**San José State University**

# Biomedical Engineering BME 135, Biomedical Engineering Design Methods, Fall 2022

## Course and Contact Information

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| Instructor: | Hoang Nguyen |
| Office Location: | TBD / Zoom preferably |
| Telephone: | Email/canvas message/ zoom |
| Email: | [hoang.d.nguyen@sjsu.edu](mailto:hoang.d.nguyen@sjsu.edu) / Canvas message |
| Office Hours: | Tuesday 1-2 PM  Anytime that works – please canvas message |
| Class Days/Time: | TUE – 10:30am – 11:20am (lecture) – Engr 333  MON – 9:00am – 11:45am (lab) – E407  FRI – 4:30pm – 7:15pm (lab) – E340 |
| Classroom: | Lecture: E333  Monday Lab – E407  Friday lab – E340 |
| Prerequisites: | Engr 10 & BME 25 |

## Course Format

The two-unit course consists of one 50 minute lecture and one 165 minute lab per week. Weekly homework and/or lab assignments, as well as a semester-project provide hands-on experience in applying design principals and using industry-standard computer-aided-design software for biomedical device design. Office hour will be done via zoom with the use of screen sharing remote control to help students learn and design more efficiently.

## Course Description

Review of FDA-required design methods. Application of engineering drafting and design principles to the development of biomedical devices and manufacturing processes. Use of computer-aided design (CAD) tools to generate three-dimensional models and two-dimensional drawings of parts and assemblies. The course also teaches the application tolerances for statistical process control.

### Course Learning Outcomes (CLO) (Required)

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

1. **identify** key dimensions and features of biomedical parts and devices
2. **construct** three-dimensional digital models and two-dimensional drawings with appropriate dimensional callouts fully defining all features and geometry using the SolidWorks environment.
3. **apply** both parametric tolerancing, geometric dimensioning, and tolerancing (GD&T) to biomedical parts and devices, minimize error stacking, and ensure key feature geometries are preserved
4. **read** engineering drawings and identify over-constrained and under-constrained part dimensions
5. **implement** the US Food and Drug Administration design and document control processes into product specifications, engineering drawings, and design history files

## Required Texts/Readings

### Textbook

Randy H. Shih, *Learning SolidWorks 2018: Modeling, Assembly, and Analysis.* SDC Publications. ISBN 978-1630571450.

U.S. Food and Drug Administration, *Design Control Guidance for Medical Device Manufacturers*, Center for Devices and Radiological Health, 1997 (<https://www.fda.gov/media/116573/download>)

U.S. Food and Drug Administration, *Design Controls,* Center for Devices and Radiological Health, (not dated) (<https://www.fda.gov/media/116762/download>)

### Other Readings

Oberg, E., “Machinery’s Handbook”, 29th Edition, Industrial Press  
Meadows, J.D., “Geometric Dimensioning and Tolerancing Handbook: Applications, Analysis & Measurement. ASME Press. <https://asmedigitalcollection.asme.org/ebooks/book/122/Geometric-Dimensioning-and-Tolerancing-Handbook>

Linkedin learning Solidworks Courses – Free for SJSU students. Go to one.sjsu.edu and search for ‘linkedin learning’

### Other technology requirements / equipment / material

Appropriate computer-aided design software, such as SolidWorks, Fusion Pro 360, and AutoCAD. Fusion Pro 360 is open-source software provided by Autodesk. SolidWorks and AutoCAD be accessed remotely via virtual desktop by navigating to desktop.sjsu.edu. Alternatively, the College of Engineering’s computer lab in E 390 has this software on its computers. For more information, including the open hours of this lab, navigate to: <http://www.sjsu.edu/ecs/openlabs/>. Please note that there are a limited number of licenses available. Starting on your project early in the semester can help avoid problems with license availability.

## 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 practicals. Other course structures will have equivalent workload expectations as described in the syllabus.

### Final Examination

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 will include both a written component and a design component. The written component may include multiple-choice questions, open-ended questions, long-answer problems. The design component will require students to work in the SolidWorks environment to apply course principles and techniques to create parts and/or drawings.

*F*aculty members are required to have a culminating activity for their courses, which can include a final examination, a final research paper or project, a final creative work or performance, a final portfolio of work, or other appropriate assignment.

### Homework & Lab Assignments

Homework assignments will include questions and problems related to the materials covered in the lectures, as well as assignments that require the use of SolidWorks. Students are expected and encouraged to work together on assignments. However, submitted homework should be individual work. Homework must be turned into the Canvas submission link before the due date as indicated. ***Late assignments will not be accepted. The lowest homework score at the end of the semester will be dropped.***

### Lab Assignments

Homework and Lab Assignments are to be completed and handed in to Canvas. These assignments will include questions and problems related to the materials covered in the lectures, and will require the use of SolidWorks. Students are expected and encouraged to work together on assignments. However, submitted homework should be individual work. Homework must be turned into the Canvas submission link before the beginning of class on the due date.

### Midterm examinations

There will be two mid-semester examinations. Each examination will cover the entire course material covered until the time of the examination. Examinations will include both a written component and a design component. The written component may include multiple-choice questions, open-ended questions, long-answer problems. The design component will require students to work in the SolidWorks environment to apply course principles and techniques to create parts and/or drawings.

The dates of the mid-semester examinations are indicated in the Lecture Schedule. The instructor reserves the right to assign seating for all examinations.

