

San José State University
Biomedical Engineering, College of Engineering
BME 274, Regulatory, Clinical & Manufacturing Aspects of Medical Devices,
Fall 2022

Course and Contact Information

Instructor:	Justin Lance
Office Location:	Online Only
Email:	justin.lance@sjsu.edu
Office Hours:	TBD
Class Days/Time:	Tu 6:00 – 8:45 PM
Classroom:	(Building and room number, or your online course web address)
Prerequisites:	BME 115, graduate standing; or instructor consent

Faculty Web Page and MYSJSU Messaging

Course materials such as syllabus, handouts, notes, assignment instructions, etc. can be found on the Canvas learning management system course website. All communications relevant to the course will be sent out using the Canvas messaging system (Canvas email and announcement board). Students are responsible for regularly checking with the messaging system through Canvas to learn of any updates.

Course Description

FDA regulations related to medical devices; planning and implementation of clinical trials; sterilization techniques; failure mode analysis; quality control for medical device manufacture; intellectual property; field trips to device manufacturers. Prerequisite: BME 115, Graduate standing; or instructor consent. **This course satisfies graduate-level GVAR.**

Course Goals

This course has two primary goals:

- To provide a solid foundation and appreciation of the following regulatory, clinical and manufacturing aspects of medical devices:
 - Key phases in the life cycle of a medical device, from conceptualization to post-launch activities
 - Tools to manage and document development activities
 - Regulations that relate to biomedical devices including the different classes of devices and the different regulations that pertain to each class
 - Regulations that pertain to the development and approval process and those that pertain to the manufacturing process and be able to distinguish between these
 - The manner in which clinical trials are designed and conducted, including the different requirements for different classes of biomedical devices
 - What constitutes Good Laboratory Practice (GLP)
 - What constitutes Good Manufacturing Practice (GMP)
 - Appropriate means of safeguarding intellectual property and proprietary information
 - Ethical issues related to the development, testing, deployment, and reliability of biomedical devices
 - How engineers can successfully collect users' (physicians') feedback for incorporation into design

- Industry trends and current developments and areas of focus
- **To enhance the students' competency in technical writing. This competency accounts for 30% of the grade for this course.**

Course Learning Outcomes (CLO) (Required)

Upon successful completion of this course, students will be able to:

1. **Analyze** and **describe** the numerous steps that are required in the development of a medical device from the concept phase to full-scale production, including short-term screening, qualification tests designed to characterize materials chemically and biologically, and advanced biocompatibility testing appropriate to the intended end use of the material.
2. **Identify** and **describe** quality requirements for the development, manufacturing and launch of medical devices
3. **Apply** risk assessment tools used in the medical industry for the development, manufacturing and launch of new medical devices.
4. **Identify** the different categories of biomedical devices, as defined by the Food and Drug Administration.
5. **Describe** the regulations that define the requirements to be met for FDA approval of biomedical devices.
6. **Explain** the structure and function of a Quality Management System
7. **Apply** different types of failure mode analysis with selected examples.
8. **Describe** the process of setting up pre-clinical trials for implantable medical devices or diagnostics devices and the (pre)clinical testing requirements.
9. **Describe** good laboratory practices with examples of acceptable and unacceptable laboratory practices.
10. **Describe** good manufacturing practices with examples of acceptable and unacceptable manufacturing practices.
11. **Describe** fundamentals for the selection and processing of materials used in medical devices and demonstrate knowledge of standard specifications for different materials used in different in-vitro and in-vivo applications (surgical implants, sensors, drug delivery systems, etc.) including chemical and mechanical requirements.
12. **Explain** significant current problems in medicine that require development of versatile and sophisticated biomedical devices.
13. **Demonstrate** competency in searching electronic data bases for literature relevant to a topic of interest.
14. **Demonstrate** the ability to write a cohesive and informative paper on a subject related to biomedical devices, including explaining the principles, biocompatibility considerations, design considerations, regulatory requirements, clinical trial requirements, and other pertinent factors.
15. **Describe** the packaging and marking requirements for biomedical devices.
16. **Demonstrate** the ability to discuss ethical issues related to the development, testing and use of biomedical devices.
17. **Describe** the steps that need to be taken to protect intellectual property.
18. **Demonstrate** the ability to understand future trends and road maps and the ability to use these in identifying future technological needs.

