

[54352] Syllabus

BMED 6506 Professional Communications

Tuesday/Thursday 12:30 pm - 2:40 pm Whitaker 0209A

Instructor Information

Instructor Michael Fisher	Email michael.fisher@bme.gatech.edu	Drop-in Hours & Location https://calendly.com/mfisher36
Teaching Assistant(s) N/A	Email N/A	Drop-in Hours & Location N/A

General Course Information

Description

Effective communication is an essential component of medical device engineering, design, and business success. Professional communications include topics on presentation skills, composition skills, definition of value, managing within an organization, managing your career, creating a business canvas, constructing a financial model, and describing a product's intellectual properties. Each of these topics is covered within this course and are coordinated with the sequence of required deliverables in MBID team-based project. Specific deliverables are articulated in the Course Requirements and Grading section (below).

Pre- &/or Co-Requisites

Full-time enrollment in the MBID Program

Course Goals and Learning Outcomes

Specific deliverables for this course will be delivered in four sections - Professional Presentation Skills, Organizational Dynamics and Career Management, Medical Device Reimbursement, and Professional Engineering Communications:

1. Professional Presentation Section
 - a. Project Briefs, Value Proposition, Market Revenue and Costs
 - b. Timeline, Work Streams, and Milestones
 - c. Risks (Technical, Regulatory, Clinical)
 - d. Product Roadmap and Claims Matrix
 - e. Provisional Patent Application
 - f. Business Plan, Pitch Deck, and Revenue Model
 - g. Upstream and Downstream Marketing
 - h. Grant Application
2. Medical Device Reimbursement - Susan Rowinski
 - Reimbursement and monetization planning for medical devices

Course Requirements & Grading

Assignment	Date	Weight (Percentage, points, etc)
Professionalism (attendance, participation, teamwork)	Throughout the semester	20% - individual assessment
Business Plan and Financial Model	2 nd week of June	20%
Pitch Deck and Presentation	End of June	30%
Intellectual Property - Provisional Patent Application	End of July	10%
Final MBID Presentation	July 30	20%

Extra Credit Opportunities

No extra credit is offered

Description of Graded Components

- **Professionalism** - Class attendance and/or participation will be evaluated as a component of a student's professionalism grade. Student absences must be communicated to the teaching team before the absence.
- **Business Plan and Financial Model** - Final Presentation Slide and Supporting Documents and a financial model anticipating project timeline, costs, and at least two revenue scenarios.
- **Pitch Deck and Presentation** - A 10-slide canvas based on the investor template from Y-Combinator. This is extracted from the detailed information found in the business plan and financial model, but incorporates more information about the "why is this important" aspect as opposed to the "technically, how this will be accomplished."
- **Intellectual Property and Provisional Patent Application** - Final prototype features and embodiments described in a provisional patent application that mirrors the format of a patent application, minus the claims language. The team will present a patent search, prior art discovered, and some comments on "freedom to operate."
- **Final MBID Presentation** - The team will follow the published slide deck rubric for the Phase 3 phase gate review. The focus will be on describing the prototype, the testing, and testing results. There will be an integrated perspective on the project and what the next steps would be if the project were to continue after the MBID program.

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%

Course Materials

Course Text

Yock, et al. *Biodesign: The Process of Innovating Medical Technologies* 2nd Edition.

Additional Materials/Resources

N/A Except as provided within the curricula from the teaching team

Course Website and Other Classroom Management Tools

N/A

Course Policies, 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. [Review Georgia Tech's Honor Code](#) and the [student Code of Conduct](#).

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 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. Please also e-mail me as soon as possible in order to set up a time to discuss your learning needs.

Attendance and/or Participation

At Georgia Tech, students are expected to attend class regularly, and instructors are expected to hold classes at their institutionally scheduled time. Instructors are not permitted to penalize students for not attending sessions outside of institutionally scheduled times. Likewise, students are not penalized for requesting excused absences to enable job interviews.

Collaboration & Group Work

The MBID program encourages group work alongside individual contributions. In this class, several assignments are graded for individual performances. Others are graded as team performances. Please review the grading rubric to appreciate the relative contributions to a final grade for the course.

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

Late assignments cannot be accepted as the teaching team changes throughout the semester. If there is an unavoidable reason for the late assignment, please communicate the reason within 36 hours of the delay to the professor of record (see Syllabus Header). There are some approved Institute activities (e.g., field trips and athletic events) and religious observances. [Read more about approved exceptions](#).

