

PRELIMINARY SYLLABUS

Development and Regulation of Medical Products - BME 416L Syllabus – 2022 Spring Semester Prof. Gerald E. Loeb

1. Basic Information

<i>Course name:</i>	Development and Regulation of Medical Products
<i>Units:</i>	4
<i>Place and time:</i>	Lectures: Fridays 2:00-4:50PM, THH 208 Lab Workshops: Wednesdays 3:30-6:20PM, TBD
<i>Faculty:</i>	Gerald Loeb, MD, Dept. of Biomedical Engineering, gloeb@usc.edu Office hours will follow all regular lectures (5-6PM) and other times TBD Susan Bain, D.R.Sc., Dept. of Regulatory & Quality Science, bain@usc.edu
<i>Producer:</i>	TBD
<i>Textbook:</i>	Design of Biomedical Devices and Systems, King et al., eds., CRC Press, Taylor & Francis Group, 4 th ed., 2018, ISBN: 9781138723061 (available as ebook) Clinical Evaluation of Medical Devices, Becker & Whyte, eds., Humana Press, 2006, posted electronically

2. Course Goal and Learning Objectives

2.1 Goals: BME 416 is designed to introduce you to the world of medical product development. Medical devices, drugs and diagnostics are highly regulated products. Special measures are associated with developing safe and effective products for humans and animals and these affect the way that biomedical industries are structured and operate. To be successful in such environments, the biomedical engineer should understand and be able to apply the rules and regulations that govern the design, fabrication, sale and service of medical products. He or she should also know how other aspects of the business affect the environment in which the engineer must work.

2.2 Course Objectives (relation to ABET BME Student Outcomes at the end of this Syllabus):

After completing this course, you should be able to:

- Describe the typical structure and goals of different departments in a biomedical business, and recognize when individuals from these departments should be involved in decisions about medical product development (outcomes 2, 3, 5)
- Understand intellectual property rules sufficiently to read a patent effectively, write an invention disclosure and review the patent literature without assistance (outcomes 2, 7)
- Describe the role of the FDA in the oversight of medical products, and identify the classes of products and their applicable regulations (outcomes 2, 4)
- Identify the types of safety and efficacy testing that must be applied to implantable devices and drugs prior to use in humans (outcomes 1, 2)
- Apply design controls to new product development (outcomes 1, 2, 5, 6)
- Design and manage a clinical trial under Investigational Device Exemption rules (outcomes 4, 6)
- Develop a rudimentary qualification test plan for a new product based on a faults and hazards analysis (outcomes 1, 6)
- Describe the basic principles and components of a quality assurance program (outcomes 1, 2, 6)
- Implement and maintain Good Manufacturing Practices, including standard operating procedures, travelers, inspections, etc. (outcomes 1, 2, 3, 5)
- Understand and avoid potential ethical and legal liability problems (outcome 4)
- Design, prototype, and document a health-related product accounting for design controls, validation tests, and the needs and safety of its users (outcomes 2, 3, 4, 5)

BME 416 strongly contributes to ABET student outcomes 2, 4 and 6.

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3. Course Plan:

The course plan is built around three-hour sessions designed to introduce you to different aspects of product invention and development. Case studies, projects and outside speakers will be used to help you to understand the world outside our ivory tower. As in the real world, there is a strong emphasis on teamwork and on active individual participation in the relatively long and intense classroom sessions.

Session	Date	Primary Lecturer	Guest Lecturer	Topic	Reading	Activity
1	Jan. 14	Loeb		Principles of Regulation and Development	4, 16, 17	Quiz
2	Jan. 21	Loeb	Karten Olson	Ergonomics & Design	2, 9, 10	Quiz
3	Jan. 28	Loeb	(Singh)	Design Controls, Documents, Risk	6, 7, 12, posted	Quiz
4	Feb. 4	Loeb	(Kow)	Engineering Project Management	3	First Exam 3-4PM & Discussion 4-5PM
5	Feb. 11	Loeb	(Zhou)	Biomaterials & Biocompatibility	11, 13, 14 posted	Quiz
6	Feb. 18	Richmond	(Nanduri)	Product Classification	16	Quiz
7	Feb. 25*	Bain	(Ma)	Clinical Trials	Clinical Evaluation Chapters 1&2	Quiz
8	Mar. 4*	Bain	(Ramachandran)	Quality Systems	21	Quiz Project 1 due
9	Mar. 11	Loeb	(Hauschild)	Intellectual Property	20	Quiz
	Spring break					
10	Mar. 25	Loeb		Business Plans		Final Exam 3-5PM Project 2 due
11	Apr. 1	Loeb	Richmond	Marketing & Reimbursement	posted	Final Exam Discussion 4-5PM
12	Apr. 8	Loeb		Business & Finance	24	Final Exam self-grading due
13	Apr. 15	Loeb	Richmond	Ethics & Careers & Presentations	23	
14	Apr. 22	Loeb	Bain, Richmond	Project 3 Group Presentations		Group oral presentations
15	Apr. 29*	Bain	Doris Ng Santiago Kow	Field Trip – Medtronic Diabetes Care, Chatsworth		
	May 6					Group written reports due
Suggested opportunity				MD&M Exposition – Anaheim, April 12-14 https://mdmwest.mddionline.com/		

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Laboratory Topics by session (tentative):

1. Business Plan Templates for MS-Word - Loeb
2. Human Factors Analysis – Aly McDonald
3. Risk Analysis
3. Validation Testing
6. FDA databases and searches - Richmond
7. Clinical Trials Searches and Reporting - Richmond
9. Patent Searches - Loeb
10. Business Plan Financial Templates for MS-Excel - Borzage
11. CMS Reimbursement Database – (CTIP)

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4. Assignments

Project 1: Clinical Trial Design: You will be asked to determine the sample size required to achieve statistical significance for demonstrating the efficacy of a new medical product according to some outcome measures.

