BMED 4602 Syllabus

Capstone Design, Section A, 3 Credits
Fall 2026

Instructor Information

CRN	Section	Instructors*	Email
26816	A		
26883	A01	Dr. Chris Revell	chris.revell@bme.gatech.edu
26901	A02		
26902	A03	Prof. Saylan Lukas	saylan.lukas@bme.gatech.edu
26903	A04		
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29469	A06		

* - Each section will have a primary instructor who will serve as the lead instructor for students in that section.

Office Hours are available to book by appointment with instructor or teaching assistant via email or online booking request.

General Course Information

Description

The BME Capstone Senior Design course is the culmination of a BME student's undergraduate education. The course combines a student's technical and design knowledge and partners student teams with an unmet clinical need provided by a Project Sponsor (Clinical or Industry representative).

The course provides student teams with hands-on experience with project planning, concept and prototype development, risk analysis, design verification testing, FDA Quality Systems Regulations, design controls and regulatory pathways for commercialization of medical devices. Additionally, requirements of business functions such as marketing, sales, manufacturing, finance, intellectual property and their effects on the product development process are integrated into lectures, class presentations, projects and reports.

The course also prepares students for future team activities through a project design experience incorporating relevant biomedical and engineering practices, constraints, timelines, deliverables and professional oral and written communications. To prepare students for the medical device or biopharma industry, students will get exposed to the Product Development Process and multiple elements of a Design History File (DHF).

Students form project teams within the design studio section they are registered and work to create a solution for an existing unmet clinical need. Project topics are suggested by a wide variety of healthcare professionals such as physicians, nurses, emergency technicians, medical device industry personnel and academic researchers. Projects may also be suggested by students and submitted for instructor approval. Each project will have a professional healthcare, clinical, industry or academic advisor. Teamwork skills, time management, attention to detail, active participation, oral and written technical communications are key factors for success in this course.

Course Learning Outcomes

Upon completion of this course, you should be able to:

- Perform customer discovery to understand a potential unmet clinical need, including Voice of Customer research, market research and translation of key customer insights into User Needs and Design Requirements
- Design and develop engineering solutions that address User Needs and perform regulatory, financial and patentability assessments of these solutions to understand its potential commercial viability
- Create a final functional prototype solution to an unmet clinical need and evaluate the final design against critical Design Requirements
- Communicate (via documentation and oral presentation) critical project information to both technical and non-technical audiences

Required Course Materials

There are no required course materials for this course.

Grading Policy

Guidelines and rubrics will be provided for all graded assignments.

The Capstone Design course is team-based, whereby approximately 70% of the course assignments are submitted and graded at the **team level** and approximately 30% of the assignments are submitted and graded **individually**. The expectation for the course is that the team members contribute equally toward team-based assignments. In the event that one or more team members do not meet the expected contributions, the instructors (at their discretion) may assign different grades to the team members. The following table displays a list of course assignments and the percentage of the final grade attributed to each assignment.

BMED 4602 Grading	Assignment Type	%
DHF1 Presentation	50% Team / 50% Individual	5%
DHF1 Submission	Team	10%
DHF2 Presentation	50% Team / 50% Individual	5%
DHF2 Submission (two memos)	Team	10%
Final DHF Submission	Team	15%
Final Poster & Presentation	Team	10%
Prototype Evolution Deliverables	Team	5%
Final Prototype/Design Solution	Team	10%
Electronic Notebook	Individual	5%
Studio Engagement and Preparation	Individual	10%
Weekly Updates	Team	4%
Invention Disclosure	Team	1%
Professionalism	Individual	10%
Total	70% Team / 30% Individual	100%

Final grading will be based on the Georgia Institute of Technology system (A, B, C, D, F). No plus or minuses will be applied to the final grade. Individual course deliverables will receive number grades.

A (100-90)	B (89-80)	C (79-70)	D (69-60)	F (59->)
Exceptional	Proficient	Acceptable	Novice	Failure

Disputing Grades: Starting at the time a grade is released, a student has seven (7) calendar days to dispute your grade in writing with your instructor. Any disputes after seven (7) calendar days will not be evaluated.

Description of Graded Components

Design History File Presentations and Submissions: Teams will be developing a Design History File throughout the semester that houses the product development content created for their Senior Design project. At three different times throughout the semester, teams are expected to present the information within the DHF to a technical audience as well as submit written evidence, either in the form of a report or memos, detailing the information in the DHF. Specific deliverable guidelines and rubrics will be provided for each assignment. There will be some elements that will need to be updated as part of each submission and there will be other elements that will be evaluated only once. The deadline for each DHF submission is strict and will be communicated by the instructional staff at the start of each semester.

