San José State University
College of Engineering, Department of Biomedical Engineering
BME 178, Biomedical Product Realization, Spring 2021

Course and Contact Information

Instructor:	Prof. Yun Wang
Office Location:	E 233I
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Email:	yun.wang@sjsu.edu
Office Hours:	Tuesdays and Thursdays 12:00 – 1:00 PM (https://sjsu.zoom.us/j/82828518500?pwd=cldxQzJKanhMMlFPR1dPSVJMYzZzZz09 Password: 519104)
Class Days/Time:	Mondays and Wednesdays 1:30 – 2: 45 PM
Classroom:	Zoom (https://sjsu.zoom.us/j/88908454692?pwd=UWI0RTJxWkZaNEpEd3Jvbklae nJMdz09 Password: 943966)
Prerequisites:	**ENGR 100W, BME 117, BME 174, ChE/ISE 162 (≥ C-) all with a grade of C- or better.**

Course Format

The course adopts online lecture format as a primary teaching method, both synchronous and asynchronous, combined with in-class discussions. In class each student is required to have an internet-connected device (e.g. smartphone, tablet, laptop computer) to be used exclusively for learning-related activities.

Canvas System

Course materials such as syllabus, handouts, notes, assignment instructions, etc. can be found on the Canvas learning management system course website. You are responsible for regularly checking with the messaging system through Canvas to learn of any updates. Video lectures will be posted on Canvas.

Course Description

This is a course on the basics of product realization from concept to clinical trials. It is intended to prepare students for their subsequent career(s) in a variety of bioengineering sectors; this will be reflected and emphasized throughout the course. Specific topics that will be covered include:
- Product Concept
- Research & Development
- Design Controls in Application
- Design Verification and Design Validation
- Process Control in Application
- Software Validation
- Effective Risk Management
- Engineering and Quality Management System Practices

- Project

Course Learning Outcomes (CLO)

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

1. Demonstrate knowledge of **Product Concept** in terms of: Problem Statement and Solution, Market Value & Humanitarian Use, Documentation and Intellectual Property, Preliminary Testing & Proof-of-Concept, Early Risk Assessment & Efficiency

2. Demonstrate knowledge of **Research & Development** in terms of: Team and Efficiency, Laboratory Management, Effective R&D Techniques and Timing, Goal Oriented Development, Design for Manufacturability, Early Phase Process Development

3. Demonstrate knowledge of **Design Controls in Application** in terms of: R&D, Regulatory, Quality, and Manufacturing Plans & Schedules, Design History File and Document Control, Phases and Documentation, Phase Execution & Techniques, Design Inputs and Outputs, Design Verification & Validation Model Creation

4. Demonstrate knowledge of **Design Verification and Design Validation** in terms of: Preliminary Testing, Design Verification, Design Validation, Failure Resolution and Success Planning, and Timing Techniques

5. Demonstrate knowledge of **Process Control in Application** in terms of: Process Development for Medical Devices, Process Validation, Control and Monitoring Techniques, Change Implementation

6. Demonstrate knowledge of **Software Validation** in terms of: Design Verification and Design Validation, Design Verification and Design Validation

7. Demonstrate knowledge of **Effective Risk Management** Techniques and Best Practices

8. Demonstrate knowledge of **Engineering & Quality Management System Practices** in key areas of Material Review, Corrective and Preventative Action, Product Experience using key techniques such as Root Cause Analysis, Justification Techniques and Documentation, Verification of Effectiveness

Required Texts/Readings

Textbook

FDA based Materials (posted on Canvas)

Other Readings

1. FDA Medical Devices Listing of CDRH Humanitarian Device Exemptions
   https://www.fda.gov/medical-devices/hde-approvals/listing-cdrh-humanitarian-device-exemptions
2. FDA Medical Device Meetings and Workshops
   https://www.fda.gov/medical-devices/news-events-medical-devices/workshops-conferences-medical-devices
3. CDRH Learn
   https://www.fda.gov/training-and-continuing-education/cdrh-learn
4. Jadad Alejandro R , Enkin Murray W. (2007), ***Randomized Controlled Trials: Questions, Answers and Musings***, BMJ Books.
5. World Health Organization (2005), ***Handbook for good clinical research practice (GCP) : guidance for implementation***. http://whqlibdoc.who.int/publications/2005/924159392X_eng.pdf. Accessed on 12/20/2012.
6. Box G. E. P., Hunter J. S., Hunter W. G. (2005), ***Statistics for experimenters: design, innovation, and***

discovery, Wiley Interscience.

