

BMED 6503 Syllabus

Medical Markets and Clinical Specialties

Section B, 3 credits, Monday & Wednesday, 6:30 - 7:45 p.m., Room L1105 Ford Environmental Science & Technology (ES&T) Building

Fall Semester, 2026-2027 Academic Year

Instructor Information

Instructor

Rafael V. Andino, M.S., M.B.A.

Email

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Office Hours & Location

By appointment.

Teaching Assistant(s)

N/A

Email

N/A

Office Hours & Location

N/A

General Information

Description

In this course, BioD students will study the breadth of their industry, its structure, markets, specialties, and commercial opportunities. U.S. medical device and biologics markets generate over billions of dollars in annual commercial sales. This business relies on continued research, innovation, and translational development to deliver advancements in medical diagnosis techniques, therapies and treatment modalities, rehabilitation, and home healthcare. Changes in technologies, demographics of patient populations, national healthcare policies, and reimbursement continue to reshape the industry and healthcare delivery in the U.S., Europe, and developing countries.

Pre- &/or Co-Requisites

N/A.

Course Goals and Learning Outcomes; Upon successful completion of this course, students will be able to:

- Become familiarized with the breadth of the medical device industry; its structure, markets, specialties, and commercial opportunities
- Become familiarized with the process of identifying unmet needs that can lead to the development of new medical technologies
- Understand the inherent drivers that create the existing needs in the markets - demographics, diseases, clinical treatment modalities, cost containment, etc.
- Understand the main macro factors that color and contribute to medical device product development - national healthcare policies, the regulatory and reimbursement landscape, intellectual property ownership, etc.
- Become proficient at making succinct oral presentations in a compressed amount of time on multidisciplinary topics in the medical space (business and technology)
- Become familiarized with developing & presenting a business case for a solution to an unmet clinical need
- Analyze the structure, stakeholders, and market dynamics of major medical technology sectors
- Identify and evaluate unmet clinical needs using demographic, economic, and healthcare delivery data

- Assess regulatory, reimbursement, and intellectual property considerations influencing product development
- Develop and deliver concise multidisciplinary oral presentations
- Construct a structured business case for a novel biomedical technology opportunity

Course Requirements & Grading

Assignment	Weight (Percentage, points, etc.)
Class participation/case discussions	25%
Presentations	30%
Paper 1	5%
Paper 2	10%
Final Paper	30%
Total	100%

Extra Credit Opportunities

There is no extra credit for this course.

Description of Graded Components

Assignments:

Students will complete the following graded assignments:

1. **Class Participation and Case Discussions (25%)**
Active participation in class discussions based on assigned readings, Harvard Business School cases, guest lectures, and in-class exercises. Students are expected to demonstrate preparation, engagement, and thoughtful contribution.
2. **Individual Demographic Trend Paper and Presentation (Paper 1 - 5%)**
Each student will prepare a short written paper and deliver an oral presentation analyzing a significant demographic or healthcare trend that may generate unmet clinical needs and market opportunities.
3. **Team Unmet Clinical Need Analysis Paper and Presentation (Paper 2 - 10%)**
Student teams will conduct deeper research on a specific unmet clinical need, including demographic drivers, disease burden, and societal healthcare implications. Findings will be presented both orally and in written form.
4. **Team Midterm Presentation(s) (Included in Presentations - 30% total)**
Teams will present structured analyses of clinical markets, healthcare trends, and unmet needs as part of staged project development milestones.
5. **Final Team Business Case Project and Presentation (Final Paper - 30%)**
Teams will develop and present a comprehensive business case addressing an unmet clinical need. The final deliverable will include:
 - Market opportunity analysis
 - Competitive landscape

- clinical and economic burden assessment
- regulatory and reimbursement considerations
- intellectual property considerations
- preliminary commercialization strategy

This project culminates in a formal oral presentation and written report.

