Course Syllabus
BME 417/490 – BIOMEDICAL ENGINEERING CAPSTONE DESIGN I & II

Contact Information & Office Hours
See Canvas course website for current contact information.

Course Description:
Throughout your education in Biomedical Engineering, you have learned the processes of Design for medical and biological devices and many of the necessary skills needed to accomplish such design. The purpose of these capstone courses (BME 417 and 490) now is for you to use this knowledge to undertake this process from needs analysis, concept generation, prototyping, validation and verification, design transfer in a framework that is appropriate for medical device development including appropriate knowledge of and use of regulatory requirements, technical standards, ethical expectations, and market forces.

Objectives and Learning Outcomes:
- A primary objective of the BME Capstone Design is for each of you to be competent in acquiring and successfully applying the following capstone design skillsets:
- An ability to identify, formulate, and solve complex engineering problems by applying principles of engineering, science, and mathematics.
- An ability to develop and conduct appropriate experimentation, analyze and interpret data, and use engineering judgment to draw conclusions.
- An ability to apply engineering design to produce solutions that meet specified needs with consideration of public health, safety, and welfare, as well as global, cultural, social, environmental, and economic factors.
- An ability to function effectively on a team whose members together provide leadership, create a collaborative and inclusive environment, establish goals, plan tasks, and meet objectives.
- An ability to communicate effectively with a range of audiences.
- An ability to recognize ethical and professional responsibilities in engineering situations and make informed judgments, which must consider the impact of engineering solutions in global, economic, environmental, and societal contexts.
- An ability to acquire and apply new knowledge as needed, using appropriate learning strategies.

Grading:

Letter	Percentage	Grading
A+	100% - 97%	Exceeds
A	97% - 93%	
A-	93% - 90%	
B+	90% - 87%	Meets-High
B	87% - 83%	
B-	83% - 80%	
C+	80% - 77%	Meets-Low
C	77% - 73%	
C-	73% - 70%	
D+	70% - 67%	Does Not Meet
D	67% - 63%	
D-	63% - 60%	
E	0%	No Submission/Non-responsive

Grades for each assignment (Design Tasks & Action Items) will be based on the rubrics, where the rubric equates a meets expectations grade. The default grading percentage will be the midpoint for each grading range i.e., the Meets-High default is 85%. Within each grading range, the grader's assessment of overall quality of work will determine any modifications to the percentages.

No Submission and Non-responsive submissions will receive 0%. Non-responsive submissions are submissions that contain little, or no content related to the substance of the assignment. Late submissions without contacting the capstone team prior to assignment due date/time will be considered No Submission and receive 0%. Please pay careful attention to the due dates and times of assignments and give yourself a time buffer to submit assignments through Canvas. Double check that the assignment was correctly submitted and is readable on the Canvas website.

There are two types of assignments

1) Main Task assignments are assignments that are completed within one module.
2) Ongoing Task assignments are assignments that span and are updated across multiple modules

You/your team have **one week** to resubmit Main Task assignments one time in response to the grader comments to move up one level (Does Not Meet to Meets-Low, Meets-Low to Meets-High). It is not possible to receive an Exceeds on any resubmission. No Submission, which includes late submissions without contacting the capstone team prior to assignment due date/time, and non-responsive submissions are not eligible for resubmission. Resubmission is not available for the assignments from the final module of the semester due to timing constraints from submitting grades to the University. Ongoing assignments are not available for resubmissions.

If you contact the Capstone Teaching Team prior to the due data/time, late submissions of Ongoing Task assignments **may** be eligible for up to 50% credit if turned in prior to next assignment due date for that Ongoing Task. After the next due date/time the assignment will be graded No Submission.

Only three late submissions will be accepted during a semester. Even with contacting the Capstone Teaching Team prior to the due data/time, any late submissions beyond three with be treated as No Submission.

COMMUNICATION IS VITAL AND WE CAN ONLY SUPPORT YOU IF WE HAVE THE REQUIRED INFORMATION.

Grade breakdown

60% Design Tasks (DTs, Modules)
10% Symposium
10% Professionalism
10% Product Development Report (PDR)
10% Binder

Required readings, assignments, examinations

Textbook: Biomedical Engineering Design: A volume in Biomedical Engineering, Joseph Tranquillo, Jay Goldberg, and Robert Allen, Academic Press, Copyright © 2023 Elsevier Inc. https://www.sciencedirect.com/book/9780128164440/biomedical-engineering-design or can navigate to it from https://lib.asu.edu/find-ebooks

Assignments and the itinerary will follow the modules on the course Canvas website. There are no examinations for this course.

