

San José State University
College of Engineering, Department of Biomedical Engineering
BME 187, Medical Device Quality Systems, Fall 2022

Course and Contact Information

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| Instructor: | Madu Maruthamuthu |
| Office Location: | TBD |
| Email: | madu.maruthamuthu@sjsu.edu |
| Office Hours: | Monday & Wednesday 10:00AM-11:00AM |
| Class Days/Time: | Tuesday & Thursday 04:30PM-05:45PM |
| Classroom: | ENG341 |
| Prerequisites: | BME 147, BME 174; or instructor consent |

Course Format

Faculty Web Page and MYSJSU Messaging

Course materials such as syllabus, handouts, notes, assignment instructions, etc. can be found on [Canvas Learning Management System course login website](http://sjsu.instructure.com) at <http://sjsu.instructure.com>. 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

Introduction to the medical device quality systems framework. Topics covered include: document control, supplier management, training, audits, reliability assessment, feedback and monitoring, quality tools for investigation, and continuous improvement techniques. By the end of this course the student will have a good understanding of the principles of QMS, and the principles of product and service quality evaluation and control. Prerequisites: BME 147, BME 174; or instructor consent.

Course Learning Outcomes (CLO)

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

1. **complete** a basic regulatory compliance document for biomedical devices;
2. **formulate** basic statistical approaches towards maintaining quality systems in a biomedical manufacturing environment;
3. **apply** Good Laboratory Practices and Good Manufacturing Practices to examples from the biomedical device industry;
4. **describe** the FDA audit processes, including proper documentation;
5. **employ** standard Post Market Surveillance procedures to document, summarize, and interpret customer complaints and extract actionable items

6. **implement** Failure Modes and Effects Analysis (FMEA) and risk mitigation approaches, including Corrective and Preventive Actions (CAPA) to biomedical device manufacturing.
7. **discuss** the importance of the continuous improvement process and approaches to implementing it in a sustainable manner.

Required Texts/Readings

Required textbook (Note: Recommended for reference- generic quality engineering concepts)

- Sarah E. Burke, Rachel T. Silvestrini, The Certified Quality Engineer Handbook, Fourth Edition, Hardcover, 684 pages, Published 2017, ISBN: 978-0-87389-944-4

Other Readings

- “21 CFR Part 820 Quality System Regulation. Good Manufacturing Practice for Medical Devices” by Food & Drug Administration, Revised as of April 1, 2016. *A copy of this reference booklet is online and a link is provided in the schedule of topics and assignments.*

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

Phone: (408) 808-2089

Email: anamika.megwalu@sjsu.edu

Course Requirements and Assignments

“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 practice. 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 homework, two mid-term examinations, the final examination, and the term paper.

Homework

Homework assignments will include questions and problems related to the materials covered in the lectures. Students are expected and encouraged to work together on assignments. However, submitted homework should be individual work. Homework must be turned in at the **beginning of class** on the due date. **Late assignments** will be assessed 10%/day off of the maximum possible score.

Term paper

Each student is required to prepare and submit a term paper on a subject relevant to quality management systems for medical devices (in consultation with the course instructor).

The topic of the paper should focus on a documented example of product/process failure in the field of medical equipment and devices, with emphasis on possible violation of regulations and good manufacturing practices. The

paper should include a set of recommendations put forth by the student, that would have prevented the failure and/or mitigated its consequences on patients and healthcare system.

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.

Students will work in teams. Students will complete the project report in three stages, with three deliverables due by week 5, 10, and 14. Feedback will be provided for all three deliverables; only the final, complete draft will be graded. The report must include an Acknowledgments section indicating the specific contributions of each student. Students with no contribution will receive no credit for the term paper. 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, (2) quote 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 of the term project report are strongly discouraged. However, under exceptional circumstances and pending instructor approval, in case of late submission of the term project report, 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 project 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."

Midterm examinations

There will be one mid-semester examinations. The midterm exam will cover the entire course material covered until the time of the examination. It may include multiple-answer questions, open-ended questions, and problems. During the exam, students can have only a non-programmable scientific calculator. Internet-connected devices, books and notes are not allowed. The tentative date of the midterm examination is indicated in the Lecture Schedule.

Final Examination or Evaluation

The final examination will be held on the date and time stipulated by SJSU's Final Examination Schedule for the particular semester. 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. During the exam, students can have only a non-programmable scientific calculator. Internet-connected devices, books and notes are not allowed.

Grading Information (Required)

Determination of Grades

Letter Grades

A plus = 96 to 100%

A = 93% to 95%

A minus = 90% to 92%

B plus = 86% to 89%

B = 83% to 85%

B minus = 80% to 82%

C plus = 76% to 79%

C = 73% to 75%

C minus = 70% to 72%

D plus = 66% to 69%

D = 64% to 65%

D minus = 60% to 62%

F = 59% or lower

Determination of Grades

Grades will be determined based on all the assignments and examinations, weighted as reported in the table below:

Homework = 10%

Midterm Exam = 30%

Final Exam = 35%

Term Project = 20%

Term Project Presentation = 5%

Absence during examinations, without prior approval, will result in a zero. Prior approval will be given only under exceptional circumstances. Students should contact the instructor as soon as possible to seek approval.