7. Vidakovic B. (2011), ***Statistics for Bioengineering Sciences,*** Springer.

Library Liaison

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Course Requirements and Assignments

SJSU classes are designed such that in order to be successful, it is expected that students will spend a minimum of forty-five hours for each unit of credit (normally three hours per unit per week), including preparing for class, participating in course activities, completing assignments, and so on. More details about student workload can be found in University Policy S12-3 at http://www.sjsu.edu/senate/docs/S12-3.pdf.

Reading Assignments

Students are required to complete reading assignments that correspond with the topics listed in the course schedule. This will prepare them for answering questions based on specific topics covered.

Seminar

Product Realization related events. Attend a minimum of 6 events and write a 200-word summary for each event you attend.

- Bio2device: Bio2Device Events Typically on Tuesdays
- Bay area Life Science events
- Rosenman Institute: D-Series
- Green Light Guru: Webinars and events
- SJSU Events
- (Mandatory) Bay Area Biomedical Device Conference: https://www.biomedconference.org/

Assignments and requirements will be posted on Canvas. *Late submissions* of all assignments will be assessed 1.5%/hour off of the maximum possible score.

Grading Policy

The percentage weight assigned to various class exams and assignments are listed in the table below

		Component	Contribution (%)
A+	> 97%		
A	> 93% – 97%		
A-	> 90% – 93%	Requirements Specification	30
B+	> 87% – 90%	Seminar	10
B	> 83% – 87%	Business Model Canvas (BMC)	10
B-	> 80% – 83%	S and E quiz	10
C+	> 77% – 80%	Final Exam (cumulative)	30
C	> 73% – 77%	Reading	10
C-	> 70% – 73%	Extra Credit	5
D+	> 67% – 70%		
D	> 63% – 67%		
D-	> 60% – 63%	Total	105
F	< 60%		

NOTE that University policy F69-24 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."

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 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 for synchronous sessions. 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. During the online synchronous sessions, the use of electronic devices (laptops, tablets, smartphones) should be limited to activities closely related to the learning objectives. All cell phones must be silenced prior to entering the synchronous sessions.

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.

Online Instruction Policies and Expectations

Proctoring software and exams

Exams will be proctored in this course. Please note it is the instructor's discretion to determine the method of proctoring. If cheating is suspected the proctored videos may be used for further inspection and may become part of the student's disciplinary record. Note that the proctoring software does not determine whether academic misconduct occurred, but does determine whether something irregular occurred that may require further investigation. Students are encouraged to contact the instructor if unexpected interruptions (from a parent or roommate, for example) occur during an exam.

Recording zoom classes

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 shared with students 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.

Technology requirements

Students are required to have an electronic device (laptop, desktop or tablet) with a camera and microphone. SJSU has a free equipment loan program available for students. Students are responsible for ensuring that they have access to reliable Wi-Fi during tests. If students are unable to have reliable Wi-Fi, they must inform the instructor, as soon as possible or at the latest one week before the test date to determine an alternative. See Learn Anywhere website for current Wi-Fi options on campus.

Zoom classroom etiquette

- Mute your microphone: To help keep background noise to a minimum, make sure you mute your microphone when you are not speaking.
- Be mindful of background noise and distractions: Find a quiet place to "attend" class, to the greatest extent possible.
  - Avoid video setups where people may be walking behind you, people talking/making noise, etc.
  - Avoid activities that could create additional noise, such as shuffling papers, listening to music in the background, etc.
- Position your camera properly: Be sure your webcam is in a stable position and focused at eye level.
- Limit your distractions/avoid multitasking: You can make it easier to focus on the meeting by turning off notifications, closing or minimizing running apps, and putting your smartphone away (unless you are using it to access Zoom).
- Use appropriate virtual backgrounds: If using a virtual background, it should be appropriate and professional and should NOT suggest or include content that is objectively offensive or demeaning.

Online exams

Testing Environment: Setup (example)

- No earbuds, headphones, or headsets visible.
- The environment is free of other people besides the student taking the test.
- If students need scratch paper for the test, they should present the front and back of a blank scratch paper to the camera before the test.
- No other browser or windows besides Canvas opened.
- A workplace that is clear of clutter (i.e., cellphone, tablets, smart watches, monitors, keyboards, gaming consoles, etc.)
- Well-lit environment. Can see the students' eyes and their whole face. Avoid having backlight from a window or other light source opposite the camera.
- Personal calculators.

