



BME 423: Biomedical Engineering Senior Design

Catalog Description:

Senior design provides, over the course of two semesters, a collaborative design experience with a significant biomedical problem related to human health. The project will often originate with an industrial sponsor or a medical practitioner at a nearby medical facility and will contain a clear implementation objective (i.e. for a medical device). It is a capstone experience that draws extensively on the student's engineering and scientific background and requires independent judgments and actions. The project generally involves a determination of the medical need, a detailed economic analysis of the market potential, physiological considerations, biocompatibility issues, ease of patient use, an engineering analysis of the design, manufacturing considerations and experimentation and/or prototype construction of the device. The faculty advisor, industrial sponsor or biomedical practitioner works closely with the group to ensure that the project meets its goals in a timely way. Leadership and entrepreneurship are nourished throughout all phases of the project. The project goals are met in a stepwise fashion, with each milestone forming a part of a final report with a common structure. Oral and written progress reports are presented to a panel of faculty at specified intervals and at the end of each semester.

Prerequisites:

Prerequisites: Seniors Only and BME 322

Recommended textbook:

Product Design and Development, Karl T. Ulrich and Steven D. Eppinger, 7th Edition

Course Outcomes:

Student Outcome 2: (Design)

- 2.1. Schedule a project in accordance with the industry accepted methods, including the Critical Path Method or a Gantt chart. (Proposal)
- 2.2. Identify the unmet technical, clinical and market needs for a given clinical problem (Proposal)
- 2.3 Identify design constraints in proposed solution of the unmet clinical need

Student Outcome 3: (Communication)

- 3.1. Apply engineering and physiology training and use standard resources to design a solution to a clinical problem (i.e. write a project proposal).
- 3.2. Present your project effectively, including a concise mission statement that explains how the project will save/improve lives and make \$\$\$ (or save costs).

Student Outcome 4: (Ethical and Professional Conduct)

- 4.1. Design a simple and effective "proof of concept" model to address an unmet clinical need in a collaborative manner with medical and/or industry professionals
- 4.2 List examples of where equity and inclusion can be included as a best practices for medical device design.

Student Outcome 7:

7.1. Develop a project strategy that takes these aspects into consideration:

- a. Intellectual Property
- b. FDA/ Regulatory
- c. Resource availability

Topics Covered:

- User-centered design
- Product development process
- Specifications
- Prototyping and testing
- Entrepreneurship
- Safety, reliability, liability
- Regulatory
- Ethics
- Project planning
- Proposal writing

Contact information:

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Office hours: Monday 10:30am to 12:00pm on Zoom or by appointment

TA:

- Section B: John Battikha, jbattikh@stevens.edu
Office hour: Tuesday 2:30pm- 3:30pm Mclean B3

COURSE REQUIREMENTS

All assignments are due at the **beginning of the class**, unless otherwise noted.

Late Policy

- If your assignment is late by less than 24 hours, a 10% deduction will be applied to your grade. For each day an assignment is late, 10% will be deducted. After 5 days, it will not be accepted (grade will be a 0%).

Evaluation

Attendance and Participation	10%
(Including attendance, participation, weekly reports, weekly effectiveness surveys)	
Quizzes	10%
Engineering Notebooks	10%
Proposal presentation	10%
Proposal paper	10%
Final presentation	20%
Final paper	20%
Peer assessment	10%

Weekly progress report (WPR)

Use the template provided. These reports need to be completed each week and submitted via Canvas by **9 AM on Tuesday**. If it is not received by 9:00 AM on Tuesday, it will be considered late (see late policy above).

- ✓ File must be saved as "BME 423_Team name_WPR#1" (update WPR number each time)
- ✓ File must be submitted as a pdf file

Make sure to rotate the author of the progress report each time.

Bi-weekly Effectiveness Survey

Fill out a short survey every two weeks to evaluate your teammates via Canvas. This will be due at 5:00pm on the Friday of that week. It is important that everyone works as a team and contributes to the success of the project.

Engineering Notebook

Each individual must maintain an engineering notebook for each semester. This will outline your individual contribution as well as team progress.

The design team is expected to meet as a group **outside the assigned class time**. Minutes from these meetings must be documented in the team's notebook.