Capstone Final Prototype/Design Solution: The Capstone Design Course culminates in each team creating a functional solution/prototype that addresses the unmet clinical need your team has been working on throughout the course. Progress towards completion of the prototype will be assessed along the way through deliverables/assignments in the final third of the semester. The final prototype will be assessed according to its creativity, functionality,

and its ability to meet user needs and design requirements. The project team will present the proposed solution at the Georgia Tech Capstone EXPO at the end of the semester.

Electronic Notebooks: Each student is required to maintain an up-to-date electronic, project notebook to document their work on the project. All communications, meetings, research and project work should be documented in the student's project notebook on an ongoing basis. Additionally, the lectures will at times contain activities to be performed by students and documented in their project notebook. Students are expected to follow the provided electronic notebook guideline and rubric. There will be three random and unannounced notebook checks for grading.

Studio Engagement and Preparation:

- Each student is expected to come to class prepared for the week's activities.
- Preparation includes having watched the digital material before class and coming to class able to discuss the digital content and prepared questions related to the lecture content.
- All students should be able to discuss the status of the team's project, including achievements in the past week, possible roadblocks and hurdles the team is facing and next steps for the project.
- Students will be assessed individually on engagement and preparation on a weekly basis and these grades will be combined for a final engagement and preparation grade at the end of the semester.

Weekly Updates: Each group is required to submit a weekly update to your Project Sponsor and TA that contains a one-page summary slide and a one-page Gantt Chart in a combined PDF document. The purpose of these updates is to show both assigned report development AND device development occurring throughout the semester.

Professionalism: This course aims to introduce students to the professional expectations that come with post-graduation career opportunities, including industry, graduate and/or medical school. The professionalism portion of a student's grade will be assessed three times throughout the semester and will include evaluations of team contribution, conflict management, respect, interpersonal dynamics, general professional behaviors and studio attendance.

- We treat studio attendance and performance as though it is a professional work environment. As such, being late for studio, or not attending (without excused absence) is not tolerated.
- ***Tardiness Penalty:*** One point is deducted for each minute you arrive late or leave unexcused from studio, without reasonable justification and notifying your instructor and TA. By way of example, 75 minutes late, without a valid excuse, results in 75 points dropped from Professionalism. 100 minutes, or missing studio entirely results in zero (0) for Professionalism grade for that grade period, representing a third of a letter grade loss.
- The final professionalism grade will be an average of the three professionalism assessments performed throughout the semester. However, the instructor may

amend the final professionalism grade in the event that a student's behavior and contributions positively or negatively impact the performance of the team.

USG Required Course Policies

Attendance and/or Participation

Course Structure: The BMED Capstone Design course is structured with **weekly asynchronous lectures** posted on Canvas and **weekly in-person, problem-based learning experiences**. Students are expected to attend classes, actively participate in team meetings and contribute work to meet milestones for projects and course deliverables in a timely and professional manner. Each student is expected to dedicate **at least 5 hours per week** (80 hours per semester) outside class time toward meeting project goals and course requirements.

Asynchronous Lectures:

- Student viewing of all digital education recordings is expected and required. The weekly topics focus on device engineering and product development as typically practiced in the medical device industry including defining users and their requirements, functional requirements, developing and evaluating concepts for solutions, project planning methods, human factors and ergonomics, communications and engineering ethics. The **weekly education** will be delivered asynchronously via video link posted in your Canvas section.
- **There will NOT BE in-person lectures.**
- This digital education content may contain questions throughout to evaluate student knowledge and the instructors will be reviewing results of these questions to gauge student learning. You will not be graded on the correctness of your answers.
- In addition to videos prepared by the instructors, additional resources will also be provided. These will include YouTube videos, podcasts, and other resources. It is expected that all students will come prepared for class each week having reviewed the content and prepared to ask questions.

Studio:

- Students will meet **weekly in person** with their instructor and team in a problem-based learning environment where they will work together on their design project as well as seek advice and guidance on their work effort.
- As described in the Professionalism section above, studio **attendance is mandatory**. As such, being late or not attending (without an excused absence) will not be tolerated.
- Studio sections will held in the BME Design Garden, which is located under the Veterans Resources Center between the Ford Environmental Sciences and Technology (ES&T) building and Molecular Sciences and Technology (MoSE) building

Academic Integrity

Georgia Tech aims to cultivate a community based on trust, academic integrity, and honor. Students are expected to act according to the highest ethical standards. Review Georgia Tech's Honor Code and the Student Code of Conduct.

Any student suspected of cheating or plagiarism on a quiz, exam, or assignment will be reported to the Office of Student Integrity, who will investigate the incident and identify the appropriate penalty for violations.

