

University of Texas at El Paso

Course Title: BME 5304/6304: Device Design and Regulation

CRN: 22209 (BME 5304)
22210 (BME 6304)

Class Time: Spring 2022 Semester
TR 9:00 – 10:20 a.m.

Textbook: none, course materials will be posted on UTEP Blackboard

Instructors: Dr. Sylvia Natividad-Diaz

Contact: UTEP Email or Microsoft Teams
slnatividad@utep.edu

Office hours: Online via Blackboard Zoom or in-person (SND Office)
Tues. 10:30 a.m. – 11:30 a.m.
Wed. 6:00 p.m. – 7:00 p.m. (by appointment, online only)

Goals:

Since medical devices are applied for the diagnosis, mitigation, treatment, or prevention of diseases, it becomes essential to regulate the use of such products. In the USA, the Food and Drug Administration (FDA) is responsible for the regulation of medical devices with the purpose of protecting the safety and needs of the people. This course aims to provide an overview of device development and the FDA, and to offer students an opportunity to gain the foundations necessary to build a strong understanding of regulatory affairs.

Course Outcomes: By the end of this course, students should be able to:

1. Apply the principles of engineering design from recognition of need to a fully-tested product.
2. Organize and manage a design project and work effectively in a team to complete the project.
3. Understand the need for regulatory constraints in medical device development, and the ability to design, build, and test a medical device within those constraints.
4. Communicate items 1 through 3 in written, oral, and graphical form.
5. Gain and appreciate the need for standards in the design of biomedical devices
6. Understand and communicate the data requirements addressing quality, safety and usefulness/efficiency, and the conditions to successfully fulfill these requirements

Prerequisites: BME minor or consent of instructor.

POINTS DISTRIBUTION:

In-Class Activity Participation: 20%

Weekly Design Review presentation: 20%

Midterm Report and Presentation: 20%

Final Report and Presentation: 40%

Approximate Schedule:

Week 1: The Engineering Design Process, Recognition of Need-Case Study

Week 2: Recognition of Need Due, Requirements Elicitation

Week 3: Problem Formulation, Design Review 1

Week 4: Verification/House of Quality, Problem Formulation Due, Design Review 2

Week 5: Solution Formulation, Design Review 3

Week 6: Feasibility

Week 7: Organization/ Work Breakdown

Week 8: Proposal Prep, Design Review 4

Week 9: Spring Break

Week 10: Proposal Prep, Formal Proposal Due, Failure Mode Analysis

Week 11: Verification and Validation, Design Review 5

Week 12: Benefits and Risks, Design Review 6

Week 13: FDA Regulatory Process-QSR Design Review 7

Week 14: Medical Device Safety, Design Review 8

Week 15: Guidance for Industry and FDA Staff,

Week 16: Final Presentation and Report

Technology Requirements

Some course content is delivered via the Internet through the Blackboard learning management system. Ensure your UTEP Blackboard account is working and that you have access to the Web and a stable web browser. Google Chrome and Mozilla Firefox are the best browsers for Blackboard; other browsers may cause complications. When having technical difficulties, update your browser, clear your cache, or try switching to another browser.

You will need to have access to a computer/laptop, scanner, a webcam, and a microphone. You will need to download or update the following software: Microsoft Office, Adobe Acrobat Reader, Windows Media Player, QuickTime, and Java. Check that your computer hardware and software are up-to-date and able to access all parts of the course.

If you do not have a word-processing software, you can download Word and other Microsoft Office programs (including Excel, PowerPoint, Outlook and more) for free via UTEP's Microsoft Office Portal. Click the following link for more information about [Microsoft Office 365](#) and follow the instructions.

IMPORTANT: If you encounter technical difficulties beyond your scope of troubleshooting, please contact the UTEP [Help Desk](#) as they are trained specifically in assisting with technological needs of students. Please do not contact me for this type of assistance. The Help Desk is much better equipped than I am to assist you.

Course Communication

- **Office Hours:** Online via Blackboard Zoom or in-person (SND Office)
Tues. 10:30 a.m. – 11:30 a.m.
Wed. 6:00 p.m. – 7:00 p.m. (by appointment, online only)
- **Email:** UTEP e-mail is the best way to contact me. I will make every attempt to respond to your e-mail within 24-48 hours of receipt. When e-mailing me, be sure to email from your UTEP student account and please put the course number in the subject line. In the body of your e-mail, clearly state your question. At the end of your e-mail, be sure to put your first and last name. **Emails related to this course sent to my Blackboard account will not be answered.**
- **Discussion Board:** If you have a question that you believe other students may also have, please post it in the Student Community Board of the discussion boards inside of Blackboard. Please respond to other students' questions if you have a helpful response. I will not check this as often as Blackboard email, so please send urgent questions to me directly (via Blackboard).
- **Announcements:** Check the Blackboard announcements frequently for any updates, deadlines, or other important messages.

Netiquette

As we know, sometimes communication online can be challenging. It's possible to miscommunicate what we mean or to misunderstand what our classmates mean given the lack of body language and immediate feedback. Therefore, please keep these netiquette (network etiquette) guidelines in mind. Failure to observe them may result in disciplinary action.