Testing Environment: Scan (example)

Before students can access the test questions, they are expected to conduct a scan around their testing environment to verify that there are no materials that would give the student an unfair advantage during the test. The scan will include:
- the desk/work-space
- a complete view of the computer including USB ports and power cord connections
- a 360-degree view of the complete room
Students must:
- Remain in the testing environment throughout the duration of the test.

- Keep full face, hands, workspace including desk, keyboard, monitor, and scratch paper, in full view of the webcam

Technical difficulties

Internet connection issues:

Canvas autosaves responses a few times per minute as long as there is an internet connection. If your internet connection is lost, Canvas will warn you but allow you to continue working on your exam. A brief loss of internet connection is unlikely to cause you to lose your work. However, a longer loss of connectivity or weak/unstable connection may jeopardize your exam.

Other technical difficulties:

Immediately email the instructor a current copy of the state of your exam and explain the problem you are facing. Your instructor may not be able to respond immediately or provide technical support. However, the copy of your exam and email will provide a record of the situation.

Contact the SJSU technical support for Canvas:

Technical Support for Canvas
Email: ecampus@sjsu.edu
Phone: (408)924-2337
https://www.sjsu.edu/ecampus/support/

If possible, complete your exam in the remaining allotted time, offline if necessary. Email your exam to your instructor within the allotted time or soon after.

University Policies

Per University Policy S16-9 *(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), 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.

General Expectations, Rights and Responsibilities of the Student

As members of the academic community, students accept both the rights and responsibilities incumbent upon all members of the institution. Students are encouraged to familiarize themselves with SJSU's policies and practices pertaining to the procedures to follow if and when questions or concerns about a class arises. See University Policy S90–5 at http://www.sjsu.edu/senate/docs/S90-5.pdf. More detailed information on a variety of related topics is available in the SJSU catalog, at http://info.sjsu.edu/web-dbgen/narr/catalog/rec-12234.12506.html. In general, it is recommended that students begin by seeking clarification or discussing concerns with their instructor. If such conversation is not possible, or if it does not serve to address the issue, it is recommended that the student contact the Department Chair as a next step.

Dropping and Adding

Students are responsible for understanding the policies and procedures about add/drop, grade forgiveness, etc. Refer to the current semester's Catalog Policies section at http://info.sjsu.edu/static/catalog/policies.html. Add/drop deadlines can be found on the current academic year calendars document on the Academic Calendars webpage at http://www.sjsu.edu/provost/services/academic_calendars/. The Late Drop Policy is available at

http://www.sjsu.edu/aars/policies/latedrops/policy/. Students should be aware of the current deadlines and penalties for dropping classes.

Information about the latest changes and news is available at the Advising Hub at http://www.sjsu.edu/advising/.

Consent for Public Sharing of Instructor Material

University Policy S12-7, http://www.sjsu.edu/senate/docs/S12-7.pdf, requires students to obtain instructor's permission to record the course and the following items to be included in the syllabus:
 "Course material developed by the instructor is the intellectual property of the instructor and cannot be shared publicly without his/her approval. You may not publicly share or upload instructor generated material for this course such as exam questions, lecture notes, or homework solutions without instructor consent."

Academic integrity

Your commitment, as a student, to learning is evidenced by your enrollment at San Jose State University. The University Academic Integrity Policy S07-2 at http://www.sjsu.edu/senate/docs/S07-2.pdf requires you to be honest in all your academic course work. Faculty members are required to report all infractions to the office of Student Conduct and Ethical Development. The Student Conduct and Ethical Development website is available at http://www.sjsu.edu/studentconduct/.

Campus Policy in Compliance with the American Disabilities Act

If you need course adaptations or accommodations because of a disability, or if you need to make special arrangements, please make an appointment with me as soon as possible, or see me during office hours. Presidential Directive 97-03 at http://www.sjsu.edu/president/docs/directives/PD_1997-03.pdf requires that students with disabilities requesting accommodations must register with the Accessible Education Center (AEC) at http://www.sjsu.edu/aec to establish a record of their disability.

Accommodation to Students' Religious Holidays

San José State University shall provide accommodation on any graded class work or activities for students wishing to observe religious holidays when such observances require students to be absent from class. It is the responsibility of the student to inform the instructor, in writing, about such holidays before the add deadline at the start of each semester. If such holidays occur before the add deadline, the student must notify the instructor, in writing, at least three days before the date that he/she will be absent. It is the responsibility of the instructor to make every reasonable effort to honor the student request without penalty, and of the student to make up the work missed. See University Policy S14-7 at http://www.sjsu.edu/senate/docs/S14-7.pdf.

