology experts, "hands-on" practicums and a student driven design project. Approval to register in the course must be obtained from the Associate Chair, IBBME - Undergraduate. Course Description Reference:

[https://portal.engineering.utoronto.ca/sites/calendars/current/Course\\_Descriptions.html](https://portal.engineering.utoronto.ca/sites/calendars/current/Course_Descriptions.html)

## 2. Course Overview

BME498 is a capstone design project course intended to have students identify unmet clinical needs and/or healthcare-related problems and define a design challenge. In the course of proposing an innovative solution, students are expected to apply their technical background to address the design challenge. Students will be expected to perform additional self-study to understand their challenge but course expectations will be supported by “hands-on” activities presented in lecture and laboratory periods to orientate each team toward proper engineering design. The student-driven design project will take place over both semesters as each team proposes a project and develops a design from initial concept to final working prototype.

The goal of this course is to provide students with the opportunity to practice innovation and engineering design skills within a biomedical context and increase awareness of future entrepreneurial activities. Topics will include needs finding, needs screening, product design specifications, concept generation, concept screening, prototyping, risk assessment, and quality control of medical devices. Each team will have a budget not exceeding \$750 and access to the IBBME design studio (MB64/78) for prototyping their project.

## 3. Learning Outcomes and Graduate Attributes

At the end of this course, you will be able to:

1. Identify user/stakeholder needs through a user-centered approach
2. Describe a credible and professionally acceptable approach to “engineering design”
3. Summarize and justify design choices in oral and written formats
4. Incorporate realistic constraints of medical technology development into engineering design
5. Plan and manage engineering activities to within time and budget constraints
6. Document an engineering design in a form suitable for intellectual property protection



7. Develop a functioning engineering prototype of a product or service

Graduate Attribute Table

#### 4. Timetable

Section	Day of the Week	Start Time	Duration (Minutes)	Location
Pra	W	09:00	180	MB 78
Lec	W	12:00	60	MB 78
Lec	F	13:00	60	BA B026

Office Hours: Mondays 13:00 – 14:00 in MB321A

#### 5. Course Instructors

Course Coordinators

Name	Phone	Office	Email
Chris Bouwmeester	(416) 978-3702	MB321A	chris.bouwmeester@utoronto.ca

Prof. Bouwmeester is be the main point of contact for students and is responsible for evaluating and providing feedback to students.

Teaching Assistants

Name	Phone	Office	Email
Arushri Swarup			arushri.swarup@mail.utoronto.ca
Philippa Gosine			p.gosine@mail.utoronto.ca

Ms. Swarup will be available to individual teams as she will be present in the design studio to help you with technical aspects of your design projects. In her role as project supervisor she will be linked with individual teams and be the first person that students should turn to for help. In this way she is a bridge between the course instructor and the individual teams. As such, she will attend all of your team meetings to monitor how well individuals are functioning as part of a team and provide evaluations of your team engagement as well as written and oral deliverables. In the winter semester Ms. Gosine will come on board and act more as a project manager and focus on teams producing a product/working prototype.

Design Studio & Teaching Laboratory Coordinators

Name	Phone	Office	Email
Max Giuliani	(416) 978-7188	MB78	design.ibbme@utoronto.ca
Lindsey Fiddes	(416) 978-1467	MB325	teachinglab.ibbme@utoronto.ca

Dr. Giuliani is available to help you use the resources in the Design Studio and Prototyping Suite, which may include light fabrication or rapid prototyping. Dr. Fiddes is available to help you use the resources in the Teaching Lab, which may include wet lab facilities or microscopy.



Communication Instructor

Name	Phone	Office	Email
Nikita Dawe			nikita.dawe@mail.utoronto.ca

Ms. Dawe will provide support and feedback regarding your written and oral communications. She will provide feedback on your engineering communication specifically for the project proposal to enable your improvement for the final report. She will also give you feedback on a practice oral presentation before your final presentation to clients and your fellow students.