Expected student behavior

Students in this class are expected to acknowledge and embrace the FSE student professionalism expectation located at: https://engineering.asu.edu/professionalism/

Use of Generative AI

Generative AI is a technology that can often be useful in helping students learn the theories and concepts in this course. However, unless explicitly allowed by your instructor, the use of generative AI tools to complete any portion of a course assignment or exam will be considered academic dishonesty and a violation of the ASU Academic Integrity Policy. Students confirmed to be engaging in non-allowable use of generative AI will be sanctioned according to the academic integrity policy and FSE sanctioning guidelines.

You must cite or notate your use of any generative AI (AI model used and the prompt), document how you modified the work produced by the AI model, and how verified the work produced by the AI model.

Additionally, if your capstone team has an outside of ASU corporate or clinical partner, your team is required to get the approval of the partner before using generative AI on assignments related to the project. Generative AI systems often use information in the prompts they receive as training data which could be a violation of policy and any Non-Disclosure Agreement.

Academic Integrity
All engineering students are expected to adhere to the ASU Student Honor Code and the ASU academic integrity policy, which can be found at https://provost.asu.edu/academic-integrity/policy). Students are responsible for reviewing this policy and understanding each of the areas in which academic dishonesty can occur. If you have taken this course before, you may not reuse or submit any part of your previous assignments without the express written permission from the instructor.

All student academic integrity violations are reported to the Fulton Schools of Engineering Academic Integrity Office (AIO). Withdrawing from this course will not absolve you of responsibility for an academic integrity violation and any sanctions that are applied. The AIO maintains a record of all violations and has access to academic integrity violations committed in all other ASU college/schools.

Specific rules for this class are to operate machinery and function in a laboratory environment within safe practice policies as called out for by EH&S mandates for good laboratory practices. Safety training will be given on the first lab day, anyone missing the first day will be required to take a mandatory laboratory and fire safety course scheduled at their own time with ASU EH&S.

Copyright
You must refrain from uploading to this course shell, discussion board, website used by the course instructor or any other course forum, material that is not your own original work, unless you first comply with all applicable copyright laws. Course instructors reserve the right to delete materials from the course shell on the grounds of suspected copyright infringement.

The contents of this course, including lectures and other instructional materials, are copyrighted materials. Students may not share outside the class, including uploading, selling or distributing course content or notes taken during the conduct of the course. Any recording of class sessions by students is prohibited, except as part of an accommodation approved by the Disability Resource Center. (see ACD 304–06, "Commercial Note Taking Services" and ABOR Policy 5-308 F.14 for more information).

Non-disclosure and student-created works
In cases where a capstone student team works on a project with a clinical/industry mentors and sponsors (hereinafter referred to as "Partners"), the Partner may ask students to sign a non-disclosure agreement *in advance of performing any work*. IP is not expected to be developed in these projects, but should the Partner determine it is necessary, the Partner may request students assign IP rights to the Partner or to ASU. It is the responsibility of the Partner to obtain this waiver from each of the Student Participants prior to the start of any work. Any such requirements must be clearly stated in the initial project proposal, and any agreement must be approved by the student(s), the Partner, and the faculty mentor(s) before the project begins. Students are not required to sign any agreement. Any student who is unwilling to agree to a confidentiality and/or intellectual property agreement associated with a given project may request to be assigned to a

different project. Non-compete agreements are not appropriate for an academic experience; students should not be asked to sign such agreements.

Any non-disclosure agreement notwithstanding, the Partner understands that for the students to complete the requirements of the capstone course, the student teams must brief the faculty course instructor(s), course grader(s), instructional assistant (IA), and other relevant parties sufficiently in design reviews, team presentations, final reports, and such, so that they may be graded appropriately on their projects. The Partner understands that students must also give a substantive poster presentation concerning the capstone project to an audience that will not have signed non-disclosure agreements, and that such a presentation will include information about the Partner. The presentation should not, however, contain Confidential Information, as the Partner will work with the students to prevent the inclusion of Confidential Information in the poster presentation and any written materials prepared by the students. Any Confidential Information in the presentation and related written materials must be redacted by the Partner as soon as possible, and no later than three (3) business days prior to the poster presentation submission deadline (TBA). Students are responsible for providing a presentation draft to the Partner for review in a timely manner prior to the deadline. The Partner permits the students to share sufficient information about the project with the public at the semesterly Capstone Symposium Showcase event to fulfill the capstone course requirements, and to discuss the project with any potential employer in a job interview for purposes of seeking employment, provided Confidential Information is not disclosed.

Classroom and on Campus Behavior/Threatening Behavior
Students, faculty, staff, and other individuals do not have an unqualified right of access to university grounds, property, or services (see SSM 104-02). Interfering with the peaceful conduct of university-related business or activities or remaining on campus grounds after a request to leave may be considered a crime. All incidents and allegations of violent or threatening conduct by an ASU student (whether on- or off-campus) must be reported to the ASU Police Department (ASU PD) and the Office of the Dean of Students.

Absence & Make-Up Policies
Students are expected to attend all classes and labs, and the facilitators will be taking attendance for each team during lab. If you will be absent, please notify the capstone team as soon as possible, or withing 24 hours at the latest.