Final Team Business Case Project:

Using the two previous research efforts as underpinning work, the student teams (4 per team) will work to present a full business case on the opportunity presented by the unmet need, the surrounding market landscape information (competition, clinical costs of problem to society, reimbursement challenges, regulatory challenges, etc.) and other key elements of a business case of this kind. This will be presented orally to the class and in a written report.

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

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

Commercializing Successful Biomedical Technologies: Basic Principles for the Development of Drugs, Diagnostics, and Devices, S. Mehta, Cambridge University.

Additional Materials/Resources

Other Reading Materials:

Select Harvard Business School case studies from the medical device and pharmaceutical industry.

Select documents from the United Nations World Health Organization and the Us Department of Health and Human Services.

Course Website and Other Classroom Management Tools

N/A

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 are a student with learning needs that require special accommodation, contact the Office of Disability Services at (404)894-2563 or <http://disabilityservices.gatech.edu/>, 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

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 & Classroom 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 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, iPad, 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.

Grade Calculation Method Statement: Final grades are calculated as a weighted average of all graded course components. Students are responsible for monitoring their performance.

Collaboration and Generative AI Policy: Students may use generative AI tools for idea exploration unless otherwise specified. All substantive use must be disclosed. AI may not replace original analysis or writing. Unauthorized use may constitute an academic integrity violation.

Inclement Weather / Digital Learning Policy: If campus operations are modified due to weather or emergencies, instruction may transition to digital delivery. Guidance will be communicated via official Georgia Tech channels.

Core IMPACTS Statement: This course does not satisfy Core IMPACTS requirements.

Graduate Student Academic & Professional Resources: Students are encouraged to consult the Office of Graduate and Postdoctoral Education for academic support, career services, and research resources.

Student Well-Being Statement: Georgia Tech supports student mental, physical, and social well-being. Students experiencing challenges are encouraged to use campus wellness resources in the Student Resource Guide.

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 online.

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

(Note: Guest Speaker and Lecture dates subject to change)

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Prof. Rafael V. Andino

<u>Class Number</u>	<u>Class date</u>	<u>Topics</u>	<u>Source Materials</u>	<u>Assignments Due</u>
1	18 Aug	Introductions, Expectations and Objectives for the Class, Reading HBS cases and World Health Statistics and Demographics - Uncovering Needs	WHO and US HHS Reports and Sect 1.1 Zenios	
2	20 Aug	US Healthcare Statistics and Demographics and Healthcare IT - Uncovering Needs (cont.)	US HHS Reports, US Standard of Living Report, US Healthcare Reform Int. Perspectives HBS case, and American Well HBS case, and Sect 1.1 Zenios	Read Zenios sects 1.1, and Oral case discussions
3	03 Sept	American Board of Medical Specialties (ABMS) - Overview and WHO Medical Device Regulations Document and Disease State Fundamentals (1)	Lecture, Zenios 2.1 and 2.2, website with info, and WHO Med Device Regulations document	Review WHO documents and Zenios 2.1 and 2.2
4	08 Sept	US FDA Product Categories and Product Codes - Introduction	Lecture, Zenios 4.2 & US FDA HBS case and http://www.youtube.com/watch?v=IfV6Fk5L6w and http://www.youtube.com/watch?v=omhCdV-5Qo4	Read Zenios 4.2 and Oral case discussion
5	10 Sep	Product Development Process, Trends and Innovation and Needs Statement Development - Part 1	Zenios 1.3 & HBS cases: 3M Innovation, Turn Customer Input into Innovation, Mapping Innovation Strategy; and MDDI Award Winners over past 5 years; Zenios overview; BMD tracking tool template	Read Zenios 1.3 and Oral case discussions
6	15 Sep	Product Development Process, Trends and Innovation and Needs Statement Development - Part 2	Zenios 1.3 & HBS cases: 3M Innovation, Turn Customer Input into Innovation, Mapping Innovation Strategy; and MDDI Award Winners over past 5 years; Zenios overview; BMD tracking tool template	Read Zenios 1.3 and Oral case discussions