## 6. Final Grade Determination

The final grade in this course will be based on the following components:

Component	Learning Outcome(s) Evaluated	Due Date	Weight
Individual			
Pre/Post-Class Assignments & Design Notebook		See Schedule	10 %
Progress Presentations		See Schedule	5 %
Laboratory Participation		Nov 15 Jan 17	5 %
Team			
Project Requirements		Nov 3	10 %
Project Proposal Presentation		Dec 6	5 %
Project Proposal		Dec 18	15 %
Preliminary Test Results Presentation		Feb 14	5 %
Demonstration Day Presentation		Apr 4	10 %
Final Report		Apr 4	25 %
Team Meetings		See Schedule	10 %

**Total:**

	100 %
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## 7. Deliverables

All written submissions must be received by 11:59 PM on the date listed. Additional details related to each deliverable are given in guideline documents posted in the Assignments Submission section in Blackboard.



### Peer Evaluations

The purpose of peer evaluations is to: 1) allow your project supervisor to understand how well your team is functioning after you submit your proposal, 2) promote positive team discussions that allows individual's to improve their performance, and 3) to allow, if necessary, grades for the report to be scaled appropriately to reflect individual effort. Both the proposal and report must include a peer evaluation that each individual will complete for all other team members. You must send your project supervisor your evaluation of your peers using the following evaluation matrix shown below. The peer evaluation component is worth 1% of your proposal or report grade and all team members must submit a peer review to receive full marks.

For the proposal, the peer evaluation will not be used to scale individual grades and instead will be used by your project supervisor to identify any issues that can hopefully be used as a basis for discussion amongst your team. For the report, the peer evaluations will be used to scale individual grades if the same issues identified via peer evaluation of the proposal have not been ameliorated. If the report peer evaluations display the same pattern as the proposal, then the peer evaluations will be incorporated directly but if the final report peer evaluations shown an unprecedented pattern, the instructor may only allow half of potential scaling to occur. Individual grades for the final report grade may be scaled up to a maximum of  $\pm 10\%$  according to a scaling factor derived by dividing an individual's peer evaluation score by the average grade of all peer evaluation scores.

### Peer Evaluation Matrix

<b>Indicator</b>	<b>Score of 1 Description</b>	<b>Score of 2 Description</b>	<b>Score of 3 Description</b>	<b>Score of 4 Description</b>
<b>Completion of tasks</b>	Assigned tasks are not completed or not completed by deadline	Completes some tasks by deadline (or completes tasks only if repeatedly reminded)	Completes all assigned tasks by deadline	Completes work in advance with enough time to improve quality before deadline
<b>Meetings</b>	Often late and/or absent without notifying the team	Sometimes late and/or absent; may notify the team	Attends team meetings regularly and on time; consistently notifies team if late or absent	3 + notifies team as far as possible if late or absent; follows up with team members to catch up on what they missed
<b>Quality of Work</b>	Work not usable by the team	Quality is inconsistent; may need to repeat some parts of the individual's efforts	Quality of work is satisfactory; only minor improvements required	3 + proactively helps team members who produce work that requires improvements
<b>Communication</b>	Does not communicate or communicates with team members disrespectfully using ineffective tone, body language, and facial expressions	Communicates respectfully but does so inconsistently and/or to select team members	Communicates respectfully with all team members using effective tone, body language, and facial expressions	3 + encourages other team members to communicate respectfully

Pre/Post-Class Assignments & Design Notebook: See Schedule

The goal of pre/post-class assignments is to come to class prepared to work on an important component of your project. Each assignment is linked to an key component of the reports and presentation. The aim is to do individual work that can be combined with your team to prepare



for these deliverables, which getting feedback on how to do these activities proficiently during class.

Pre-class assignments must be submitted (in Blackboard) before the class, in which they are associated with, begins. Pre-class assignment review material and instructions will be presented in the lecture and posted on Blackboard before these assignments are due. You must keep up to date regularly of any scheduling changes during the semester. As table 1 below shows, grades will be given for: 1) completion and delivery of the assignment and 2) participation during class. For example, full marks (i.e., 3/3) would be given for an assignment handed in on time and participation during class. In this course, active participation is defined by asking questions and/or participating in activities either with your group or individually. Passive participation, which means simply showing up for class, is not enough to be considered active participation. If you cannot attend the lecture associated with the pre-class assignment, please see the attendance policy in section 11.

