

2026 BMED 6502 Syllabus

(Clinical Literacy and Experience)

Section A, 3 credits, TR 3:30 pm - 4:20 pm, Whitaker 0209A

Instructor Information

Instructor	Email	Office Hours & Location
Catherine Wallace MD :D	catwallace@gatech.edu	
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Teaching Assistant(s)	Email	Office Hours & Location
N/A	N/A	N/A

General Information

Description

The development and commercialization of medical products entails multiple stakeholders with unique clinical inputs and perspectives. This course will provide graduate students with essential clinical literacy skills necessary for the medical device development industry. This course will cover fundamental concepts in medical pathology and terminology, healthcare systems, ethics and proper conduct, and the practical application of clinical knowledge in medical device development. The course will enable students to explore the medical world through shadowing and visits to the hospital and supporting facilities.

Pre- &/or Co-Requisites

Enrollment in Georgia Tech MBID program.

Course Goals and Learning Outcomes

Students will learn the ability to communicate with healthcare professionals in a clinical setting in order to identify unmet clinical needs and how to conduct themselves in a clinical environment in order to be able to make accurate observations. They will also gain exposure and experience with using medical terminology, discussing medical diagnoses and plans, and efficiently evaluating medical journals for significant findings.

This course has modules on the following topics:

- Basic understanding of medical terminology and disease states
- Understand how to behave in clinical environments
- Learn various roles and responsibilities within a hospital and be able to identify the right person for the right question during shadowing experiences
- Read, interpret, and critically analyze clinical research articles
- Understand how innovation is introduced into healthcare systems

- Understand ethical considerations in hospital settings and clinical research
- Apply clinical literacy skills in the context of developing needs statements, and uncovering unmet needs

Weekly Syllabus

Week 1: Intro to clinical literacy

- 1) Overview of clinical literacy and why it is important in the biomedical device industry
 - i) During design process for research
 - ii) Regulatory approval: publications and documentation
- 2) Introduction to medical terminology
 - a) Anatomy (ant/post, eversion, pronation, adduction)
 - b) Systems (Body level to cellular level: osteo- , -blast)
 - c) Procedural (-scopy, -stoma, -ostomy)
- 3) Homework: color a page of the illustrated Netter's anatomy.
 - a) (probably the one where they overview the anatomical planes) and/or student choice
 - b) Maybe to motivate them do a fun group quiz at the start of next lesson on the what they colored (cadaver lab style, point and identify)

Week 2: Healthcare Systems and Delivery

- 1) Structure and function of healthcare systems in the US (maybe even other countries)
 - a. Overview of insurance policy groups: HMO vs PPO (how hospitals get paid)
 - b. EMTALA concept
- 2) Patient care pathways and clinical workflows (brief intro to roles in healthcare)
 - a. Focus on how a patient gets from initial complaint to intervention and recovery (# of facilities, wait times, ease of navigating system, financial)
 - b. Include MD perspective (diagnostics, care plans, scheduling)
 - c. Circle back on other country healthcare systems if their flows are dramatically different
- 3) Homework: ask someone in your life who has ever had any surgery what the process was like for them, submit a 1 paragraph reflection

Week 3: Roles and responsibilities in a hospital

- 1) Review homework – 5-10 minutes open discussion of insights
- 2) Understanding the roles of healthcare professionals:
 - a. MD vs DO, NP vs RN vs PA
 - b. technicians, administrators, and support staff
 - c. What is the difference in training and scope of practice?
 - d. How would that relate to product innovation (who has the most pull)
- 3) Identifying the right person for specific questions during shadowing
- 4) Effective communication strategies with healthcare providers
 - a. Must set up reminder framework
 - b. How to motivate people in healthcare
- 5) Homework: Pick a random person on linkedin and compose an email that you might send to them specifically as if you wanted to set up a meeting to discuss working together. Be as creative as you need to be, ex. Make up a product that you are working on that they could provide feedback on.

Week 4: Medical terminology and clinical documentation

- 1) Discuss homework: pick 2-3 best and worst (could be improved)
- 2) Detailed discussion on medical terminology, expanding into disease classification
 - a. Overview of some of the most common (BMI, BP, asthma)
 - b. Include how this effects diagnostic codes and what THAT means
 - c. Connect back to how understanding the jibberish will help with journal club/skimming
- 3) Understanding clinical documentation
 - a. HIPAA compliance
 - b. informed and implied consent components – reminder they have a HW on this in week 10
 - c. Why do we document and is it required for EVERYTHING
 - d. Demonstrate how to skim a patient chart?
- 4) Preliminary shadowing at hospitals ? like a how to? Could discuss template for documenting shadowing insights
- 5) Discuss the start of journal club, importance and expectations
 - a. 15-30minutes at the end of class, 5m per article to be discussed)
 - b. Each journal club will be about one specialty, can either assign one journal per group or have one journal per person in a group (and only that group presents, all other groups are supposed to read the articles but not present)
 - c. Quick example of a journal club presentation (oral, how to be brief about medical terms)

