

**San José State University**  
**College of Engineering, Department of Biomedical Engineering**  
**BME 276, Project Management in Biomedical Technologies, Fall 2022**

**Course and Contact Information**

Instructor(s):	C. Travis Rappleye
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Office Hours:	By arrangement in person or Zoom
Class Days/Time:	MW 7:30-8:45pm
Classroom:	CL202
Prerequisites:	Graduate standing, or instructor consent

**Course Description**

Project management integration into functional and decision-making processes; project management leadership skillset; fundamentals of project management tools applied to product R&D and commercialization, with emphasis on regulatory pathways, timeline management and risk mitigation; examples of project management challenges and opportunities.

**Course Format**

The course adopts traditional lecturing as a primary teaching method, combined with in-class discussions and problem-solving sessions.

**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 Learning Outcomes (CLO)**

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

1. **Discuss** the importance of project management in the biomedical technology sector.
2. **Distinguish** between a technical subject matter expert (SME) and a technically-savvy project manager.
3. **Formulate** strategies to maximize contribution as the member of a cross-functional project team.
4. **Evaluate** the design & tradeoffs of various organizational models used to enable project management.

5. **Develop** various device and therapeutic regulatory pathways, in light of the requirements and challenges discussed in class.
6. **Apply** techniques to develop and manage cross-functional timelines and manage risk in cross-functional, technical environments.
7. **Describe** the combination of soft (people) and hard (technical) skills required for project success as well as the power dynamics and political challenges typically faced by project teams.
8. **Identify** Project Management strategies to address challenges related to globalization and virtual teams.
9. **Compare** how Project Management is applied across the product development continuum and in big vs. small companies.

## Required Texts/Readings

### Required textbook

This class does not have a required textbook. Lecture slides and selected readings will cover most of the topics. Reference articles will be provided for those who would like to acquire background knowledge or seek more detail on the topics covered in class.

### 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

Phone: (408) 808-2089

Email: [anamika.megwalu@sjsu.edu](mailto: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. More details about student workload can be found in [University Syllabus Policy S16-9](http://www.sjsu.edu/senate/docs/S16-9) at <http://www.sjsu.edu/senate/docs/S16-9.pdf>.

Attainment of the course learning outcomes (as listed above) will be assessed via homework, in-class quizzes, two mid-term examinations and the term project.

### 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. Homework will either be required to be submitted individually or as a group, as noted in the assignment. Homework must be turned on the due date.

**Late assignments** will be assessed 10% per day off of the maximum possible score.

### **In-class quiz**

There will be regular in-class quizzes based on multiple-answer questions to help the instructor understand what you know and gives everyone a chance to participate in class.

### **Term project**

All students are required to complete a term project to demonstrate their applied knowledge of project management principles and techniques. The project will focus on the use of concepts and tools learned in this course. To successfully complete the term project, students will need a good understanding of the fundamentals of project management, the unique aspects of medical device and pharma development activity sequences and regulatory pathways, and issues stemming from organizational design and politics.

The requirements for the term project and the evaluation criteria will be posted on Canvas. Students will work in teams of two or three. A final project report will be submitted by the students through Canvas. 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.

A detailed description of the term project, including tentative timeline and grading rubric, will be distributed in class at the beginning of the semester.

**Late submissions of the term project** 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 two mid-semester examinations. The midterm exams 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 dates of the midterm examinations are 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**

### **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*

### **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 1 = 20%  
Midterm exam 2 = 20%  
Final exam = 20%  
Term Project = 30%  
Extra-credit = 2%

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. 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.

## **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 university policy concerning all courses, such as student responsibilities, academic integrity, accommodations, dropping and adding, consent for recording of class, etc. and available student services (e.g. learning assistance, counseling, and other resources) are listed on [Syllabus Information web page](http://www.sjsu.edu/gup/syllabusinfo) (<http://www.sjsu.edu/gup/syllabusinfo>), which is hosted by the Office of Undergraduate Education. Make sure to visit this page to review and be aware of these university policies and resources.