COMMUNICATION IS KEY. EARLY AND CONSISTENT COMMUNICATION WILL RESULT IN THE BEST OUTCOME FOR EVERYONE.

Accommodations will be made for religious observances provided that students notify the instructor at the beginning of the semester concerning those dates. Students who expect to miss class due to officially university-sanctioned activities should inform the instructor early in the semester. Accommodations will also be made for absences due to military line of duty activities. Alternative arrangements will generally be made for any examinations and other graded in-class work affected by such absences. The preceding policies are based on ACD 304–04,

“Accommodation for Religious Practices” and ACD 304–02, “Missed Classes Due to University-Sanctioned Activities", ACD 304-11, "Missed Class Due to Military Line of Duty Activities," and SSM 201-18, "Accommodating Active Duty Military".

Disability Accommodations
Suitable accommodations are made for students having disabilities. Students needing accommodation must register with the ASU Student Accessibility and Inclusive Learning Services (SAILS) office and provide documentation of that registration to the instructor. Students should communicate the need for an accommodation in enough time for it to be properly arranged. See ACD 304-08 Classroom and Testing Accommodations for Students with Disabilities.

SAILS accommodations are not a blanket ability to submit late assignments. Once SAILS has determined the need for accommodations, it is the student’s responsibility to write up an Accommodations Plan and have it approved by SAILS and the Capstone Teaching Team. Until the Accommodations Plan is approved, students are subject to the standard class policies.

Harassment and Sexual Discrimination
Arizona State University is committed to providing an environment free of discrimination, harassment, or retaliation for the entire university community, including all students, faculty members, staff employees, and guests. ASU expressly prohibits discrimination, harassment, and retaliation by employees, students, contractors, or agents of the university based on any protected status: race, color, religion, sex, national origin, age, disability, veteran status, sexual orientation, gender identity, and genetic information.

Title IX is a federal law that provides that no person be excluded on the basis of sex from participation in, be denied benefits of, or be subjected to discrimination under any education program or activity. Both Title IX and university policy make clear that sexual violence and harassment based on sex is prohibited. An individual who believes they have been subjected to sexual violence or harassed on the basis of sex can seek support, including counseling and academic support, from the university. If you or someone you know has been harassed on the basis of sex or sexually assaulted, you can find information and resources at https://sexualviolenceprevention.asu.edu/faqs.

As mandated reporters, Professors are obligated to report any information they become aware of regarding alleged acts of sexual discrimination, including sexual violence and dating violence. ASU Counseling Services, https://eoss.asu.edu/counseling is available if you wish to discuss any concerns confidentially and privately. ASU online students may access 360 Life Services, https://goto.asuonline.asu.edu/success/online-resources.html.

Photo requirement
Arizona State University requires each enrolled student and university employee to have on file with ASU a current photo that meets ASU's requirements (your "Photo"). ASU uses your Photo to identify you, as necessary, to provide you educational and related services as an enrolled student at ASU. If you do not have an acceptable Photo on file with ASU, or if you do not consent to the use of your

photo, access to ASU resources, including access to course material or grades (online or in person) may be negatively affected, withheld or denied.

Human Research Policies and Procedures

It is the policy of Arizona State University that no research activity involving human subjects shall be undertaken unless the University Human Subjects Institutional Review Board (IRB) has reviewed and approved such activity. ASU is guided by the ethical principles regarding all research involving humans as subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled Ethical Principles and Guidelines for the Protection of Human Subjects of Research. In addition, the requirements set forth in Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46) are upheld. ASU has chosen to require that all research covered by its assurance be conducted in accordance with the requirements of 45 CFR 46. Students registered for BME Capstone Design (417 or 490) who will use human subjects during the course of their design project must work with their faculty 'mentor' to submit a human subjects protocol to the ASU IRB. This protocol must be approved *prior* to any use of human subjects. The ASU Human Research Policies and Procedures Manual describes the regulations that apply to the use of human subjects in research, as well as how to submit a protocol to the ASU IRB.

Animal Care and Use Policies and Procedures

All Arizona State University animal facilities and programs are operated in accordance with the requirements and recommendations in the Public Health Service Guide for the Care and Use of Laboratory Animals, the Animal Welfare Act, and other applicable federal, state and local laws, regulations, and institutional policies. These requirements and regulations are described in the Syllabus of Humane Practice of Animal Care and Use which is published and distributed by the Central Laboratory Animal Care Program of ASU. Students registered for BME Capstone Design (417 or 490) who will use laboratory animals during the course of their design project must work with their faculty 'mentor' to submit an animal care and use protocol to the ASU Institutional Animal Care and Use Committee (IACUC). This protocol must be approved by the IACUC *prior* to any use of animals.

Syllabus Changes

Any information in this syllabus (other than grading and absence policies) may be subject to change with reasonable advance notice.