SJSU Peer Connections

Peer Connections, a campus-wide resource for mentoring and tutoring, strives to inspire students to develop their potential as independent learners while they learn to successfully navigate through their university experience. You are encouraged to take advantage of their services which include course-content based tutoring, enhanced study and time management skills, more effective critical thinking strategies, decision making and problem-solving abilities, and campus resource referrals.

In addition to offering small group, individual, and drop-in tutoring for a number of undergraduate courses, consultation with mentors is available on a drop-in or by appointment basis. Workshops are offered on a wide variety of topics including preparing for the Writing Skills Test (WST), improving your learning and memory, alleviating procrastination, surviving your first semester at SJSU, and other related topics. A computer lab and study space are also available for student use in Room 600 of Student Services Center (SSC).

Peer Connections is located in three locations: SSC, Room 600 (10th Street Garage on the corner of 10th and San Fernando Street), at the 1st floor entrance of Clark Hall, and in the Living Learning Center (LLC) in Campus Village Housing Building B. Visit Peer Connections website at http://peerconnections.sjsu.edu for more information.

SJSU Writing Center

The SJSU Writing Center is located in Clark Hall, Suite 126. All Writing Specialists have gone through a rigorous hiring process, and they are well trained to assist all students at all levels within all disciplines to become better writers. In addition to one-on-one tutoring services, the Writing Center also offers workshops every semester on a variety of writing topics. To make an appointment or to refer to the numerous online resources offered through the Writing Center, visit the Writing Center website at http://www.sjsu.edu/writingcenter. For additional resources and updated information, follow the Writing Center on Twitter and become a fan of the SJSU Writing Center on Facebook. (Note: You need to have a QR Reader to scan this code.)

SJSU Counseling Services

The SJSU Counseling Services is located on the corner of 7th Street and San Fernando Street, in Room 201, Administration Building. Professional psychologists, social workers, and counselors are available to provide consultations on issues of student mental health, campus climate or psychological and academic issues on an individual, couple, or group basis. To schedule an appointment or learn more information, visit Counseling Services website at http://www.sjsu.edu/counseling.

BME 178, Biomedical Product Realization, Spring 2021

Course Schedule (*Schedule is subject to change with fair notice in class or via notice on Canvas*)

Week	Date	Topics	Assignments	
1	1/27	Overview/Problem Statement		
2	2/1	Design Controls		
	2/3	Guest lecture: Process overview	Select FDA approved medical device	
3	2/8	Design Process		R1
	2/10	Phase 1 - Set Objectives		Q1
4	2/15	Design for customers	Complete Phase 1	R2
	2/17	Meet with your group	Start BMC	Q2
5	2/22	Phase 2 - Analyze and Detail Functions	Submit BMC 1	R3
	2/24	Phase 2 Workshop	Complete FAST	Q3
6	3/1	Phase 2 - Matrix Checklist	Review Matrix	R4
	3/3	Phase 3 - Introduction, Standards and Regulations	Identify Regulation	Q4
7	3/8	Phase 3 - Functional Properties	Section 1, 2	R5
	3/10	Phase 3 - Physical Properties, Interface Requirements, Additional Performance Requirements	Section 3	Q5
8	3/15	Phase 3 - Environmental Conditions and Maintenance	Section 4, 5, 6	R6
	3/17	Phase 3 - Disposal and Schedule	Section 7, 8	Q6
9	3/22	Phase 3 - Validation and Manufacturability	Section 9, 10	R7
	3/24	Phase 3 - Distribution and Storage Requirements, Installation	Section 11, 12	Q7
10	3/29	NO CLASS - Spring Recess		
	3/31	NO CLASS - Spring Recess		
11	4/5	Phase 3 - Training of Personnel and Safety	Section 13, 14	R8
	4/7	Phase 3 - Cost and Documentation	Section 15, 16	Q8
12	4/12	Phase 3 Workshop	Section 17, 18	R9
	4/14	Preclinical	Submit Req Spec 1	Q9
13	4/19	Investigational Device Exemption		R10
	4/21	Clinical Trails		Q10
14	4/26	FDA Case Studies		R11
	4/28	Guest Lecture		Q11
15	5/3	Guest Lecture		R12
	5/5	Guest Lecture	Submit BMC 2	Q12
16	5/10	Guest Lecture		
	5/12	Guest Lecture	Submit Req Spec 2	
17	5/17	Final exam review	Submit Seminar Summary	
	5/19	**FINAL EXAM (12:15 – 2:30 PM)**		