2026 BMED 6501 Syllabus

(Fundamentals of Biomedical Innovation and Development Processes)

Section A, 3 credits, MW 5:00 – 6:15 pm, Room Whittaker 0209A

Instructor Information

Instructor	Email	Office Hours & Location
Michael Fisher	Michael.Fisher@bme.gatech.edu	https://calendly.com/mfisher36
Michael Fonseca, Ph.D.	Michael.Fonseca@bme.gatech.edu	By appointment
Ken Kukla, Ph.D.	Ken.Kukla@bme.gatech.edu	By appointment
Brett Rogers, MBID	Brett.Rogers@bme.gatech.edu	By appointment

Teaching Assistant(s)	Email	Office Hours & Location
N/A	N/A	N/A

General Information

Description

The development and commercialization of medical products entail multiple stakeholders and unique regulatory requirements for engineering design, clinical testing, and FDA pre-market notification or approval of safety and effectiveness. This course will provide the framework in the design and commercialization process of medical products, including requirements and interdependencies of key stakeholders such as medical professionals (users), patients, and engineering development personnel, as well as regulatory requirements, intellectual property protection, commercialization strategy, project funding, clinical validation studies, manufacturing, distribution, reimbursement, and post-marketing surveillance requirements.

Pre- &/or Co-Requisites

Enrollment in Georgia Tech MBID program, only.

Course Goals and Learning Outcomes

Gain an overview and understanding of the life cycle development processes of Biomedical products from concept through commercialization phases, covering the major domains of Research, Pre-Clinical Development, Regulatory Approvals, Clinical Evaluations, Process Scale-Up, Manufacturing Validations and Market Launch.

Be able to apply above knowledge to the MBID Master's clinical projects in translating an unmet clinical need into a potential commercial medical device or treatment technique.

This course will cover following modules related to life cycle medical device development processes:

A. Needs finding based on clinical observations to develop needs statement

B. Concept Phase Research & Pre-Clinical Development

C. Design Controls, Risk Management & Regulatory

D. Overview of Quality Management Systems, Process Development & Manufacturing

Each of the above modules will be taught by a different Professor with extensive medical device industry experience as follows.

A. Needs Finding – Prof. Michael Fisher

B. Concept Phase Research – Prof. Michael Fonseca

C. Design Controls – Professor Michael Fisher

D. Quality Engineering – Professor Brett Rogers

<table>
<tr><th>Class Number</th><th>Topic</th><th>Assignments</th></tr>
<tr><td colspan="3">A. Introduction, Overviews & Needs Finding (Prof. Fisher)</td></tr>
<tr><td>1
(Fisher)</td><td>Introduction- Grading Policy, Expectations, Objectives of Course

Define Innovation
The Right Way to Innovate
Innovation Strategies</td><td rowspan="5"><u>1. Case Study Assignments for Class:</u>

Text Book: “Biodesign: The Process of Innovating Medical Technologies, Zenios, Makower, Yock, Cambridge University Press, 2015.

All students must read and conduct detailed review & analysis of Acclarent Case Studies - Stages 1 – 6 from the above text. Each Team to present and facilitate one of these case studies in Prof. Fonseca’s class on Sep 26 as noted.

Team analyses, discussions & presentations on above case studies will be assignments for Prof. Fonseca during his classes.

<u>Presentation Guidelines for Acclarent Case studies:</u></td></tr>
<tr><td>2
(Fisher)</td><td>Cross Functional Product Development Team Structures, Formation of Teams & TC, Assignment of Roles & Responsibilities</td></tr>
<tr><td>3
(Fisher)</td><td>Planning New Product Development</td></tr>
<tr><td>4
(Fisher)</td><td>Developing Needs Statement</td></tr>
</table>

	Clinical Mentor Meeting – Overview of unmet clinical needs across various therapies – Innovation Strategy Homework: Clinical Trial or FDA TPLC Due 9/11	**10 min presentation of ppt slides + 5 min Q&A** **Slide deck must be sent to Profs. Fisher & Fonseca 24 hrs in advance of presentation time as ppt file (not online ppt or pdf).**
B. Fundamentals of Concept Phase Research for Biomedical Devices (Prof. Fonseca)		
5 (Fonseca)	Fundamentals of Concept Phase Research for Biomedical Devices (Prof. Fonseca) Overview of Concept Phase Research in Medical Device & Development	
6 (Fisher)	Overview of Stage Gate Design Process in Medical Device Product Development	
7 (Fonseca)	CardioMEMS Story – Concept through Commercialization & Evolution of Prototype Designs	
8 (Fonseca)	Brainstorming Strategies for Concept Development	
9 (Fonseca)	Video Visit of Abbot-Atlanta facilities (CardioMEMS)	
10 (Fonseca)	Team Presentations of Acclarent Case	