Week 5: Basics of Clinical Research

- 1) Intro to clinical research methodologies
 - a. Stages of FDA approval/phases of clinical trials
 - b. Overview statistical models commonly used and how that would affect study design
- 2) How to research journal articles
 - a. Literature review approaches, formats
 - b. How to evaluate new vs old medical research, not like basic science (the facts change)
- 3) First journal club discussion, plan for closer to 30m for more teaching this first time
- 4) Homework: urology-based journal club (special guest Urologist Dr. Harper)

Week 6: Critical Analysis of clinical research articles

- 1) Dr. Harper would be leading journal club for this session, since that is basically the entire goal for this class he could take longer to discuss how he analyzes or we dive deeper into understanding statistical models. Could consider switching week 5 and 6 lecture content so that we can flow from the first journal club presentations into more about clinical research articles and put off FDA/lit review discussion for week 6.
- 2) How to read and interpret clinical research papers
- 3) Understanding study designs and results
- 4) Homework: endocrinology/internal med based journal club (special guest Endocrinologist Dr. Cramer)

Week 7: Regulatory Frameworks in Biomedical innovation*

- 1) Overview of regulatory bodies
 - a. May be overviewed enough by now, this may be a good overflow week if it takes longer than expected to get through any earlier content
- 2) Key regulations and guidelines (GCP, ISO standards)
- 3) Regulatory pathways for medical devices
- 4) Homework – journal club break or space for scheduling conflict (drs sometimes have emergencies)
 - a. Write an informed consent for a procedure in your group’s specialty

Week 10: Ethics in Hospitals and Clinical research

- 1) Ethical principles in healthcare (autonomy, beneficence, non-maleficence, justice)
- 2) Informed consent in clinical settings
 - a. Go over homeworks and provide feedback
- 3) Handling ethical dilemmas in hospital environments
 - a. Present common board exam questions about this as difficult examples
- 4) Case studies on ethical issues in clinical research
- 5) Homework – anesthesia or pharmacy journal club (special guest Dr. Mehta)

Week 11: Clinical Application in Biomedical device development

- 1) Translating Clinical research into finding an unmet need
 - a. Check in on group project status, roadblocks, questions with 2 weeks until due date
- 2) Case studies of medical device development
- 3) Developing needs statements using evidence-based research
- 4) Homework – cardiothoracic journal club (special guest Dr. Odeh)

Week 12: Emerging trends in Clinical Research and Innovation

- 1) Personalized medicine and genomics
 - a. Role of AI in every crevice of healthcare (research, documentation, prosthetics/implants)
 - b. Patient initiated care and therapy – social trend
- 2) Digital Health and telemedicine
 - a. Role of app-based care
- 3) Future directions of clinical science and biomedical innovation
- 4) Homework: use AI in some aspect of your group project and document its use appropriately

Week 13: Final assessment (group project presentation)

Course Requirements & Grading

Description of Major Graded Components:

The principle deliverables for this course are the following: I didn’t alter this but I can tell it needs adapting

- A. Documentation of understanding for critical lecture materials (HIPPA, consent, etc.)
- B. Critiques of medical literature
- C. Observational journals from clinical shadowing
- D. Final project team presentation

Student teams are expected to finalize the above items for their clinical projects by end of Fall semester.

Assignment	Weight (Percentage, points, etc)
Weekly Homeworks	10%
Presentation Quizzes	10%
Journal Club	10%
Hospital Shadowing Journals	30%
Final Project Presentations	20%
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

Identify someone on your healthcare team that you have worked with enough for them to provide feedback on you. Spend at least 1 hour in a setting outside of the hospital to have an open conversation to discuss your performance as well as how they think a biomedical engineer could best support their work/clinic/etc (open-ended). Give a 5 minutes oral presentation to the class or write a one page single space reflection.

OR

Hand-write at least 3 personalized thank you notes to people you worked closely with in your placement. Send a picture showing evidence they were mailed/delivered for credit (picture at the mailbox or of a letter in a mail cubby ok).

These could both turn into homeworks instead for teams not actively working on journal club articles

Course Materials

Course Text

Biodesign: The Process of Innovating Medical Technologies, Zenios, Makower, Yock, Cambridge University Press, Second edition, 2015.

Additional Materials/Resources

N/A

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 experiences 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.
- Avoid 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 be 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 (typically a letter grade per week after the original due date, in the absence of an accommodation).

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 avoid using cell phones during class. All laptops, iPads, Kindles, and other electronic devices etc. must be turned off during class unless being used for notes or as part of a classroom exercise. You may be dismissed from class if you are using an electronic device that causes a disturbance and is 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 are used for this course, Canvas 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 Georgia Tech research facilities.

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