

BMED 6509 Syllabus (Masters Project II)

Section A, 3 credits, Tuesday, Thursday: 11.00 -12.15 pm, Whitaker 209

Instructor Information

Instructor
Michael Fisher

Email
michael.fisher@bme.gatech.edu

Office Hours & Location
<https://calendly.com/mfisher36>

Teaching Assistant(s)
N/A

Email
N/A

Office Hours & Location
N/A

General Information

Description

This course will continue development of the proof of concept activities initiated in BMED 6508. The goal is to complete the bench-to-bedside pre-clinical, product development activities for the clinical problem identified in BMED 6501.

Pre- &/or Co-Requisites

Completion of BMED 6508 in Spring and BMED 6501 in Fall.

Course Goals and Learning Outcomes

The goal of this course is to enable the development of a product that addresses an unmet clinical need, Each team identified an unmet clinical need in BMED 6501 and refined that need into a project in BMED 6508. Like previous courses, BMED 6509 uses real-world product development quality systems, design history file documentation, phase gate reviews, and design reviews to help students learn how to develop medical products. Listed below are the major elements of this course.

1. Completing product development activities per the quality system used throughout the MBID program.
2. Prototype, build, and test solutions to the unmet clinical need.
3. Collect and analyze test data for each prototype or system being evaluated.
4. Finalize design history file documentation for the Final Phase Gate Review.
5. Present the Final Phase Gate Presentation to address the unmet clinical need.

Course Requirements & Grading

Description of Major Graded Components:

The principle deliverables for this course are the following:

- A. Complete Phase 2 phase gate activities per the MBID quality system (SOP-0006)
- B. Development of prototypes capable of being tested with a goal to evaluate at least three design input requirements.
- C. Data analysis and reporting of data similar to what is expected of a verification report for a regulated medical device.

- D. Refinement and completion of required design history file documentation per the MBID quality system for Phase 2 Phase Gate Review.
- E. Final presentation of each team project to the MBID program and faculty.

<u>Graded Components</u>	<u>Weight (Percentage, points, etc)</u>
Prototype Development	30%
Prototype Testing and Report	30%
Final Design History Files	10%
Final Presentation	20%
Professional Attributes	10%

Description of Graded Components

Prototype Development: Medical product development is comprehensive and expensive. This course aims to develop a prototype medical device that is able to be tested. Every prototype must have a purpose, design plan, and evaluation strategy. In many cases, the prototype represents a sub-system or feature of the finished device. Often, the testing involves a study concerning a critical or essential design input requirement. Developing a good test method is as important as developing the prototype.

<u>Grading Rubric:</u>	<u>Percent of Graded Component</u>
Prototype strategy was documented and followed	10%
Prototype models critical features of the device's intended use	50%
Prototype has a traceable design	10%
Prototype is able to be tested	30%

Prototype Testing and Report: A test method must be developed to test a prototype and the data from the test method is used to evaluate the prototype and overall project. The test method is associated with a critical design input requirement. The data generated in the test is used to evaluate both the test method and the prototype. At the end of the testing, a report is generated to describe the test method, the test subject (prototype), and the test data. The report contains a conclusion about the prototype that is based on the data.

<u>Grading Rubric:</u>	<u>Percent of Graded Component</u>
Prototype test protocol(s) created <u>prior</u> to testing	10%
Protocol(s) evaluate at least <u>three</u> critical device functions	30%
Protocol(s) contain <u>specifications</u> and <u>acceptance</u> criteria	20%
Protocol(s) reference data collection procedures and sample sizes	20%
Protocol(s) describe how test data will be reported	20%

Design History Files for Phase 2: Quality Systems SOP-0006 describes the design controls used in the MBID program. The design history files required for Phase 2 of product development are enumerated in the standard operating procedure. All teams must complete the design control requirements for Phase 2 of the product development process, as amended for the MBID academic program. Each design history file document named below will be graded for completeness and quality.

Grading Rubric:	Percent of Graded Component
Assignment/Deliverable	Weight
Product Design Updates (50% of total)	
Design Trace Matrix & Design Requirements (TEM-0012)	25%
Product Architecture & Use Workflow (TEM-0008 per WI-0019)	2%
Human Factors Usability Engineering Plan (TEM-0018 Memo)	3%
Prototype Strategy (TEM-0018 Memo) – This memo describes the prototype strategy that is being executed during the semester. The memo must contain a prospective timeline of activities. This memo will be presented weekly at BMED 6509 classes to track team plan and execution according to the plan. The memo will be revised each week to trace team performance per the plan. Traditional revisions will be tracked in the revision block of the memo.	20%
Manufacturing (10% of total)	
Prototype Design and Manufacturing Memo (TEM-0018) – This memo must describe the prototype that was built and tested. The memo references the specific critical design features that were prototyped, the design of the prototype, the methods used to build the prototype, and the bill of materials used in the prototype (thus establishing traceability of the design, components, and manufacturing methods).	10%
Testing (30% of total)	
Prototype Verification & Validation Plan (TEM-0021)	5%
Test Method Development (TEM-0016 per WI-0006)	5%
Design and Development Test Protocols (TEM-0014)	10%
Design and Development Test Reports (TEM-0015)	10%
Risk Management (10% of total)	
Risk Management Plan and Report Update (TEM-0017)	3%
Risk Assessment: dFMEA (TEM-0025 per WI-0003)	7%

Final Presentation: The final presentation for BMED 6509 includes both Phase 2 Phase Gate review and a wrap-up of the MBID program for each team. The presentation is the capstone experience for MBID students and precedes graduation from the program. This presentation is intended to complete the Phase Gate review process, present the prototype(s) and testing data, and include a description of the next activities required for the product development process.