19. **Demonstrate** the ability to deliver a professional presentation, using presentation software, to an audience of peers.

Required Texts/Readings

Textbook

There is **no required textbook** for this course.

Other readings

Reading materials, including instructor handouts, lecture slides, published papers, and relevant chapters from other books will be provided via Canvas as either downloadable files or links to contents accessible via the university library. Students are expected to expand and supplement the readings provided by the instructor, by searching for additional peer-reviewed sources (books, journal articles...).

Library Liaison

Anamika Megwalu

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Course Requirements and Assignments

This is a three-unit course, letter-graded. This course can be used to satisfy the Graduate Writing Assessment Requirement (GWAR) if the student passes this course.

NOTE that [University Policy S16-9](http://www.sjsu.edu/senate/docs/S16-9.pdf), Course Syllabi (<http://www.sjsu.edu/senate/docs/S16-9.pdf>) states that “Success in this course is based on the expectation that students will spend, for each unit of credit, a minimum of 45 hours over the length of the course (normally three hours per unit per week) for instruction, preparation/studying, or course related activities, including but not limited to internships, labs, and clinical practica. Other course structures will have equivalent workload expectations as described in the syllabus.”

Attainment of the learning objectives (as listed above) will be assessed via assignments, field trip reports, quizzes, class projects, the final examination, and the term paper and presentation.

Homework assignments

Students are expected and encouraged to work together on assignments. However, the submission should be prepared individually. Homework must be turned in at the **beginning of class** on the due date. **Late submissions** will be assessed 10%/day off of the maximum possible score.

Writing assignments

A one-page, minimum 250-word report summarizing the key concepts covered by each guest lecturer must be turned in at the beginning of the following class period. Submission of a minimum of five such reports is required. This **weekly report** should clearly demonstrate what the student thought were the most important concepts covered, why they are important, and how they relate to biomedical devices. All assignments are to be word processed, Times New Roman 12pt font size, or equivalent, with one-inch margins. Hard copies of all assignments are to be submitted at the **beginning of class**.

Field trip reports

Two field trips to companies/facilities that are closely related to medical devices will be arranged during the semester. These field trips will occur during regular class meeting times, however it is possible that their

duration will exceed a class period. Attendance is **strongly encouraged** as this is a very important part of the class. The detailed schedule of the field trips, as well as the companies that will be visited, will be provided by the instructor at the beginning of the semester. For each one of the field trips, students will submit a *Field Trip Report*, which will follow the same format as the weekly writing assignments.

Term paper

Each student is required to prepare and submit a term paper addressing a technology or device that is currently available or is under development, with potential for future deployment. The term paper should focus either on a particular medical device, or a case history of a medical device failure. If the term paper focuses on a medical device, then it should include the following: (a) a general description of the device, (b) the related physiology and the problem/issue it addresses, (c) the market it serves and the potential size of the market, in the US and globally, (d) the regulatory aspects related to the device, (e) the pre-clinical trials required for the device, and (f) how the device is manufactured, or at the very least how one component of the device is manufactured, in detail. Students interested in writing their term paper on a case history of a medical device failure are required to discuss this with the course instructor first.