	Studies of Product Development.	
11 (Fonseca)	Present stages 1-6 as follows: Team 1 – Stage 1 Team 2 – Stage 2 Team 3 – Stage 3 Team 4 – Stage 4 Team 5 – Stage 5 Team 6 – Stage 6	
12 (Fonseca)	Guest Lecture – TBD	
C. Overview of Design Controls, Risk Management & Regulatory (Prof. Fisher)		
N/A	Fall Break	
13 (Kukla)	Importance of Leadership Trust	
14 (Kukla)	Building Leadership Trust: Key ingredients	
15 (Kukla)	Identifying Communication Styles	
16 (Kukla)	Communicating skills	
17 (Kukla)	Team Development	
18 (Kukla)	Managing Conflict	
19 (Kukla)	Difficult Conversations	
20 (Fisher)	Review prior to Midterm	
21 (Fisher)	Team Projects and Presentations November 5, 4 pm - 7 pm:	

	Combined Mid-Term Exam Presentations for Profs. Fisher & Andino Deliverables for each Team Presentation: Power Point Presentation covering the following for their clinical project: 1. Clinical Problem Selection Rationale 2. Project Charter/Scope 3. Need Statement 4. User Needs 5. Overview of Regulatory & Reimbursement Strategy Slide deck needs to be submitted to Profs. Fisher & Andino 48 hrs in advance of presentation time as a ppt file attachment in email (not online ppt or pdf). Teams must prepare for 15 min presentation and 10 min Q&A.	
D. Overview of Quality Management Systems, Process Development & Manufacturing (Prof. Rogers)		
22 (Rogers)	Introduction to Quality Management System (QMS) requirements 1. Title 21 CFR part 820 – FDA Website 2. ISO 13485:2016 3. Key components of a QMS Quality department's role within a medical device company Typical division of the quality department Quality careers	MAUDE Review Report – Team Each Team will review three MAUDE database entries resulting in death or serious injury. Team will prepare a summary of the findings and commentary on what the manufacture could have done to detect or correct for the root cause sooner in development process.
23 (Rogers)	Design Development	

	Requirements and Structure 1 Stage gate process	
24 (Rogers)	Typical Regulatory Testing: Bioburden, sterile dose, and packaging validation requires The Quality prospective of DFMEA's and PFMEA's Design specification generation Role of Design Verification Testing (DVT)	Teams will review a part drawing, IFU / manual, physical samples to determine what part dimension are Critical to Quality/Function (CTQ/CTF).
25 (Rogers)	The role of Quality Assurance/Control Statistical process control and trending Manufacturing process and software validation requirements 1. SAT/FAT, IQ, OQ, and PQ 2. System revalidation 3. 100% verifiable systems	
26 (Rogers)	Non-conformances, supplier corrective action request/report 1. cGMP requirements 2. Investigations, corrective actions, and dispositions	

	Corrective action / preventative actions 1. How CAPAs differ from NCRs 2. What triggers a CAPA	
27 (Rogers)	Good and the bad of the quality and manufacturing relationship Process development 1. Process mapping 2. PFMEAs 3. Work instructions, standard operating procedures, and set-up sheets 4. Training and best practices	Each team will create a Process map, Control Plan and PFMEA for a simulated production process.
28	FINAL DAY OF INSTRUCTION	
N/A	Slide decks for Final Exam submitted to Profs. Fisher & Andino as a ppt file attachment in email	
12/8/2025	Final Exams & Presentations	

Deliverables for each Team:

A. Power Point Presentation covering the following for their clinical project:
Monday, Dec 7, 25: 2 pm – 5 pm: Oral Presentation

1. Clinical Problem Selection Rationale – Final Version
2. Project Charter/Scope – Final Version
3. Need Statement – Final Version
4. User Needs – Final Version
5. Overview of Regulatory & Reimbursement Strategy

Slide deck needs to be submitted to Profs. Fisher & Andino by midnight on 12/06 as a ppt file attachment in email. Teams must prepare for 20 min presentation and 10 min Q&A.

B. Project Design History Files (DHF) - no DHF files, at this time

Course Requirements & Grading

Description of Major Graded Components:

The principle deliverables for this course are the following:

A. Identification of a valid clinical problem to solve with suitable rationale based on two criteria – 1. Clinical impact and 2. Business impact,

B. Well defined Need Statement for the chosen clinical problem and

C. User Needs for the Clinical problem to be solved.

Student teams are expected to finalize the above three items for their clinical projects by end of Fall semester and execute it for the duration of the program in their clinical Project courses in Spring and Summer, BMED 6508 & 6509, respectively. There will be team-based mid-term presentations as well as a semester end presentation cum design history file report.

Assignment	Weight (Percent of Final Grade)
Innovation Exercise	10% (ClinicalTrials.gov or FDA TPLC Reports)
Mid-Term Presentation	30% (November)
Final Exam Presentation	40% (Final Exam)
Professionalism†	20%

† - Class attendance, participation, work ethic, and team contribution

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, Second edition, 2015.