7	17 Sep	The US reimbursement process - An Overview - Part 1	Lecture, Zenios 4.3, and GE Reimbursement Overview & Novasys HBS case	Read Zenios 4.3 and Oral case discussion
8	29 Sep	The US reimbursement process - An Overview - Part 2	Lecture, Zenios 4.3, and GE Reimbursement Overview & Novasys HBS case	Read Zenios 4.3 and Oral case discussion
9	01 Oct	The US reimbursement process - An Overview - Part 3	Lecture, Zenios 4.3, and GE Reimbursement Overview & Novasys HBS case	Read Zenios 4.3 and Oral case discussion
10	08 Oct	Uncovering unmet clinical needs and ethnographic research technique	Lecture, Sect 1.2 Zenios, ethnographic study presentations & Holding Fast HBS case	Read Zenios 1.2 and Oral case discussion
11	13 Oct	Cardiology - Market Needs, Trends, Devices and Firms	Lecture and Drug Eluting Stent HBS case	Oral case discussion
12	15 Oct	Ophthalmology Market Needs, Trends, Devices and Firms	Lecture from Dr. Samir Patel, Director of R&D and Co-Founder, Clearside Biomedical	
13	20 Oct	US or Global Healthcare Trends - Setting the Market Opportunity	Student Presentations (Individual) part 1	Individual paper and presentation on a key demographic trend with ensuing US or global health care consequences that will lead to a potential customer need
14	22 Oct	US or Global Healthcare Trends - Setting the Market Opportunity	Student Presentations (Individual) part 2	Individual paper and presentation on a key demographic trend with ensuing US or global health care consequences that will lead to a potential customer need

15	27 Oct	US or Global Healthcare Trends - Setting the Market Opportunity	Student Presentations (Individual) part 3	Individual paper and presentation on a key demographic trend with ensuing US or global health care consequences that will lead to a potential customer need
16	29 Oct	Critical Care Medicine - Market Needs, Trends, Devices and Firms	Lecture from John Gohde – Healthcare Executive, Dentsply Sirona	
17	03 Nov	Open Topic Lecture	Lecture from Manuel Kingsley - Owner, The Questus Group	
18	05 Nov	Global Healthcare Issue – Presentations -All groups	Student Presentations (Teams Midterm)	Team Paper and Presentation of unmet US or global clinical user need
19	10 Nov	Orthopedics - Market Needs, Trends, Devices and Firms	Lecture	
20	12 Nov	Nursing Services -Market Needs, Trends, Devices and Firms	Lecture	
21	17 Nov	Surgical Specialties Needs and Trends, Devices and Firms	Lecture and Hospital Equipment Corp HBS case	Oral case discussion
22	19 Nov	Emergency Medicine - Market Needs, Trends, Devices and Firms	Lecture and Zoll Medical HBS case	Oral case discussion
23	24 Nov	Urology, Endourology, and Nephrology - Market Needs, Trends, Devices and Firms	Lecture	
24	01 Dec	Developing specifications - a primer	Lecture on writing a specification	Lecture

25	03 Dec	A Primer on Intellectual Property Strategy	Lecture, Sect 4.1, and Incept LLC HBS case	Read Zenios 4.1 and Oral case discussion
26	08 Dec	Final Exam Period - Final Projects Due	Student Presentations (All Teams)	Team presentation of business case (front end of business plan) to address unmet clinical need

Grade Components:

Class Participation/ Case discussions:	25%
Presentations (3):	30%
Paper 1:	5%
Paper 2:	10%
Final Paper:	30%
Total:	100%

Recommended Text Books:

Zenios, Stephanos, et al; Biodesign The process of Innovating Medical Technologies; Cambridge University Press; 2012.
 Mehta, Shreefal S.; Commercializing Successful Biomedical Technologies; Cambridge University Press; 2009.

Other Reading Materials:

Select Harvard Business School case studies from the medical device and pharmaceutical industry
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