Mark	Completion and Delivery Criteria
2	<ul style="list-style-type: none"><li>• Assignment submitted before class</li><li>• Complete answers</li></ul>
1	<ul style="list-style-type: none"><li>• Assignment submitted late but before the end of class</li><li>• Incomplete answers</li></ul>
0	<ul style="list-style-type: none"><li>• Assignment handed in late</li></ul>

Mark	Participation Criteria
1	<ul style="list-style-type: none"><li>• Active participation</li></ul>
0	<ul style="list-style-type: none"><li>• Absent from class</li></ul>

Table 1: Pre/Post Class Assignment Rubric

Design notebooks are important to document your individual and team progress and good practice will prepare you for your future careers. At 4 team meetings (see schedule), you will schedule 5 extra minutes to have the project supervisor review your individual progress in keeping your design notebook. Therefore, you will need to bring the physical copy for inspection, which will be evaluated according to table 2. (N.B., each new entry should occupy a new page for easy review).

Mark	Completion and Delivery Criteria
3	<ul style="list-style-type: none"><li>• More than 2 entries per week</li></ul>
2	<ul style="list-style-type: none"><li>• 2 entries per week</li></ul>
1	<ul style="list-style-type: none"><li>• 1 entry per week</li></ul>
0	<ul style="list-style-type: none"><li>• Not submitted for review / absent</li></ul>

Table 2: Design Notebook Rubric

Progress Presentations: See Schedule

Regular progress reports are necessary get feedback from the course instructor and other students in the class regarding how your team is progressing in the course. See the course schedule for the



dates (and suggested topics of review) where each team will nominate an individual member to give a one-slide, 5-minute presentation on their progress to date. As an individual presenter, your goal is to present your progress clearly and succinctly (if there was no progress, the presenter will discuss the technical hurdles encountered and the plan to overcome them). Each student will receive full marks for presenting 2 progress reports for their team. You are also strongly encouraged to attending all other progress reports that you do not present personally.

Laboratory Participation: Nov 15 and Jan 17

The creation of prototypes will help your team build a working solution by the end of this course and considering how incorporate quality control and risk analysis into your design will ensure that you are successful. Therefore, there are 2 major activities that require mandatory attendance. You will receive full participation marks for attending Lab 1 and 2.

Project Requirements: Nov 3

Gathering information about your chosen problem and building an accurate understanding of your healthcare-related need will allow you define what a design *must do* to be an acceptable solution. Furthermore, your must also be able to find ways to differentiate different designs you create and define what a design *should be* and/or *must be* in order to be successful. Your team is responsible for submitting a concise document that communicates the design requirements (specifications) of your stated need. Please refer to '*Guidelines for Project Requirements*' (posted on Blackboard) for more information.

Project Proposal Presentation: Dec 6

Each team will present an overview of their project and show preliminary prototypes created so far. The aim of this presentation is to demonstrate your knowledge of a healthcare need and the problem you have chosen to solve. This presentation is also a good opportunity to get feedback before the project proposal is due and set your team up for potential iterations during the winter term dedicated to building a prototype. Please refer to '*Guidelines for Project Proposal Presentation*' (posted on Blackboard) for more information.

Project Proposal: Dec 18

Your team is responsible for drafting a project proposal document that: 1) defines the design problem, 2) proposes possible solutions and selects the most promising design, and 3) provides a plan to carry out the proposed solution. Please refer to '*Guidelines for Project Proposal*' (posted on Blackboard) for more information.

