

**BMED 4823 Fundamentals of Medical Device Development**

Instructors/ Martin C. Jacobson James B. Stubbs, Ph.D

Contact Info: (MCJ) - [marty@gatech.edu](mailto:marty@gatech.edu) (JBS) - [stubbs@gatech.edu](mailto:stubbs@gatech.edu)

Office Hours: Open Door and By Appointment (email request)

TA: Elisabeth Stayduhar ([estayduhar3@gatech.edu](mailto:estayduhar3@gatech.edu))

Prerequisites: BMED 2310 prerequisite

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

The Fundamentals of Medical Device Development (FMDD) course provides student teams with an overview and hands-on experience with critical aspects of developing a new medical device;

1. Business and economic considerations for product choice (competitive landscape, market size estimation, product pricing/costs),
2. Regulatory, clinical and reimbursement strategies
3. Intellectual property assessment & creation
4. Quality Management Systems, including Design Control and Review
5. Risk Management
6. Quality assurance, Inspection and Metrology
7. Design for manufacturing & assembly (stack up and tolerances, GD&T, material properties, optimization)

The FMDD course includes daily lectures, weekly student-team presentations and project-based learning experiences. Students are expected to attend classes, actively participate in team meetings and contribute in work to meet milestones for projects and course deliverables in a timely and professional manner. Each student is expected to dedicate at least 10 hours per week (summer section only) outside class time toward meeting project goals and course requirements.

***Course Objectives:*** To provide a detailed overview of the medical device development process starting from concept ideation through all phases of development to point of transfer to manufacturing (ready for commercialization). Students will receive didactic overviews of the critical aspects of product choice, development tasks, business decision-making, value creation and the engineering activities necessary to produce a product in a regulated industry. Additionally, students will conduct various research and development (R&D) functions such as Failure Mode Effects analyses, tolerance/stack-up assessments and verification/validation test protocol creation. The FMDD course is designed to provide a 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.

***Classes*:** 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. Over the 5 weeks of classes, there will be 7 projects assigned. Information presented in class along with techniques and processes described in the text should be used the project work and deliverables.

***Projects:*** 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 four (4) students. (Teams of three (3) may be formed with instructor permission.) 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.

**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.

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

**Course special notes**:

* The syllabus, course assignments and reference materials will be posted on T-Square 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.
* Plagiarism and dishonesty are violations of the Student Honor Code. In fairness to the honest majority, **ALL** incidents of suspected academic misconduct will be reported to the Office of the Dean of Students. References of work of others used in projects and reports require proper reference citations. Ref: www.honor.gatech.edu, [www.deanofstudents.gatech.edu/codeofconduct](http://www.deanofstudents.gatech.edu/codeofconduct)
* Students declaring special needs must registered with the ADAPTS office (adapts.gatech.edu). Please inform the instructor by the second day of class if you register.

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| BMED 4823 Grading50% Team and 50% Individual Performance | % | Due  Date |
| Project 1: Market Size | 10% | 5/23/18 |
| Project 2: Reimbursement and CPT Codes | 10% | 5/30/18 |
| Project 3: Quality & Design Testing | 10% | 6/06/18 |
| Project 4: Failure Modes Effects Analyses | 10% | 6/11/18 |
| GD&T Exercise | 5% | 6/14/18 |
| Project 5: Stack Up/Metrology Exercise | 5% | 6/14/18 |
| SolidWorks Topology Development Exercise | 5% | 6/18/2018 |
| Project 6: Manufacturing Methods | 10% | 6/18/18 |
| Project 7: IP – File Wrapper and WO Claims | 10% | 6/19/18 |
| Irish Medical Device Industry Tours | 5% |  |
| Professionalism/Attendance | 10% |  |
| Final Presentation | 10% | 6/21/18 |
| Total | 100% |  |