

BMED 6507 Syllabus – Medical Device Regulatory Requirements

Section A, 3 credits, Tuesday / Thursday 3:30-5:40 p.m., Location Whitaker 0209A

Instructor Information

Instructor Michael Fisher, BS MS	Email mfisher36@ gatech.edu	Office Hours & Location https://mfisher36.youcanbook.me/
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General Information

Description

U.S. and international regulations and standards are essential requirements for commercialization of medical products, including design and development, clinical testing, manufacturing, distribution and promotion, and post-market surveillance. This course will address regulatory requirements for the U.S, EU, and select global locations for submissions to gain market approval for medical devices.

Pre- &/or Co-Requisites

Enrollment in the Master of Biomedical Innovation and Development (MBID) program.

Course Goals and Learning Outcomes

Upon completion, students will be able to:

Read and understand various regulatory submissions such as a 510(k), de novo, PMA, IRB, and Technical File

Classify a medical device

Make a Q-submission to FDA

Find consensus standards to support regulatory filings

Apply these learning objectives to their MBID team projects (assessed in BMED 6509)

Course Requirements & Grading

Description of Graded Components:

The principle graded deliverables for this course are the following:

Assignment	Due By End Of:	Weight (Percent)
Class Attendance & Participation	Continuous	20%
510(k) Synopsis	First Week of June	20%

Guidance Documents, Biocompatibility, and Predicate Device Selection	Third Week of June	20%
Indications for Use Statement	First Week of July	10%
De Novo Synopsis	Second Week of July	20%
Project Regulatory Assessment	Last Week of July	10%

Grading Scale

Final grades 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

No text book is required for this course. Lecture notes will be distributed after each lecture.

Additional Materials/Resources

See regulatory filings on Canvas files page

Course Website and Other Classroom Management Tools

Special Topic Presentations will be scheduled in the semester. The dates and topics of these presentations are pre-defined and the project teams are already organized.

Specialized guest lecturers are invited to speak to class throughout the semester.

Development Standard Operating Procedures (SOP's) and Template Documents (TEM) will be distributed for student use.

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>. 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.
- Avoid leaving the classroom once class starts.
- Talking and other disruptive behaviors during class are not permitted.
- Eating food is not permitted during class time.
- Professional attire is required.
- All reports must be submitted by 11:59 PM of the specified due date.

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 expectation 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 encouraged to mute cell phones during class. You may 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 or if your device is distracting to other students.

Additional Course Policies

You are responsible for setting yourself up to receive official class communications. Both of the following is used for this course, T-Square and the MBID Listserv email distribution list. All course announcements will use your GT email address. If you do not use your Georgia Tech email address, you should have your GT email forwarded to an account that you check several times each day.

Changes to any part of this document may be made to reflect changing situations. They will be announced in class or via email and posted on-line.

Campus Resources for Students

Students are strongly encouraged to consult the library and engage the services of a research librarian who may be able to help them identify important resources for use in completing their project.

Additional Syllabus Components

N/A

Course Schedule

Class Number	Instructor	Topic	Assignment
	FIRST DAY OF CLASS		
1	FISHER	Syllabus Review, Overview of Global Medical Device Regulation, Role of Regulatory Associate (RA) and RAPS Career Guideline	
2	FISHER	continued	
3	POWERS	Lecture: Classification Overview <ul style="list-style-type: none"> • USA Classification of devices • Overview of 510(k) and PMA submissions • USA Digital health regulation overview • MDR Regulation and Classification overview • Intl classification resources 	Assignment: <ul style="list-style-type: none"> • Read a 510(k) from FOIA K233508 and write a synopsis.
4	FISHER	Q&A - 510(k)'s	
5	POWERS	Lecture: Class 2 devices and 510(k)s <ul style="list-style-type: none"> • 510(k)s and Substantial Equivalence • Predicate searching • eSTAR 510(k) <ul style="list-style-type: none"> o Estar Information o RTA Guidance • How do each element link to DHF? • Guidance documents: <ul style="list-style-type: none"> o Electromagnetic Compatibility o Biocompatibility o Sterility o Human Factors 	Assignment: <ul style="list-style-type: none"> • Identify guidance documents that may be helpful for your project. • Is biocompatibility required and if so what tests? • Identify predicates or similar products to your project.
6	SIMS/CLARK	Institutional Review Boards (IRB's) and the IRB Process for First Use of Devices in Human Clinical Trials	Assignment: <ul style="list-style-type: none"> • Complete the IRB forms for questions on clinical trials and medical devices for your project
7	POWERS	Lecture: De Novos and Q-Submissions <ul style="list-style-type: none"> • 510(k) Wrap Up • De Novo • Q-Submissions 	Assignment: <ul style="list-style-type: none"> • Write Indications for Use statement and Pre-Submission questions for your project
8	FISHER	Q&A - IFU presentations and discussions	
9	FISHER	Review of Project Management and Regulatory Compliance Exercises	

10	FISHER		
11	POWERS	<p>Thursday July 10 (12:30-2:40pm)- Lecture: PMAs, CE Mark and Change Assessments</p> <ul style="list-style-type: none"> • PMAs • EU Technical Documentation Overview (CE Mark) • Change Assessments <ul style="list-style-type: none"> o 510(k) Changes <ul style="list-style-type: none"> o 510(k) Change Guidance o SW Change Guidance o PMA Changes <ul style="list-style-type: none"> o Post Market Submissions o EU NBOG and Article 120. 	<p>Assignment:</p> <ul style="list-style-type: none"> • Read a de novo (classification order and decision summary) Apple Hearing Aid Feature DEN230081 and write a synopsis.
12	FISHER	Q&A	
13	POWERS	<p>Thursday July 17- Lecture: Wrap Up</p> <ul style="list-style-type: none"> • Using what we have learned- Regulatory Assessments • Wrap Up • Q&A time with each group 	<p>Assignment:</p> <ul style="list-style-type: none"> • Finish regulatory strategy/assessment for FINAL
14	FISHER	Applying regulatory lessons to projects	
30-Jul-26	GRADUATION CLASS OF '26		