BMED 4823 Syllabus

Fundamentals of Medical Device Development (3 credit hours)
Summer 2026

Instructor Information

Instructor	**Email**
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Location, teaching assistant contact info, and office hours will be provided on Canvas once finalized. The syllabus, course schedule, assignments, and reference materials will be posted on Canvas and are subject to modification during the semester. Changes will be announced and posted; students are responsible for keeping up-to-date on all course requirements.

Prerequisites

BMED 2310

General Course Information

Description

Georgia Tech BME undergraduate students develop excellent analytical and process skills while taking a broad range of technically focused biomedical engineering classes. BME students, whether planning to enter industry, graduate school, or medical school, can benefit from having the knowledge and experience of combining technical and business aspects of design and development processes used by the medical device industry to create and commercialize biomedical/surgical products.

The goal of Fundamentals of Medical Device Development (FMDD) course is to continue to build on technical engineering skills while providing student teams with an overview and hands-on experience of critical aspects of developing a new medical device that are specific to careers in industry, including:

1. Business and economic considerations for product choice
2. Regulatory and clinical strategies
3. Quality Management Systems Regulations, including Design Control and Review
4. Risk Management
5. Quality assurance
6. Design for manufacturing & assembly

In the first lecture, students will form teams and will be given an actual medical device. Each team will investigate and reverse-engineer their device to successfully complete course deliverables. The FMDD course includes daily lectures, student-team presentations, and project-based learning experiences. Students are required to attend classes, actively participate in team meetings, and contribute to 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 for the fall section and 10 hours per week for the summer section outside class time toward meeting project goals and course requirements.

Course Announcements: The primary communication method for all course-wide announcements and official course communication will be via Canvas.

Course Learning Outcomes

The FMDD course is designed to provide practical experience in key aspects of medical device development and prepare students for employment by providing a real-world experience of the commercial R&D processes. Upon successful completion of this course, you will be able to:

- demonstrate knowledge of relevant governmental regulations and all phases of the medical device product development process from concept ideation through transfer to manufacturing.
- conduct various research and development (R&D) functions such as tolerance/stack-up assessments (TSA), design verification/validation (V&V) test protocol creation.
- conduct risk management activities including hazard analysis, Failure Mode Effects Analyses (FMEA), and risk-benefit analysis.
- generate computer aided design (CAD) models, assemblies, and drawings utilizing SolidWorks software.

The final project of the course is the Design Challenge, where each team designs a component or system to meet specific engineering constraints. Each team must apply course material to design the part from scratch using SolidWorks drawings and simulations, as well as any other relevant engineering methods necessary to develop the design to produce a credible solution representing a clear value for the intended use. Teams will propose a solution for different material and manufacturing processes and cost constraints, as if they are competing for a client at an engineering consulting firm. Each team will give a business pitch for their final product.

Required Course Materials

There is no required reading for this course.

Grading Policy:

Description of Graded Components

Guidelines and rubrics will be provided for all graded assignments.

Disputing Grades: Starting at the time your grade is released to you, you have 7 days to dispute your grade in writing with your instructor. Any disputes after 7 days will not be evaluated.

Team Project: Project topics are governed by the course schedule of topics and cover the full spectrum of activities typically found in a commercial medical device R&D team. Students will form teams of three (3) or four (4) students. Teams will remain intact for the duration of the class (new teams will NOT be formed for each new project). Teamwork skills, active participation, oral and written technical communications are key factors for success in this course. Teams will be required to deliver two (2) formal presentations and two (2) reports.

Team Briefs: Teams will submit three (3) short (1-2 page) briefs regarding relevant course content pertaining to their specific assigned medical device product.

Individual stand-up presentations: Each student will be required to make two (2) presentations (3-5 minutes in length).

CAD Models & Drawings: Each student will be required to make CAD Models, Assemblies, Drawings and complete a Tolerance Stack-up Analysis for their specific assigned medical device product.

Self-reflections: Each student will be required to submit a weekly self-reflection regarding their experience abroad, relevant course content, and their personal development plan.