The term paper is an individual assignment. No collaboration with other students is allowed in the preparation and revision of this report. This report will be used to assess the student's competency in technical writing. **The competency demonstrated in technical writing accounts for 30% of the grade for this course.**

The paper must follow a minimum-length requirement of 3,000 words of text (approximately 12 double-spaced pages), **not including figures, tables, front and back materials.** *Front materials* should include a title page, abstract, table of contents, list of figures, list of tables, and list of symbols (when applicable). *Back materials* should include appendices (when applicable), acknowledgments (when applicable), and a list of all the references cited in the report. Page margins should be 1" on all sides and the font size should be 12 point. The term paper must be prepared in accordance with the Biomedical Engineering Department's Thesis Guidelines (posted on Canvas). **Citations and bibliography should follow the *Annals of Biomedical Engineering* referencing style.** In particular, references in the Bibliography section must list all sources that were used in preparing the report. They should be double-spaced, arranged alphabetically by author, and numbered serially, with only one reference per number. When using a citation manager software, such as EndNote, Mendeley, Zotero, PaperPile, etc., the proper citation format should be selected. **A minimum of 15 references from appropriate sources, such as books and peer-reviewed journal articles will be required.**

Students will complete the project report in four stages, with four deliverables. Feedback will be provided by the instructor for the first two and the final deliverable. The first deliverable will include a 250-word abstract and a proposed Table of Contents for the term paper, to be submitted no later than the *third week of the semester*. Second, a comprehensive literature review, including complete citations and abstracts, will be submitted no later than the *fifth week of the semester*. A preliminary draft of the final paper will be submitted by the *tenth week of the semester*. Each preliminary report will be peer-reviewed by two students selected randomly. Based on this feedback, the students will prepare a final, complete draft of the term paper, *due by the fourteenth week of the semester*. The purpose of the two early drafts is to provide students with adequate opportunity to receive instructor feedback and revise their paper accordingly. Each draft of the term paper must be submitted electronically to Canvas by the indicated deadline, and it will be scanned for plagiarism according to SJSU policy. Acceptable file formats are: .doc, .docx, .pdf. Additional, specific requirements for the term paper and the evaluation criteria will be posted on Canvas.

Students must cite any and every source of data or information used in the term paper. Quoting verbatim (i.e. "copy and paste") from papers, textbooks, websites or other is strongly discouraged. Very limited use of verbatim quotes is acceptable only if (1) the quoted text is short (maximum 50 words), (2) quotation marks are used to delimit the quoted

text, and (3) an appropriate reference is provided, with a citation number added immediately after the quoted text. Failure to comply with this requirement may be interpreted as plagiarism, which constitutes a violation of academic integrity. All term paper submissions will be automatically scanned in Turnitin to locate matching or similar text within the paper. The instructor will decide whether there is plagiarism case-by-case, in which case academic and administrative sanctions will be assigned according to the [University Academic Integrity Policy S07-2](http://www.sjsu.edu/senate/docs/S07-2.pdf) (<http://www.sjsu.edu/senate/docs/S07-2.pdf>). For additional information, students are encouraged to review the [video on plagiarism](http://libguides.sjsu.edu/plagiarism) at <http://libguides.sjsu.edu/plagiarism>.

Late submissions are strongly discouraged. However, under exceptional circumstances and pending instructor approval, in case of late submission of the term paper, points will be deducted as follows:

- One day late: -10%
- Two days late: -25%
- Three days late: -50%

No submission will be accepted later than three days after the deadline. Please note that this late submission policy only applies to the term paper assignment.

NOTE that [University policy F69-24](http://www.sjsu.edu/senate/docs/F69-24.pdf) at <http://www.sjsu.edu/senate/docs/F69-24.pdf> states that “Students should attend all meetings of their classes, not only because they are responsible for material discussed therein, but because active participation is frequently essential to insure maximum benefit for all members of the class. Attendance per se shall not be used as a criterion for grading.”

Presentations

All students are required to present their term paper in class, on the 14th and 15th week of the semester. The instructor will randomly select the sequence of presentations. Students must submit their presentation slides via Canvas by the 13th week of the semester. A group of SJSU faculty and external industry experts will be invited to evaluate and grade the presentations. The presentation will be graded separately from the term paper, as per Grading Policy section.

Final Examination or Evaluation

The final examination will be held on the date and time stipulated by SJSU’s Final Examination Schedule. The final examination will cover the entire course material covered during the semester. The final examination may include multiple-choice questions, open-ended questions, and problems.

