

BMED 6505 Syllabus – Fall, 2026**Module 1: Project Management****Instructor Information**

Michael Fisher

Email: michael.fisher@bme.gatech.edu

Class Times

6:30-7:45 pm

Module 2: Fundamentals of Biomedical Innovation, Development Processes and Manufacturing Strategy**Instructor Information**

Tom Godfrey

Email: tom.godfrey@clearsidebio.com

Class Times

6:30-7:45 pm

Module 3: Introduction to Lean Six Sigma**Instructor Information**

Dr. Robert (Bob) Myers

Phone: 404-385-4474

Email: bob.myers@scheller.gatech.edu

Class Times & Dates

6:30-7:45 pm

Final Grade

Module 1	33%
Module 2	33%
Module 3	33%

BMED 6505 Syllabus – Fall, 2026**BMED 6505 Syllabus (Module 1): Product Planning and Project Management****Class Times**

6:30-7:45 pm

Instructor Information

Michael Fisher

Email: mfisher36@gatech.edu

Phone: 774-766-2793

Scheduling: <https://calendly.com/mfisher36> or office hours**Required Materials**

- No textbook required
- Harvard Business Publishing course pack available on-line electronically or in print at: <http://cb.hbsp.harvard.edu/cbmp/access/66719707>

General Information**Description**

In this course, students will learn and start using the tools and practices used in medical product development.

Medical devices are defined by regulatory agencies as any product intended for use in the diagnosis or treatment of disease or other conditions in animals or man.

Every product ever developed, every building ever built, every program ever written, every app that was ever downloaded is the result of a project.

A project is a temporary endeavor undertaken to accomplish a unique product, service, or result.

Project Managers play an essential role in the smooth and successful execution of initiatives. Often working in teams, they ensure project alignment with business objectives, secure and track resource use, keep channels of communication open with all important stakeholders, and apply best practices of the project management field to complete projects on time, within budget, and to meet specifications. This section of the class will educate the student about project management principles and best practices in addition to compliance requirements super-imposed by key regulatory agencies (US FDA Quality Systems Regulations and ISO 13485 Quality Management System).

Pre- &/or Co-Requisites

MBID student status

Course Goals and Learning Outcomes

Each assignment, activity and evaluation in this course relates to one or more of these five course objectives:

1. Define basic concepts of project management as evidenced by homework and tests
 - a. Project Management International (PMI) terminology, processes, and tools
 - b. Project management within a regulatory framework (FDA Quality Systems Regulations and ISO 13485)

2. Create a project team by defining roles, responsibilities, and deliverables as evidenced by each team's RACI matrix (Responsible, Accountable, Consulted, Informed)
3. Create a project charter as evidenced by each team's project charter
4. Create a work break down structure (WBS) for a project that complies with regulatory requirements as evidenced by each team's WBS
5. Translate a WBS into a Gantt chart and project plan that reflects current best practices in the medical industry as evidenced by each team's Gantt chart and class presentation
6. Demonstrate the importance of communication, leadership, and ethics in project management, the nature of the challenges managers face, and some methods for meeting those challenges as evidenced by individual attestation to Georgia Tech's ethics policy and completion of homework assignments
7. Demonstrate proficiency in updating the various parts of a project plan as the project unfolds, and communicating changes to stakeholders as evidenced by revisions to WBS and Gantt chart deliverables

In addition, as future graduates of the Georgia Tech, students are expected to demonstrate these abilities:

1. to be effective as part of a team
2. to create and convey deliverables in accord with techniques and standards common in industry and acceptable to the School

Course Grading Policy

Assignment	Weight (Percentage, points, etc)
Charter	10%
WBS and Presentation	20%
RACI Matrix	10%
Gantt Chart	20%
Class Participation	20%
Final Exam	20%

Extra Credit Opportunities

There is no extra credit. *Just do the work.* Posted grades are final unless the instructor failed to record a grade correctly or made a math error.

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 Expectations & Guidelines

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.
- Turn off cell phones during class. All laptops, iPads, and other electronic devices must not be a distraction 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).
- No leaving the classroom once class starts (unless needed bathroom break).
- Casual talking and other disruptive behaviors are not permitted while classes are in session.
- Food/eating is not permitted during class time.

- Professional attire is required when visiting off campus sites (including Grady rotations).
- All reports must be turned in on time per the deadlines mentioned in class.

GA Tech Honor Code

All students are expected to do original work for all course assignments and exams. Students are responsible for their own conduct and expected to adhere to GT Student Honor Code at the following site: <http://www.policylibrary.gatech.edu/student-affairs/academic-honor-code>

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 present generative AI content 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. Generative AI is a tool with appropriate and inappropriate uses. Use good judgement in using generative AI.

While students are permitted to use AI tools in this class, all work submitted for grading must be performed by the student. 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, and make sure that your brain and experience benefit from using this tool.