Project 2: Patent Analysis: Pick any medical product in which you might be interested (hint: pick something related to your Project 3 topic). Find a few of the most relevant patents and explain what licenses you might need to make and sell a competing or improved product.

Project 3: New Product Development: You will work as a team to perform a business analysis of a new medical product opportunity. This can be to meet an unfilled need of which you are personally aware, a new technology that interests you, or a new product being developed by academia or industry. You may choose to conduct and present this analysis from the perspective of the technology team that is pitching the opportunity, senior management of a company that is considering acquiring the product or the company that developed it, or venture capitalists considering investing in the opportunity.

BUSINESS ANALYSIS

(typical structure listed below; inclusion and emphasis will depend on nature of the product)

- 1 **Executive Summary**
- 2 **Market Opportunity and Requirements**
- 3 **Product Design, Intellectual Property and Competition**
- 4 **Risk Analysis and Regulatory Strategy**
- 5 **Business Plan for Non-Recurring Engineering, Manufacture, Sales & Marketing, Reimbursement and Cash Flow**
- 6 **Team Organization and Individual Contributions**
- 7 **Appendices (statistical analyses, pro forma budgets, important patents, etc.)**

The written Business Analysis can be any length and can include any supporting documentation deemed important, but it will be graded primarily on its prioritization of the most important issues for the product opportunity, its coherence with the Executive Summary and the support for those conclusions. One important part of a Business Analysis would be an assessment of the contributions and capabilities of the team performing the analysis (Item 6). The Business Analysis will be presented orally to judges in the last session. This presentation should include only a brief technical description to introduce the concept and its state of development, focusing on those aspects that are most important for the feasibility of the business. One or more members of your team may present orally but the total time must not exceed the time allotted for the team.

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5.0 Evaluation & Computation of Final Grade

Class Quizzes (best 6 of 8)	10%	
Individual Project 1	10%	
Individual Project 2	10%	
Group Project 3		
Oral Presentation	20%	
Written Report	10%	
First examination	10%	covering material in the prior lectures
Final examination	30%	cumulative of all material in sessions 1-9

Exams are intended mostly to focus you on the important knowledge of the course rather than to assess your performance. All quizzes and exams will be given within the regularly scheduled class session **IN REAL TIME ONLY**. The exams are open book and open notes but email or other messaging is prohibited. The questions will be mostly short answer and essay forms requiring subjective analysis rather than just memorization. The final exam will be graded initially as received, followed by a discussion next week of useful answers. Students will then be asked to mark up their own exams with their own grades and comments and corrections, which will be taken into account in assigning a final grade.

The brief quiz at the beginning of the 8 designated lecture sessions will cover the assigned readings. This is to assure that everyone is prepared for a useful discussion. Only the best 6 of 8 such quizzes will be counted, so no problem if you miss a live class. The **first exam** is intended to help students calibrate their study methods and performance answering questions that require the ability to integrate knowledge to solve realistic problems.

Delays in submitting reports will be tolerated only if special circumstances exist and permission is granted before the deadline. Otherwise marks will be subtracted at a rate of 5% per day.

My philosophy of teaching, grading and cheating:

You are here to prepare for careers, not to get your ticket punched for the next academic hoop. When you apply for a job or are evaluated in one, the only thing that will matter is what you know and what you can do. I have interviewed and hired a lot of people when working in both industry and academia and I have never asked a student what grade they got in a course. I barely look at their cumulative GPA. I ask them probing questions like the ones I will ask you on the essay exams. I select those questions based on the courses and projects that they list on their resumes because by listing them they are claiming expertise. My job is to verify that they have that expertise. Getting A grades and a degree without having earned them simply postpones a career disaster until you have no opportunity to recover.

BME Student Outcomes:

Students who complete the BME program have:

1. an ability to identify, formulate, and solve complex engineering problems by applying principles of engineering, science, and mathematics
2. an ability to apply engineering design to produce solutions that meet specified needs with consideration of public health, safety, and welfare, as well as global, cultural, social, environmental, and economic factors
3. an ability to communicate effectively with a range of audiences
4. an ability to recognize ethical and professional responsibilities in engineering situations and make informed judgments, which must consider the impact of engineering solutions in global, economic, environmental, and societal contexts
5. an ability to function effectively on a team whose members together provide leadership, create a collaborative and inclusive environment, establish goals, plan tasks, and meet objectives
6. an ability to develop and conduct appropriate experimentation, analyze and interpret data, and use engineering judgment to draw conclusions
7. an ability to acquire and apply new knowledge as needed, using appropriate learning strategies.