The team's notebook should contain the following:

- Weekly team meeting minutes
- Literature search (including interview notes) and references used
- Gantt Charts
- Design ideas (including sketches of designs)
- Decision matrices
- Specifications and detailed design
- Plans for testing
- Budget
- Novel ideas
- Test Data
- Experimentation (should be repeatable)

Material should be dated and signed by the team member(s) responsible for the document

For team documents, please save the files as the following:

- Name the file as "BME 423_Team name_ Name of assignment"
- Save it as a pdf file

Team budget

Each team has a budget of \$400 for the year. **Any items purchased must be justified and approved by your section instructor.** The team must submit budget proposal before purchase. If additional budget is needed, consult your instructor and course coordinator.

Academic Integrity

Enrollment into the undergraduate class of Stevens Institute of Technology signifies a student's commitment to the Honor System. Accordingly, the provisions of the Stevens Honor System apply to all undergraduate students in coursework and Honor Board proceedings. It is the responsibility of each student to become acquainted with and to uphold the ideals set forth in the Honor System Constitution. More information about the Honor System including the constitution, bylaws, investigative procedures, and the penalty matrix can be found online at <http://web.stevens.edu/honor/>

Learning Accommodations

Stevens Institute of Technology is dedicated to providing appropriate accommodations to students with documented disabilities. The Office of Disability Services (ODS) works with undergraduate and graduate students with learning disabilities, attention deficit-hyperactivity disorders, physical disabilities, sensory impairments, psychiatric disorders, and other such disabilities in order to help students achieve their academic and personal potential. They facilitate equal access to the educational programs and opportunities offered at Stevens and coordinate reasonable accommodations for eligible students. These services are designed to encourage independence and self-advocacy with support from the ODS staff. The ODS staff will facilitate the provision of accommodation on a case-by-case basis.

Inclusivity

Stevens Institute of Technology believes that diversity and inclusiveness are essential to excellence in academic discourse and innovation. In this class, the perspective of people of all races, ethnicities, gender expressions and gender identities, religions, sexual orientations, disabilities, socioeconomic backgrounds, and nationalities will be respected and viewed as a resource and benefit throughout the semester.

You are expected to treat your instructors, mentors, consultants, and all other participants in the course with courtesy and respect. Disrespectful conduct and harassing statements will not be tolerated and may result in disciplinary actions.

Week	Topic	Assignment
Week 2- 9/5, 7	Syllabus, Expectations, Project Announcements	Purchase Engineering Notebook
Week 3- 9/12, 14	Library, Putting together a proposal (Gantt chart)	Due 9/14- Team contract Selection and justification of projects
Week 4- 9/19, 21	Design Constraints and Specifications	Weekly report due Peer assessment (end of week)
Week 5- 9/26, 28	Engineering Analysis, Brainstorming	Quiz on Design Constraints and Specifications Weekly report due
Week 6- 10/3, 5	FDA Regulations	Weekly report due Peer assessment
Week 7- 10/10, 12	In class activities; Prototypes	Due 10/12- Engineering Notebooks Weekly report due
Week 8- 10/17, 19	Planning and Design Schedule	Due 10/17- Proposal and Presentation Weekly report due Peer assessment
Week 9- 10/24, 26	Putting together a Final plan (budget), Intellectual Property	Due 10/26- Peer Evaluation Weekly report due
Week 10- 10/31, 11/2	Final Presentation Guidelines Ethics/ Diversity, Equity and Inclusion, IRB	Weekly report due Peer assessment Please bring in an article on ethics in the medical field. This can relate to your project 11/2
Week 11- 11/7, 9	In class project planning activities, Speaker Tor Alden (Tuesday 11/7)	Weekly report due Quiz on FDA 11/9
Week 12- 11/14, 16	Design Freeze	Due 11/16 Budget Justification Weekly report due Peer assessment
Week 13- 11/21	Happy Thanksgiving	Weekly report due
Week 14- 11/28, 30	Ordering once approved	Quiz on Ethics 11/28 Weekly report due Peer assessment
Week 15- 12/5, 7	Presentations	Due 12/5- Final Presentation

Week 16- 12/12	Presentations	Due 12/12- Final Paper, Peer Evaluation, Engineering Notebooks due
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