Unauthorized use of any previous semester coursework is prohibited in this course (i.e., Word). Using these materials will be considered a direct violation of academic policy and will be dealt with according to the GT Academic Honor Code.

Core IMPACTS

Not applicable.

Additional Georgia Tech Required Policies

Accommodations for Students with Disabilities

If you are a student with learning needs that require special accommodation, contact the Office of Disability Services (404-894-2563) as soon as possible to make an appointment to discuss your special needs and to obtain an accommodations letter. Please also e-mail your instructor as soon as possible in order to set up a time to discuss your learning needs.

If you are a student with learning needs that require special accommodation, contact the Office of Disability Services (404-894-2563) as soon as possible to make an appointment to discuss your special needs and to obtain an accommodations letter. It is the students' responsibility to proactively discuss this with the instructors. Please also e-mail your instructor as soon as possible in order to set up a time to discuss your learning needs. Students who experience hardships for any number of reasons that interfere with their ability to attend class, meet course expectations, and collaborate with their teams need to receive approval from the Dean of Students office.

Student-Faculty Expectations Agreement

At Georgia Tech, we believe that it is important to strive for an atmosphere of mutual respect, acknowledgement, and responsibility between faculty members and the student body. The Student-Faculty Expectations articulate some basic expectations that you can have of your instructors and that we have of you. In the end, simple respect for knowledge, hard work, and cordial interactions will help build the environment we seek. Therefore, we encourage you to remain committed to the ideals of Georgia Tech while in this class.

Course Expectations, Policies, and Resources

Pre- &/or Co-Requisites

The following two courses are **pre-requisites** for BMED 4602: **BMED 2310** (Intro to BME Design) and **BMED 3410** (Introduction to Biomechanics).

Additionally, **BMED 3110** (Quantitative Engineering Physiology Lab I) is a **pre-requisite with concurrency requirement** (must be taken prior to or at the same time) for BMED 4602.

Collaboration, Group Work, and Use of Generative AI

We recognize that AI, and in particular Generative AI, is transforming all aspects of biomedical engineering and want to encourage design teams to use AI responsibly.

- We want you to learn the engineering design process and be able to communicate this; we do not want to read completely AI-generated text, data, designs, or figures, which will be considered plagiarism. The content that your team produces can use AI as an aid, not as a sole creator.
- Examples of acceptable AI usage include, but are not limited to, general background research, competitive product and patent landscape search, brainstorming, and general writing improvement.
- Transparency is important; all written assignments will require an AI attestation, where each individual will need to clearly state how they leveraged AI in the preparation of the assignment. The AI attestation will not contribute towards your overall word count, so we expect a thorough explanation of how AI was used. If AI is used, links to the full threads must be provided.
- All written assignments must be generated in a digital document that illustrates every addition and change made by each team member.
- All written documents will be analyzed by TurnItIn, the GT AI/plagiarism checker. You will have immediate access to the report when you submit your assignment. Please carefully review this before submission. Any suspected instance of dishonesty will be reported to the Office of Student Integrity.
- **If you have any questions about the appropriate use of AI please ask your TA and/or Instructor prior to submission.**

Extensions, Late Assignments, & Re-Scheduled/Missed Exams

Late Penalty: If an assignment is submitted late, but on the same day as the due date, 10% will be deducted from the assignment grade. After the due date, 20% per day will be deducted from the assignment grade.

Institute-Approved Absences and Religious Observances

The attendance requirements for this course are described above and are in accordance with the Georgia Tech Attendance Policy.

Students who are absent from Studio due to an Institute-approved absence should notify their Instructor and Teaching Assistant by the end of the class meeting immediately following **receipt** of their approval notice (per the Institute policy).

Students who are expected to be absent from Studio due to participation in a particular religious observance must inform their Instructor and Teaching Assistant of the upcoming absence, in writing, within the **first two weeks of class** (per the Institute policy).

Students who are absent from Studio due to an excused absence should work with their Instructor and Teaching Assistant **before** the expected absence to establish reasonable deadlines and/or make-up materials for missed work.

Inclement Weather and Digital Learning Days

In the event of a weather-related event on campus, this course will follow guidance from the Institute and the Office of the Provost. Once a decision regarding campus operations has been made by the Institute, the instructors will contact all students via Canvas about plans for a digital learning day (preferred) or cancelling class.

Campus Resources for Students

Undergraduate Student Academic Success Resources

A list of resources for undergraduate students' academic success and information about advising can be found at Success at Tech.

Student Well-Being

At Georgia Tech, we are concerned about your overall physical, social, and mental well-being. A comprehensive list of wellness related resources has been compiled and maintained by the Office of the Vice President for Student Engagement and Well-being (student-resource-guide (gatech.edu)).