Inclement Weather and Digital Learning Days

If a weather-related event affects campus operations, instructors have the discretion to cancel class or pivot to digital instruction. Informed by departmental and/or program considerations, you may choose to include language here that proactively instructs students what they should expect in such an event. Read more about the policy regarding the requirements, procedures, and responsibilities related to [Digital Learning Days for Modified Campus Operations](#).

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.

Student Use of Mobile Devices in the Classroom

Any use of mobile and digital devices in the classroom is expected to be in support of the class and materials being taught. Importantly, use of digital technology during class cannot disrupt other students' learning.

Campus Resources for Students

Students are encouraged to use all available campus resources (e.g., the library, The Communication Center, or Tutoring and Academic Services, ASTM Compass for standards, etc.).

Graduate Student Academic and Professional Success Resources:

A list of resources for graduate students is given on the Office of Graduate and Postdoctoral Education website. Specific information for current graduate students includes

- [Academic Resources](#) such as the Communications Center, Language Institute, Library, Catalog, Registrar, resources for conducting research, Advocacy and Conflict Resolution resources, and how to manage unexpected situations that may impact your academic performance
- [Student Resources](#) such as Campus Services, Child Care/Family programs, Health & Wellness, Career Services, and the Student Resource Guide
- [Professional Development](#) such as the programming from the Career Center and other professional development resources and events

Student Well-Being

Georgia Tech cares about student 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 \(gatech.edu\)](#)).

Additional Syllabus Components

The course instructor's goal is for students who successfully complete this course to be competent in the professional realm of medical product development. This requires students to complete assignments on their own or in concert with their project team. Practical use of the skills taught in this course will translate into professional success.

The MBID curricula and classroom focuses on creating an inclusive environment for learning and discussion of topics that may be sensitive or difficult. We ask students to adopt an inclusive mindset when engaging in conversations with the class, and that students hold their professors to this standard.

If a student experiences undue stress or is unable to participate in class, please communicate this to your instructor. If the student does not feel comfortable addressing the instructor, please contact the [Dean of Students](#) to address the issue. Georgia Tech has a focus on student success - which is uniquely defined for each student. If something is preventing a student's successful completion of a course, please make us aware of the situation so a strategy can be implemented to help achieve successful outcomes.

Course Schedule

Class	Topic
Prior to start of Summer	Submit your customer needs, requirements, clin/reg strategy, prototyping documents, and other product documentation for your product prior to the course
1	<ul style="list-style-type: none"> ● Course Orientation (30-45 min) ● Annual Operating Plan and Prioritization Process - How do programs get selected? (1 hour 15-30 min) <ul style="list-style-type: none"> ○ Internal Opportunity Assessment ○ External Opportunity Assessment ○ Key Take Aways
2	<ul style="list-style-type: none"> ● Market Research: Overview <ul style="list-style-type: none"> ○ Types of Market Research ○ Preparing for various types of market research (including Voice of Customer Interviews and Healthcare System Case Visits) ○ Customer Journey Mapping ○ Key Takeaways
3	<ul style="list-style-type: none"> ● Market Research: Customer Needs <ul style="list-style-type: none"> ○ Translation of Voice of Customer into Problem Statements ○ Affinitization and Grouping ○ Translation from Problem Statements into Customer Needs ○ Prioritization ○ Metrics and Linking to System Requirements ○ Key Takeaways
4	<ul style="list-style-type: none"> ● Market Research: Voice of Business and Customer Segmentation <ul style="list-style-type: none"> ○ Voice of Business: <ul style="list-style-type: none"> ■ Collecting Voice of Business Activities (Regulatory, Clinical, Reimbursement, R&D, Quality, Operations, Management, Human Factors, etc) ■ If VOB is development/constraints related, convert into Problem Statements and Business Needs ■ VOB Prioritization ■ How it feeds into R&D plans, Quality plans, etc. ○ Customer Segmentation ○ Key Takeaways
5	<ul style="list-style-type: none"> ● Market Research: Competitive Landscape <ul style="list-style-type: none"> ○ Competitors & Market Share ○ Collecting Voice of Customer on Competitor Products (not just gold standards) and other activities to understand competitor products ○ Financial Reports of Public Competitors ○ Differentiation from Competitors ○ Key Takeaways
6	<ul style="list-style-type: none"> ● Market Access: <ul style="list-style-type: none"> ○ Reimbursement (External Speaker) ○ Case Study on Reimbursement in Medical Devices ○ Key Takeaways