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

Content	*BMED 4823 Grading 60% Team and 40% Individual*	*Indiv/ Team*	*%*
Assigned Med Device	***Team Briefs (qty=3)***	***T***	***15***
Assigned Med Device	***Team presentation #1 Product characterization***	***T***	***10***
Assigned Med Device	***Product Characterization Report***	***T***	***10***
Assigned Med Device	***Final Product Report***	***T***	***15***
Assigned Med Device	***Final Presentation***	***T***	***10***
Skill Building	***CAD Models & Drawings***	***I***	***5***
Skill Building	***Tolerance Stack-up analysis***	***I***	***5***
Skill Building	***Individual stand-up presentations (qty=2)***	***I***	***10***
Skill Building	***Self reflections (5 total)***	***I***	***10***
Skill Building	***Professionalism/Participation/Attendance***	***I***	***10***
	Total		***100***

The expectation for the course is that the team members contribute equally toward 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 individual team members.

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 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 participation as though it is a professional work environment. As such, being late for studio, or not attending (without excused absence) is not tolerated. It is expected that students participate in group activities and updates with the instructor.

Tardiness Penalty: One point is deducted for each minute you arrive late or leave unexcused from class, without reasonable justification and notifying your instructor and TA prior to the start of class. By way of example, 5 minutes late, without a valid excuse, results in 5 points dropped from Professionalism. 100 minutes, or missing class entirely results in zero (0) for Professionalism grade for that grade period, representing a full letter grade loss. 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 Participation

Student attendance at all class sessions is required. Daily (4 days/week) class lectures will focus on the engineering design process as typically practiced in the medical device industry. Lectures include significant references to current practices in biomedical engineering development, web-based resources and industry examples.

You can miss up to 1 class for any reason with no penalty. An institute-approved excuse note for any additional absences can be requested here: https://new.iaa.gatech.edu/info/

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.

Collaboration, Group Work, and Use of Generative AI

Students are encouraged to discuss course problems and concepts with classmates as part of the learning process. However, any written work that is submitted must reflect a student's own understanding and original writing. When outside resources are consulted, including textbooks, scientific literature, or generative AI tools such as Copilot or ChatGPT, students should use them as learning supports rather than sources to copy from directly. As with discussions with classmates, these tools can help clarify ideas, but students remain responsible for the accuracy, relevance, and integrity of all work they submit. 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. **If you have any questions about the appropriate use of AI please ask your TA and/or Instructor prior to submission.**

Group projects are designed to support collaborative learning. Students are expected to participate actively and contribute meaningfully to their group's work. Credit for these activities reflects both the quality of the work and each student's engagement in the collaborative process.

All course activities are governed by the university's academic integrity policies. Cases of plagiarism or academic misconduct will be addressed according to the procedures of the Office of Student Integrity.

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.

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. It is the students' responsibility to proactively discuss this with the instructors. Please also e-mail me 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 me and that I have of you. In the end, simple respect for knowledge, hard work, and cordial interactions will help build the environment we seek. Therefore, I encourage you to remain committed to the ideals of Georgia Tech while in this class.

Extensions & Late Assignments

Please contact your instructor AS SOON AS POSSIBLE if you cannot complete an assignment or take an exam on time. We are willing to make reasonable accommodations, especially for things such as approved institute activities, emergencies, or religious observances. The key here is that you need to communicate! Without any communication and/or approval, assignments will be accepted up to 48 hours after their due date, but 10% of the points will be deducted each calendar day. Assignments more than 48 hours late without communication get a 0. Extensions can only be granted for up to one week, and deliverable extensions may be limited by the course schedule.

Inclement Weather and Digital Learning Days

In case of inclement weather, the instructor may declare a Digital Learning Day. Any lectures on these days would move online during class time.

Resources for Students

Undergraduate Student Academic Success Resources

Student mental (and physical) health is very important to us. If you find yourself in a situation and are not sure how you might get some help, our door (or virtual door) is open. Asking for help is a strength, not a weakness. Georgia Tech has many resources that may be useful, so please ask if you'd like to know more. The instructional team understands the pressures of succeeding at undergraduate engineering and knows that even seemingly small problems can take their toll on your ability to do your best. At least one of our Atlanta-based faculty members is SafeZone trained to support LGBTQIA+ students and we are happy to use a name for you other than the one displayed on Canvas. A list of resources for undergraduate students' academic success and information about advising can be found at Success at Tech. This includes supplemental review (PLUS) sessions, and one-on-one appointments.

Student Wellness Resources

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)
More resources on supporting student well-being on the syllabus and beyond are available through the Learning Well Initiative.