Additional Materials/Resources

Detailed Review & Analysis of Acclarent Case Studies - Stages 1 – 6 from Text Book: "Biodesign: The Process of Innovating Medical Technologies, Zenios, Makower, Yock, Cambridge University Press, 2015.

Course Website and Other Classroom Management Tools

Special Topic Presentations will be scheduled in the semester. Presentations will be pre-assigned case studies of medical device development as well as reports of industry visits and outside guest lectures. The dates and topics of these presentations will be defined following formation of teams and finalization of projects.

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

Other available resources are videos that are relevant to student team medical device project.

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.

Artificial Intelligence (AI) Policy

Students are encouraged to explore and use generative artificial intelligence (AI) tools, such as ChatGPT, to enhance their learning and efficiency. Any such use must be appropriately acknowledged and cited, following the guidelines established by the APA Style Guide, including the specific version of the tool used. Submitted work should include the exact prompt used to generate the content as well as the AI's full response in an Appendix. Because AI generated content is not necessarily accurate or appropriate, it is each student's responsibility to assess the validity and applicability of any generative AI output that is submitted. You may not earn full credit if inaccurate, invalid, or inappropriate information is found in your work. Copying results from an AI tool without reference to the use of that tool may lead to a student code of conduct violation relating to Section D.3, plagiarism. Deviations from these guidelines will be considered violations of Georgia Tech's Student Code of Conduct. Please email me if you have questions or want clarification regarding permissible use of AI tools for a particular course or assignment.

Here are some specific expectations for your use of AI tools in this course:

- You can include AI generated content verbatim into a writing assignment with quotations and a citation.
- You can paraphrase AI generated content with a citation.
- You can include non-text AI generated content (images, video, code, etc.) with an appropriate citation, when expressly permitted in the assignment prompt.

Students are required to conduct their own research and generate bibliographies for topics that are being researched.

Students will not use or present generative AI content that is depicted as their own work. A citation is required.

Finally, it is important to recognize that generative AI tools frequently provide users with incorrect information, create professional-looking citations that are not real, generate contradictory statements, incorporate copyrighted material without appropriate attribution, and sometimes integrate biased or offensive concepts. Code generation models may produce inaccurate outputs. Image generation models may create misleading or offensive content. Like any tool, generative AI can be extremely useful, but can also create problems if used inappropriately.

While students may use AI tools in this class, it is important to note that students are responsible to generate the content that is submitted for grading. Work that is inaccurate, biased, unethical, offensive, plagiarized, or incorrect will be treated as such during the evaluation of your work.

Analogy – You get no benefit of going to the gym if your robot lifts the weights and runs on the treadmill. Let AI expand your bandwidth and create greater awareness of the topic being studied, but make sure that your brain and experience benefit of using this tool.

Mental Health and Wellbeing

Your instructors, and the BME department as a whole, care about student mental health. While your instructors can be a resource, we also want to make sure you are aware of the formal resources for receiving mental health assistance in BME and at GT. More information about these resources can be found here: https://mentalhealth.gatech.edu/

- Mental Health Care & Resources – The Center for Mental Health Care and Resources (CMHCR) is the best place to engage with mental health care at GT. They are found in the Smithgall Student Services Building and can also be reached at 404-894-2575. Their normal hours of operation are 8am to 5pm Monday through Friday. CMHCR can connect you with services including individual or group counseling, academic or personal support services, assessment and testing for learning disabilities, and other mental health providers. They can help you find the right resources for a crisis, an acute issue, or a longer-term concern.

- BME Satellite Counselor – In addition to the Center for Mental Health Care's centralized services, BME hosts a counselor, Kate Silverio, in Room 1105 of the Whitaker Building (in the back of the academic office). The Satellite Counselor offers 15 min appointments (in-person or virtual) during which students can discuss a brief or specific, non-emergency concern, and/or learn about mental health resources on campus. To schedule with the Satellite Counselor, please email her (kate.silverio@studentlife.gatech.edu).

- Crisis Services - If you require immediate support for mental health difficulties you have several options:

  During business hours (8 a.m.-5 p.m.). Call 404-894-2575 or go to Suite 238 in the Smithgall Student Services Building.

  Outside of business hours, call 404-894-2575 and select the option for the after-hours counselor.

  In an emergency, call Georgia Tech Campus Police at 404-894-2500 on campus or 911.

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 (especially important for clinical rotations and meetings with external presenters).
- All reports must turned in on time per the deadlines mentioned in syllabus.

Collaboration & Group Work

Students will work in teams selected randomly 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 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 quizzes and tests and certain in-class activities, the use of any electronic devices for any purpose, including talking, texting, web surfing, etc. is specifically *forbidden*. Exceptions will be identified by the instructor when appropriate. When in doubt, the answer is "*no*".

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.

You are responsible to complete Right to Know and Lab Safety Training and complete all building access forms to gain entry to the TEP facility.

All Hospital Clinical Observations paperwork must be completed before you are able to start clinical observations.

Machine Shop training must be completed before using any equipment.

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