Course Schedule

Fall, 2026

Class	Reading	Topics	Homework Due (Chapter- Prob.)
1	N/A	Introduction to Project Management for Medical Product Development	N/A

		<ul style="list-style-type: none"> · PMI Project Management · FDA Quality Systems Regulation · ISO 13485 Quality Management Systems 	
2	<p>Assign HBR Coursepack BMED6505 – Project Planning</p> <p>Read “The Secrets of Great Teamwork”</p>	<p>Medical Device Design Controls and Project Planning / Building the Team</p> <ul style="list-style-type: none"> · High Functioning Teams · Managing peer-to-peer · Charter Documents · Accountability and Signatures 	Questions on teams during class
3	Read “Forming the Team: The Crew and Its Charter”	Contents of a charter document, forming your team’s charter, active working on individual team charters	N/A
4		<p>Phase 1 and Forming a Project Plan</p> <ul style="list-style-type: none"> · Phase 1 Deliverables <p>Project Plan Template</p> <p>Product Development SOP</p>	N/A
5		<p>Project and Program Management Roles & Responsibilities, RACI Matrix</p> <p>Project Definitions, Planning, & Work Breakdown Structure</p> <ul style="list-style-type: none"> · How to define the work in a project · Milestones are built from details · Deliverables versus work 	
6		<p>Development of timelines</p> <ul style="list-style-type: none"> · Gantt Charts · FS, FF, SF, etc. · Critical Path · Resource allocation and limitations 	Turn in Team Charter and RACI to Professor Fisher
7	N/A	<p>Presentations</p> <ul style="list-style-type: none"> · Present WBS & Gantt Charts to class 	Each Team Presents WBS and Gantt Charts to Class
8		<ul style="list-style-type: none"> · Unique issues with medical devices (regulatory review, NPV, de-risking, etc.) · Review 	

9		Final Exam	Final Exam COMPLETED
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BMED 6505 Syllabus (Module 2): Fundamentals of Biomedical Innovation, Development Processes and Manufacturing Strategy

Class Times

6:30-7:45 pm

Instructor Information

Tom Godfrey

Email: thegodfrey@att.net

General Information

Description

An overview of the medical device manufacturing strategy, process mapping and validation for medical devices, and the practice of manufacturing scale-up.

During Part II Presentations: During the Manufacturing Overview Sections, each team will present their current projects to the class and the ideas on how the proposed device will be manufactured. During the Process Mapping lesson, all three student groups will present an analysis of their project based on the lecture and on the Process Mapping topic. The presentations will relate the lessons of the module and how it relates to their current project.

Part II Team Project: The students will work with their assigned group to develop a detailed process map of a medical device assembly: 1) How components are assembled 2) Capture raw materials used and 3) Define the quality input needed for each step.

Part II Process Map Project: The groups will present their process maps, discuss their decisions, and obtain input from their peers. Grading for Process Map project will be based on the following factors: 1) Presentation of Process Map, 2) Synthesis of facts and data 3) Generation of ideas and 4) Problem-solving approach.

Course Grading Policy

Assignment	Weight (Percentage, points, etc)
Team Project	20%
Team Presentations	20%
Discussion/write up of Case Studies presented in class	25%
Class Participation	10%
Final Exam	25%

Extra Credit Opportunities

There is no extra credit. *Just do the work.* Posted grades are final unless the instructor failed to record a grade correctly or made a math error.

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 Schedule
Fall, 2026**

Class	Reading	Topics	Homework Due (Chapter- Prob.)
1		Manufacturing Overview	
2		Manufacturing Scale Up Overview	
3		Process Mapping	
4		Process Mapping Team Presentations and Case study Introduction	
N/A		Fall Break	
5		Understanding Process Validation for Medical Devices, Quality and FDA Guidance	
6		Equipment Specifications and Considerations	
7		Technology Transfer Strategy and Process	
8		Technology Transfer Strategy and Process	
9		Packaging Design and Engineering Considerations	
10		Final Exam in Class	

BMED 6505 Syllabus (Module 3): INTRODUCTION TO LEAN SIX SIGMA

Class Times

6:30-7:45 pm

Instructor Information

Dr. Robert (Bob) Myers

Phone: 404-385-4474

Email: bob.myers@scheller.gatech.edu

Required Materials

- *MS Excel for statistics and calculations*

General Information

Description

This course is an introduction to the data driven Lean Six Sigma methodology and is structured around the five phases of the DMAIC model for improving quality and performance: Define, Measure, Analyze, Improve, and Control. Topics to be covered are shown in the course schedule below.

Course Grading Policy

The Final Grade is based on the following breakdown:

Class Participation	20%
Homework	30%
LSS Yellow Belt Exam	50%

Work Ethic & Classroom Etiquette

- This is a professional Master's Program, calling for Professionalism in all aspects.
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- Turn off cell phones during class. All laptops, iPads, and other electronic devices 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).
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- Professional attire when visiting off campus sites (including Grady rotations).
- All reports must be turned in on time per the deadlines mentioned in class.

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Course Schedule
Fall, 2025

Class	Topics	Homework Due (Chapter- Prob.)
1	<ul style="list-style-type: none"> • What is Six Sigma? • Normal Distribution • Six Sigma at Academic Medical 	
2	<ul style="list-style-type: none"> • What is Lean? • Identifying Waste • Implementing Lean at Ceasars Casino 	
3	<ul style="list-style-type: none"> • What is Lean Six Sigma? • Define <ul style="list-style-type: none"> ○ Problem/Goal Statements ○ CTQ's ○ Business Case 	
4	<ul style="list-style-type: none"> • Measure <ul style="list-style-type: none"> ○ Fishbone ○ Data Collection Plan ○ Sigma Level 	
5	<ul style="list-style-type: none"> • Analyze <ul style="list-style-type: none"> ○ Scatter Plot ○ ANOVA ○ Other tools 	
6	<ul style="list-style-type: none"> • Improve <ul style="list-style-type: none"> ○ 12 rules for idea formulation ○ Poke Yoke 	
7	<ul style="list-style-type: none"> • Control <ul style="list-style-type: none"> ○ FMEA 	
8	<ul style="list-style-type: none"> • Statistical Process Control 	
	THANKSGIVING	
9	<ul style="list-style-type: none"> • LSS Yellow Belt Exam / Wrap up 	