Grading Information

Letter Grades:

- A plus = 97 to 100%*
- A = 93% to 97%*
- A minus = 90% to 93%*
- B plus = 87% to 90%*
- B = 83% to 87%*
- B minus = 80% to 83%*
- C plus = 77% to 80%*
- C = 74% to 77%*
- C minus = 70% to 73%*
- D plus = 67% to 70%*
- D = 64% to 67%*
- D minus = 60% to 63%*
- F = 60% or lower*

Weight of class assignments and examinations:

Homework = 10%

Writing assignments = 10%

Field trip reports = 5%

Term Paper = 30%

Presentation = 10%

Final Exam = 35%

Absence during examinations, without prior approval, will result in a zero. Prior approval will be given only under exceptional circumstances. Please contact the instructor as soon as possible if you have such a situation.

Note that “All students have the right, within a reasonable time, to know their academic scores, to review their grade-dependent work, and to be provided with explanations for the determination of their course grades.” See [University Policy F13-1](http://www.sjsu.edu/senate/docs/F13-1.pdf) at <http://www.sjsu.edu/senate/docs/F13-1.pdf> for more details.

Classroom Protocol**Attendance and arrival times**

Students are expected to be set up for lecture by the time the class begins. Attendance in class is not mandatory and shall not be used per se as a criterion for grading. However, class attendance and participation are highly recommended.

Behavior

Students should remain respectful of each other at all times. Interruptive or disruptive attitudes are discouraged. While in the classroom, the use of electronic devices (laptops, tablets, smartphones) should be limited to activities closely related to the learning objectives. While in the classroom, electronic devices should not be used for personal communication, included messaging and use of social media. All cell phones must be silenced prior to entering the classroom.

Students will respect a diversity of opinions, ethnicities, cultures, and religious backgrounds. Students will treat online discussions with their peers as if they were in-class, face-to-face interactions.

Safety

Students should familiarize themselves with all emergency exits and evacuation plans. Especially since class concludes in the evening, when departing the building, students should be aware of their surroundings, and carry a cell phone.

University Policies

Per [University Policy S16-9](http://www.sjsu.edu/senate/docs/S16-9.pdf) (<http://www.sjsu.edu/senate/docs/S16-9.pdf>), relevant information to all courses, such as academic integrity, accommodations, dropping and adding, consent for recording of class, etc. is available on Office of Graduate and Undergraduate Programs' [Syllabus Information web page](http://www.sjsu.edu/gup/syllabusinfo/) at <http://www.sjsu.edu/gup/syllabusinfo/>". Make sure to visit this page, review and be familiar with these university policies and resources.

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Course Schedule

Schedule is subject to change with fair notice. Notifications regarding schedule changes will be communicated via the course website on Canvas.

Week	Date	Topics	Term paper deadlines
1	23-Aug	Introduction to BME 274, course requirements	
2	30-Aug	Medical Devices: Product Life Cycle & Project Management Tools	
3	6-Sep	Quality System and Regulatory Submissions	Abstract and TOC
4	13-Sep	Prototyping and User Needs	
5	20-Sep	Design Controls	Lit review and bibliography
6	27-Sep	<i>Field Trip #1</i>	
7	4-Oct	Verification & Validation of a Medical or Diagnostic Device	
8	11-Oct	Medical Device Statistics	
9	18-Oct	Manufacturing Processes, Outsourcing, Suppliers	
10	25-Oct	Manufacturing Technology - Silicone	Complete preliminary draft
11	1-Nov	Regulatory Affairs/Corporate Submission (Post-Launch) and Reimbursement	
12	8-Nov	Types of Intellectual Property and their creation and protection	
13	15-Nov	Sterilization Preclinical Studies and Animal Model Selection	Complete final draft and submission
14	22-Nov	<i>Term Paper Presentations</i>	
15	29-Nov	<i>Term Paper Presentations</i>	
16	TBD	FINAL EXAMINATION	