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. Students will respect a diversity of opinions, ethnicities, cultures, and religious backgrounds. Interruptive or disruptive attitudes are discouraged. While in the classroom, the use of electronic devices (laptops, tablets, smartphones) **MUST** be limited to activities closely related to the learning objectives. While in the classroom, electronic devices should not be used for personal communication, including messaging and use of social media. All cell phones must be silenced prior to entering the classroom.

Zoom (Virtual Learning)

This course or portions of this course (i.e., lectures, discussions, student presentations) will be recorded for instructional or educational purposes. The recordings will only be enrolled in the class through Canvas. The recordings will be deleted at the end of the semester. If, however, you would prefer to remain anonymous during these recordings, then please speak with the instructor about possible accommodations (e.g., temporarily turning off identifying information from the Zoom session, including student name and picture, prior to recording).

Students are not allowed to record without instructor permission.

Students are prohibited from recording class activities (including class lectures, office hours, advising sessions, etc.), distributing class recordings, or posting class recordings. Materials created by the instructor for the course (syllabi, lectures and lecture notes, presentations, etc.) are copyrighted by the instructor. This university policy ([S12-7](#)) is in place to protect the privacy of students in the course, as well as to maintain academic integrity through reducing the instances of cheating. Students who record, distribute or post these materials will be referred to the Student Conduct and Ethical Development office. Unauthorized recording may violate university and state law. It is the responsibility of students that require special accommodations or assistive technology due to a disability to notify the instructor.

Safety

Students should familiarize themselves with all emergency exits and evacuation plans. In particular, if the class meeting ends in the evening, students should be aware of their surroundings when exiting the building, and are encouraged to carry a cell phone for emergency communications.

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](#) 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

(Subject to change with fair notice)

| Week | Date | Topics, Examinations | Special topics, Deadlines |
|------|---------------|----------------------------------------------------------------------------------------------------------------|--------------------------------|
| 1 | 23-Aug | Introduction, Goals, Syllabus. | |
| | 25-Aug | Intro to Quality Management System (part 1) | Homework #0 Due |
| 2 | 30-Aug | Intro to Quality Management System (part 2) | |
| | 1-Sep | Document Control System | Homework #1 Due |
| 3 | 6-Sep | Importance of GDP in medical device industry | |
| | 8-Sep | Robust Quality Systems Training in a regulated industry | Homework #2 Due |
| 4 | 13-Sep | Review/ Discussion | |
| | 15-Sep | Medical Device Quality System Audits: Overview | |
| 5 | 20-Sep | Medical Device Quality System Audits: Practice | Term Paper Draft #1 Due |
| | 22-Sep | Supplier Controls in a regulated industry -Part 1 | Homework #3 Due |
| 6 | 27-Sep | Supplier Controls in a regulated industry -Part 2 | |
| | 29-Sep | Risk Management | Homework #4 Due |
| 7 | 4-Oct | Risk Analysis tool- PFMEA | |
| | 6-Oct | Quality Tools | Homework #5 Due |
| 8 | 11-Oct | Control of Nonconformances | |
| | 13-Oct | Design Controls, Process controls | Homework #6 Due |
| 9 | 18-Oct | Midterm Exam 1 | |
| | 20-Oct | Finished Product Testing- destructive and non-destructive tests | |
| 10 | 25-Oct | Process Validation | |
| | 27-Oct | Process Validation | Homework #7 Due |
| 11 | 1-Nov | Corrective and Preventive Action (CAPA) | Term Paper Draft #2 Due |
| | 3-Nov | Corrective and Preventive Action (CAPA) | Homework #8 Due |
| 12 | 8-Nov | Feedback and monitoring of medical devices. Differences between pre- and post-market surveillance (Complaints) | |
| | 10-Nov | Feedback and monitoring of medical devices. Differences between pre- and post-market surveillance (Complaints) | Homework #9 Due |

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| 13 | 15-Nov | Continuous Improvement: Tools and Different planning tools | |
| | 17-Nov | Continuous Improvement: Techniques and Measurements | Homework #10 Due |
| 14 | 22-Nov | Continuous Improvement: Techniques and Measurements | Term Paper Final Submission |
| | 24-Nov | Thanksgiving Holiday – No Class | |
| 15 | 29-Nov | Mean Time Between Failure (MTBF) – Application, Reliability and Maintainability: Overview | |
| | 1-Dec | Term paper classroom presentation | Presentation slides due |
| 16 | 6-Dec | Final exam review | |
| | 8-Dec | Final Exam | |