Preliminary Test Results Presentation: Feb 14

This interim presentation is a checkpoint to demonstrate you are well on your way to realizing a working prototype or model of your design. Each team will present the progress they have made toward achieving the testing they outlined in the project proposal document. The aim of this presentation is to demonstrate that your team is well on its way to proving you have created a





design that satisfies your stated need and solves the problem you believe needs to be addressed. This presentation is also a good opportunity to get feedback before the final working prototype presentation and report. Please refer to '*Guidelines for Preliminary Test Results Presentation*' (posted on Blackboard) for more information.

#### Demonstration Day Presentation: Apr 4

Each team will present their design and demonstrate their final working prototype to the project supervisors and hopefully some of the users you have connected with as well. Consider this presentation as a pitch to investors or a presentation at a design competition where you still need to clearly communicate the need you are addressing and the problem you are offering a solution to. The Focus of this presentation should be proving, with test results, that your design solves the problem you have identified. The most successful teams will be able to demonstrate how their design works and this is best achieved by performing a live demonstration. Please refer to '*Guidelines for Demonstration Day Presentation*' (posted on Blackboard) for more information.

#### Final Project Report: Apr 4

Your team must produce a final report that summarizes and documents your work and final results. While much of the project proposal can be reused, you should incorporate feedback from your client, project supervisor, teaching assistants, and fellow students (if applicable) to demonstrate you have iterated your original goals, ideas, concepts, designs, etc. The major focus of this report is to: 1) provide further documentation of your technical aspects of your design, 2) demonstrate how you have tested (e.g. performance) of module- or system-level designs, and 3) make recommendations for future development. Please refer to '*Guidelines for Final Report*' (posted on Blackboard) for more information.

#### Team Meetings: See Schedule

Meeting regularly is vitally important to make decisions as a team and document the progress your team makes throughout this course. While you are encouraged to meet as often as necessary, there are 8 dates where you must hold team meetings in the Design Studio. These mandatory meetings must be scheduled to last a maximum of 30 minutes and coordinated with your project supervisor to occur between 10:00 – 12:00 on the dates listed in the course schedule. As noted above, some of these meetings (1, 4, 6, and 8) will be used to check your individual design notebook progress. To receive full marks for this component of your overall grade you must: 1) circulate an agenda prior to meeting with your project supervisor and 2) circulate and submit (in Blackboard) the agenda plus meeting minutes by the end of the day that the meeting occurred. Please refer to '*Guidelines for Meeting Documentation*' (posted on Blackboard) for more information and templates for agenda and minutes.

## **8. Textbook**

The required textbook for this course is: Biodesign by Yock. This textbook also has a large amount of online resources (<http://ebiodesign.org/>) helpful. You may also find other design



textbooks listed below are helpful to you during the design process and in medical device development in general

**Required:**

Title	Biodesign – The Process of Innovating Medical Technologies
Author(s)	Yock, Zenios, Makower, Brinton, Kumar, Watkins, Denend
Edition, Year	2nd Edition (2015)
Publisher	Cambridge University Press

**Suggested:**

Title	The Mechanical Design Process
Author(s)	Ullman
Edition, Year	5th (2016)
Publisher	McGraw Hill

Title	Designing Engineers – An Introductory Text
Author(s)	McCahan, Anderson, Kortschot, Weiss, Woodhouse
Edition, Year	1 <sup>st</sup> (2015)
Publisher	Wiley

Title	Medical device design: innovation from concept to market
Author(s)	Peter J. Ogrodnik
Edition, Year	First edition 2013
Publisher	Academic Press

Title	Class 1 devices: case studies in medical devices design
Author(s)	Peter J. Ogrodnik
Edition, Year	2015
Publisher	Academic Press

## **9. Course Policies**

### **Accommodations for Disabilities**

Students with diverse learning styles and needs are welcome in this course. In particular, if you have a disability and/or health consideration that may require accommodations, please feel free to approach me and/or Accessibility Services at (416) 978-8060 ([accessibility.utoronto.ca](http://accessibility.utoronto.ca)).

### **Lateness Policy**

Graded assignments received later than the due date posted will be awarded a 10% deduction compounded for every day that the submission is late. Exceptions may be accommodated for valid reasons (such as severe illness or compassionate grounds), that are out of a student's





control, and may be considered if supported by written documentation. Examples of invalid reasons would include situations where Blackboard submissions were not executed properly by a student, or a student forgot the deadline.