Grading Rubric:	Percent of Graded Component
Final Phase Gate Review	100%

Professional Attributes: Class participation is a very important part of the MBID program and learning process. Although not explicitly graded, students will be evaluated on the QUALITY of

a student's contributions, insights, and participation in the MBID program. Student Professional Attributes possess one or more of the following properties:

- Augments or spearheads design history file documentation in concert with other team members;
- Offers unique, relevant, perspectives and ideas during class and the team project;
- Contributes to progressing the classroom discussion and team project;
- Builds on the work of others and acts in concert with their team;
- Exhibits elements of a good project leader and project team member as defined in BMED 6505;

Assessment of students' Professional Attributes is used to manage borderline grades. While the Professional Attributes grade is subjective, it will not be random or arbitrary. Students must contribute to the team's success. In addition, classroom attendance and participation is required except for excused absences (contact professor Fisher to be excused for class absences). ([modified from Georgia Tech's Sample Attendance and Participation policies](#))

<u>Grading Rubric:</u>	<u>Percent of Graded Component</u>
Professionalism	100%

Grading Scale

Your final grade will be assigned as a letter grade according to the following scale:

- A 90-100%
- B 80-89%
- C 70-79%
- D 60-69%
- F 0-59%

Extra Credit Opportunities

There is no extra credit for this course.

Course Materials

Course Text

- Biodesign: The Process of Innovating Medical Technologies, Zenios, Makower, Yock, Cambridge University Press, 2010.

Additional Materials/Resources

N/A

Course Website and Other Classroom Management Tools

At scheduled times in the semester, a number of external guest lectures and presentations will be scheduled in the semester from industry leaders, entrepreneurs, alums and clinicians. The topics and dates will be defined during the semester.

Course Expectations & Guidelines

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. For information on Georgia Tech's Academic Honor Code, please visit <http://www.catalog.gatech.edu/policies/honor-code/> or <http://www.catalog.gatech.edu/rules/18/>.

Any student suspected of cheating or plagiarizing 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.

Accommodations for Students with Disabilities

If you have established accommodations with the Offices of Disability Services, please communicate your approved accommodations to me at your earliest convenience so we can discuss your needs in this course. Any accommodations granted will begin after you present the documentation. No retroactive accommodations will be made. Should a new disability be identified during the term, the instructor will work with Disability Services to accommodate your needs from that time forward.

If you have a need but have not yet established accommodations through Disability Services, you should contact Disability Services at 404.894.2563 or dsinfo@gatech.edu or <http://disabilityservices.gatech.edu> (Links to an external site.)Links to an external site. Disability Services offers resources and coordinates reasonable accommodations for students with disabilities and/or temporary health conditions. Reasonable accommodations are established through an interactive process between you, your instructor(s) and Disability Services.

Other accommodations, for example those allowed under the ADA for documented conditions, might be granted in the class if they do not interfere with the normal conduct of the class, such as the posing of daily questions and quick provision of feedback, or if they do not require exemption from a crucial element of the class such as attendance, participation in a team, or making presentations.

Attendance and/or Participation

Please complete any required reading, writing, viewing, listening, problem-solving, and evaluation assigned for a meeting *before* the meeting takes place so that we may use meeting time for activities most appropriate for being in the same place at the same time.

Class participation also includes participation in guest lectures and problem discussions.

Work Ethic & Class Room Etiquette

- This is a professional Master's Program, calling for Professionalism in all aspects.
- Attendance - Arrive on time. Late arrival will be part of your class participation and you will receive a deduction because random arrivals and exits are disrespectful and distracting.
- No leaving the classroom once class starts (unless needed bathroom break).
- No talking among classmates during class. Talking and other disruptive behaviors are not permitted while classes are in session.

- Food/eating is not permitted during class time.
- Professional attire when visiting off campus sites (including Grady rotations).
- All reports must be turned in on time per the deadlines mentioned in class.

Collaboration & Group Work

Students will work in teams assigned by the program. Each student is expected to pull their weight in team projects.

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

Institute-approved absences for participation and for illness will be accommodated. Otherwise, there is no early or make up work for any assignment or activity of the class. Late work, if accepted, must be late because of significant events beyond the student's control such as death in the immediately family or an emergency medical procedure. Any late work accepted may incur a penalty.

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. See <http://www.catalog.gatech.edu/rules/22/> for an articulation of 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.

Student Use of Mobile Devices in the Classroom

Students are to turn off cell phones during class. All laptops, iPads, Kindles, and other electronic devices etc. must be turned off during class. (if you feel you have an emergency situation that requires your phone to be on vibrate, then please clear this with the professor before class starts). You might be dismissed from class if you are using an electronic device during class time for a purpose not directly related to work assigned during that class.

During class, any disturbance or use of any electronic devices for any purpose, including talking, texting, web surfing, etc. is forbidden.