### Final Project

A final project will be assigned at the mid-point of the semester, and will be due in the second-to-last week of class. For the project, students will work in teams to design a multi-part biomedical device, and generate a complete set of CAD models and 2D drawings to fully define the device design and assembly instructions, including the application of tolerancing techniques. Students will be evaluated on the completeness of the design, and its ability to be manufactured using standard procedures (machining, CNC, 3D-printing). In addition to the design files, students will submit a written report and deliver a final presentation describing the key features and manufacturing processes required to fabricate their device.

## Grading Information

### Determination of Grades

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

Homework & Lab Assignments 25%

Midterm 1 15%

Midterm 2 15%

Final Project 25%

Final Exam 20%

| *Grade* | *Percentage* |
| --- | --- |
| *A plus* | *97 to 100%* |
| *A* | *93 to 96%* |
| *A minus* | *90 to 92%* |
| *B plus* | *87 to 89 %* |
| *B* | *83 to 86%* |
| *B minus* | *80 to 82%* |
| *C plus* | *77 to 79%* |
| *C* | *73 to 76%* |
| *C minus* | *70 to 72%* |
| *D plus* | *67 to 69%* |
| *D* | *63 to 66%* |
| *D minus* | *60 to 62%* |
| *F* | *59% or lower* |

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 and lab by the time the class begins and remain in the classroom for the duration of the lecture. 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.

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.”

### *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, included 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 (Required)

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.

*If applicable, include links to your department and college-level rules, requirements and services.*

# BME 135, Biomedical Engineering Design Methods, Course Schedule

## Course Schedule is tentative and subject to change with fair notice

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| --- | --- | --- | --- |
| **Week** | **Session** | **Date** | **Lecture topics, examinations, lab activities** |
| 1 | Lecture | August 23th, 2022 | Introduction to FDA regulated design: design controls, document control, design history files |
| Lab | Fr August 26th  Mo August 29th | Review of the SolidWorks environment, creating basic parts: extrudes, cuts, revolves |
| 2 | Lecture | August 30th, 2022 | Introduction to draft design tools and features, drawing views, and projections |
| Lab | Fr Sept 2nd  Mo Sept 5th | Elegant sketching in SolidWorks – sketch dependencies, construction lines, sketch equations |
| 3 | Lecture | September 6th, 2022 | Introduction to draft design – Drawing Views and Projections |
| Lab | Fr Sept 9th  Mo Sept 12th | Symmetrical feature design, patterns, part configurations, Tutorial of Intermediate Part Creation |
| 4 | Lecture | September 13th, 2022 | Basic dimensioning in engineering drawings |
| Lab | Fr Sept 16th  Mo Sept 19th | Creating engineering drawings in SolidWorks |
| 5 | Lecture | September 20th, 2022 | Geometric dimensioning and tolerancing (GD&T) basics, hole position and size |
| Lab | Fr Sept 23th  Mo Sept 26th | Using parametric tolerances in SolidWorks, exam review |
| 6 | Lecture | September 27th, 2022 | Accounting for uncertainty: Parametric tolerancing and error propagation |
| Lab | Fr Sept 30th  Mo Oct 3rd | **Midterm Exam 1** |
| 7 | Lecture | October 4th, 2022 | Standard fits: clearance, running fits, interference fits. Use of Machinist’s Handbook **Assign Semester Project** |
| Lab | Fr Oct 7th  Mo Oct 10th | Hole wizard, hole types, standard sizes, Tutorial of Advanced Part Creation |
| 8 | Lecture | October 11th, 2022 | Tolerance stack up; Parametric tolerancing and error propagation |
| Lab | Fr Oct 14th  Mo Oct 17th | Introduction to assemblies. Tutorial of Assembly from Detailed Dimensioned Illustration, **(Device chosen, problem statement)** |
| 9 | Lecture | October 18th, 2022 | FDA regulated design: design process and FDA waterfall diagram |
| Lab | Fr Oct 21nd  Mo Oct 24th | Mating components relative to features and reference planes |
| 10 | Lecture | October 25th, 2022 | Case studies in statistical process control |
| Lab | Fr Oct 28th  Mo Oct 31st | Engineering drawings for assemblies: exploded views, bill of materials (**Initial release rev. of project)** |
| 11 | Lecture | November 1nd, 2022 | Guest Lecture – Designing for quality; ISO 9001 requirements |
| Lab | Fr Nov 4th  Mo Nov 7th | Tutorial on Motion Analysis, exam review |
| 12 | Lecture | November 8th, 2022 | Guest Lecture – Design for Manufacturability |
| Lab | Fr Nov 11th  Mo Nov 14th | **Midterm Exam 2** |
| 13 | Lecture | November 15th, 2022 | Intro to 3D printing; Design for 3D printing |
| Lab | Fr Nov 18th  Mo Nov 21nd | Design Project Presentations |
| 14 | Lecture | November 22nd,2022 | Design for manufacturing – accounting for fabrication methods: Machining and molding |
| Lab | Fri Nov 25th – NO LAB  Mo Nov 28th | Design Project Presentations |
| 15 | Lecture | November 39th, 2022 | Machine shop & makerspace tour |
| Lab | **Fri Dec 2nd**  Mo Dec 5th | Final Review / Prepare for CSWA |
| **FINALS** |  |  | **TUESDAY, DECEMBER 13TH, 9:45 AM – 12:00 PM** |
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