#### Attendance Policy

While no notification of your absence is necessary, if you are absent, you will be responsible for gathering the information you need from your peers. In the case of the progress presentation that you must deliver, you should coordinate with your team to ensure you will be able to present. If you have a time conflict (e.g., religious obligation, varsity team involvement, academic conferences) with one of the lecture or lab dates where your attendance is counted toward your participation grade you must notify the instructor beforehand to make possible alternative arrangements.

#### Online Communication Policy

Every attempt will be made to respond to emails within 2 business days but will not be answered during weekends. BME498 must be used at the beginning of the subject line to ensure prompt response to emails.

#### Academic Integrity Message

Plagiarism is taken very seriously and as per the code of behaviour on academic matters: "it is the students' responsibility to know what constitutes an academic offense". As per University of Toronto guidelines: "You need to integrate your acknowledgements into what you're saying. Give the reference as soon as you've mentioned the idea you're using, not just at the end of the paragraph. It's often a good idea to name the authors ("X says" and "Y argues against X,") and then indicate your own stand ("A more inclusive perspective, however, ...")". Specific instructions on bibliography formats will be given in assignment guideline documents but as a general rule; it is not acceptable to rely on Wikipedia or Google rather than library resources. For more information, please see ([www.writing.utoronto.ca/advice/using-sources/how-not-to-plagiarize](http://www.writing.utoronto.ca/advice/using-sources/how-not-to-plagiarize)) for a practical guide and the following links for more information on University of Toronto policies: (<http://academicintegrity.utoronto.ca/>) (<http://www.governingcouncil.utoronto.ca/Assets/Governing+Council+Digital+Assets/Policies/PDF/ppjun011995.pdf>).

#### Submission Policy

If possible please submit written documents in pdf format through the learning management system accessed through the University of Toronto Portal (i.e., Blackboard).

## **10. Additional Course Information**

#### Project budget

Up to \$750/team is provided by IBBME. An itemized budget will need to be approved by the course coordinators before beginning the project. Modifications to this budget will need to be



approved by the client and the Teaching Team as additional funds (up to \$1,000) are available to individual teams. Interested teams will need to write a one-page grant application justifying the need for the additional funds. Your client may be able to provide some resources but you will need to communicate with them directly.

#### Design Studio

**IBBME safety policy requires that all students take part in safety training prior to using the Design Studio.** This has been scheduled for September 13, in two blocks of time to accommodate all students. You must register in advance for either the 10:00 – 11:00 or 11:00 – 12:00 time slots. If students do NOT pass the safety test, they will be given one additional opportunity to rewrite and pass the test. The Design Studio introduction, safety presentation, and quiz should only take 30 minutes.

A teaching assistant will be available every week during practicum time to answer questions or help you with your projects. Students are also welcome to use the Design Studio during “Open Bookable Time”; see <http://www.ibbme.utoronto.ca/facilities/design-studio/calendar/> for availability. Please use the online booking reservation form to ensure that the design studio is available.

#### Teaching Lab

The IBBME Teaching Lab is also reserved for students in BME489 who need access to wet lab facilities. **There will be a mandatory training session for students who need access to the Teaching Lab.** To use this facility, you must contact Lindsey Fiddes in advance.

#### Awards

- John W. Senders (\$1,000)  
“For imaginative and successful application of engineering to the design of a medical device capable in generality of its application to restore normal human function.” This award is decided by the Faculty-wide, Multidisciplinary Capstone Design committee.
- IBBME Director’s Biodesign Award (\$500)  
“To the best BME489/BME498 project.” Decided by the IBBME Director.

#### Bonus Marks

You may choose to provide documentation that could be used as a submission to a relevant student design competition for bonus marks. A maximum of 2% bonus is available if you choose to do this extra work. Please see ‘*Guidelines for Bonus Marks*’ (posted on Blackboard) for more information.