7	<ul style="list-style-type: none"> ● Financial Modeling Overview (Part I) <ul style="list-style-type: none"> ○ How to Define Value of a Program - Trade Offs Over Time ○ Time Value of Money ○ What is Net Present Value & IRR ○ Break outs: Examples of calculating NPV, and IRR ○ Key Takeaways
8	<ul style="list-style-type: none"> ● Financial Modeling Overview (Part II) <ul style="list-style-type: none"> ○ Breakdown of NPV - including FCF, discount rates, etc ○ Pro Forma P&L - COGs, Revenue, etc ○ Break outs: Exercises around NPV and P&L
9	<ul style="list-style-type: none"> ● Market Sizing and Revenue (Part I) <ul style="list-style-type: none"> ○ Top / Down Approach: TAM, SAM, SOM ○ Bottom / Up Approach: Market Modeling (ASPs, Market Share, Procedures YoY, Cannibalization, etc) ○ Exercise to Build a Market Model ○ Key Takeaways
10	<ul style="list-style-type: none"> ● Patent Process & Ideation Exercise <ul style="list-style-type: none"> ○ Patent Process (Patent Attorney Speaker) <ul style="list-style-type: none"> ■ Types of Patents ■ Patent Search ■ Patent Application ■ Examination Process ■ Patent Allowance and Issuance ■ Patent Maintenance ■ International Protection outside of US ○ Patent Exercise in Class or Patent Ideation
11	<ul style="list-style-type: none"> ● Market Sizing and Revenue (Part II) <ul style="list-style-type: none"> ○ Teams present their initial market model and assumptions. Utilize their understanding of the market to make assumptions. ○ Class discussion and Q&A on the market models
12	<ul style="list-style-type: none"> ● Clinical and Regulatory Strategy (External Speaker) <ul style="list-style-type: none"> ○ Traditional Pathways ○ Methods to Accelerate To Commercialization
13	<p>“Putting It Together”</p> <ul style="list-style-type: none"> ● Project Briefs <ul style="list-style-type: none"> ○ Value Proposition ○ Market Revenue and Costs ○ Competitive Differentiation ○ Timeline, Work Streams, and Milestones ○ Key Assumptions for Nominal Timeline ○ Opportunities to Accelerate Timeline ○ Risks <ul style="list-style-type: none"> ■ Technical Risks ■ Regulatory Risks ■ Clinical Risks ■ Operations Risks

	<ul style="list-style-type: none"> ■ Quality Risks ● Business Plan / Business Reviews
14	<ul style="list-style-type: none"> ● Student Presentations of Project Briefs and Business Plan <ul style="list-style-type: none"> ○ Provide Scoring Rubric [Sara 000]
15	<ul style="list-style-type: none"> ● Student Presentations of Project Briefs and Business Plan <ul style="list-style-type: none"> ○ Provide Scoring Rubric [Sara 000]
16	<ul style="list-style-type: none"> ● Claims Matrix Development: <ul style="list-style-type: none"> ○ What is a claim? ○ Types of claims ○ Customer Needs to Claims ○ Mapping Claims to Evidence [Sara 000 - Prerecord Class]
17	<ul style="list-style-type: none"> ● Product Roadmap Development <ul style="list-style-type: none"> ○ Strategic Role of a Product Roadmap ○ Types of Roadmaps (Single program, product generation, portfolio, etc) ○ How to build a roadmap ○ Exercise to build a roadmap for your product [Sara 000 - Prerecord Class]
18	<ul style="list-style-type: none"> ● External Opportunities: Business Development and Strategy (external speaker) <ul style="list-style-type: none"> ○ Role of BD&S in Medical Device Companies ○ Types of Partnerships ○ BD&S Deal Process <ul style="list-style-type: none"> ■ Sourcing deals ■ Evaluating opportunities (strategic fit, technology readiness, financial modeling, IP, etc) ■ Due Diligence ■ Term Sheet and Deal Structuring ○ Example of a BD&S Case & Deal
19	<ul style="list-style-type: none"> ● External Opportunities: Corporate Ventures (external speaker) <ul style="list-style-type: none"> ○ Role of Ventures in Medical Devices ○ Investment Thesis ○ Attributes of Ideal Investment Targets ○ Due Diligence Process and Term Sheets ○ Example of a Ventures Case & Deal
20	<ul style="list-style-type: none"> ● Medical Device Downstream Marketing & Sales Overview (External Speaker) <ul style="list-style-type: none"> ○ Sales Process & Cycle ○ Selling to Hospitals and Health Systems (Value Analysis Committees) ○ Role of clinical specialists vs territory reps ○ Clinical sales and KOL engagement ○ Sales Channels

	<ul style="list-style-type: none">○ Sales Training and Marketing Collateral
21	<ul style="list-style-type: none">● Synthesis of the Information Learned in the Class and Synthesis of Business Deliverables
7/30	<ul style="list-style-type: none">● Final Phase 3 Presentations