- Always consider audience. This is a college-level course; therefore, all communication should reflect polite and respectful consideration of other's ideas.
- Respect and courtesy must be provided to classmates and to the instructor at all times. No harassment or inappropriate postings will be tolerated.
- When reacting to someone else's message, address the ideas, not the person. Post only what anyone would comfortably state in a face-to-face situation.
- Blackboard is not a public internet venue; all postings to it should be considered private and confidential. Whatever is posted on these online spaces is intended for classmates and professor only. Please do not copy documents and paste them to a publicly accessible website, blog, or other space.
- Keep in mind, anything posted on Blackboard is permanent even if you delete it.

Course Policies

Attendance and Participation

Attendance in the course is determined by participation in the class learning activities (Design Reviews, assignment submission, project work). Your participation in the course is important not only for your learning and success but also to create a community of learners.

Excused Absences and/or Course Drop Policy

According to UTEP Curriculum and Classroom Policies, "When, in the judgment of the instructor, a student has been absent to such a degree as to impair his or her status relative to credit for the course, the instructor may drop the student from the class with a grade of "W" before the course drop deadline and with a grade of "F" after the course drop deadline." See academic regulations in the UTEP Undergraduate Catalog for a list of excused absences.

Deadlines, Late work, and Absence policy

Assignments

- Assignments are due by r at 11:59 p.m. MST on UTEP Blackboard by the specified date.
- **Late work will not be accepted** (except in the case of UTEP documented excused absences, including UTEP COVIDAction email)

Make-up Work

Make-up work will be given *only* in the case of a *documented* emergency or excused absence by UTEP (including UTEP COVIDAction email). Note that make-up work may be in a different format than the original work. If you miss an assignment and the reason is not considered excusable, you cannot make up the work. It is therefore important to reach out to me—in advance if at all possible—and explain with proper documentation why you missed a given course requirement. Once a deadline has been established for make-up work, no further extensions or exceptions will be granted.

Alternative methods of submitting work in case of technical issues

I strongly suggest that you submit your work with plenty of time to spare in the event that you have a technical issue with the course website, network, and/or your computer. I also suggest you save (back up) all your work (answers to discussion boards, quizzes, homework, and presentations) in separate files on your own computer or external hard drive. If you are experiencing difficulties submitting your work through the course website, please contact the UTEP Help Desk. You can email me your back-up document as a **last resort**.

Incomplete Grade Policy

Incomplete grades may be requested only in exceptional circumstances after you have completed at least half of the course requirements. Talk to me immediately if you believe an incomplete is warranted. If granted, we will establish a contract of work to be completed with deadlines.

Accommodations Policy

The University is committed to providing reasonable accommodations and auxiliary services to students, staff, faculty, job applicants, applicants for admissions, and other beneficiaries of University programs, services and activities with documented disabilities in order to provide them with equal opportunities to participate in programs, services, and activities in compliance with sections 503 and 504 of the Rehabilitation Act of 1973, as amended, and the Americans with Disabilities Act (ADA) of 1990 and the Americans with Disabilities Act Amendments Act (ADAAA) of 2008. Reasonable accommodations will be made unless it is determined that doing so would cause undue hardship on the University. Students requesting an accommodation based on a disability must register with the [UTEP Center for Accommodations and Support Services](#) (CASS). Contact the Center for Accommodations and Support Services at 915-747-5148, or email them at cass@utep.edu, or apply for accommodations online via the [CASS portal](#).

COVID-19 Accommodations and Precautions

If you are experiencing difficulty completing course requirements due to COVID-19 infection, you should email me as soon as possible so we can arrange necessary and appropriate accommodations. Please do not come to class if you are sick or suspect you have been exposed to COVID-19.

According to UTEP Policy, you must STAY AT HOME and REPORT if you: (1) have been diagnosed with COVID-19, (2) are experiencing COVID-19 symptoms, or (3) have had recent contact with a person who has received a positive coronavirus test. Reports should be made at COVIDaction@utep.edu. If you know of anyone who should report any of these three criteria, you should encourage them to report. If the individual cannot report, you can report on their behalf by sending an email to COVIDaction@utep.edu. Please note, this is not a disciplinary action, this reporting system has been established by UTEP to provide support for employees and students affected by COVID-19.

Academic Integrity

Students are expected to have a commitment to honesty, reliability, and responsibility, without which you cannot earn the trust and respect of others. Therefore, plagiarism, lying, cheating, or stealing will not be tolerated in any form.

Academic dishonesty is prohibited and is considered a violation of the UTEP Handbook of Operating Procedures. It includes, but is not limited to, cheating, plagiarism, and collusion. Cheating may involve copying from or providing information to another student, possessing unauthorized materials during a test, or falsifying research data on laboratory reports. Plagiarism occurs when someone intentionally or knowingly represents the words or ideas of another as one's own. Collusion involves collaborating with another person to commit any academically dishonest act. Any act of academic dishonesty attempted by a UTEP student is unacceptable and will not be tolerated. All suspected violations of academic integrity at The University of Texas at El Paso must be reported to the [Office of Student Conduct and Conflict Resolution \(OSCCR\)](#) for possible disciplinary action. To learn more, please visit [HOOP: Student Conduct and Discipline](#).

Class Recordings

The use of recordings will enable you to have access to class lectures online via Blackboard. Recordings are governed by the Federal Educational Rights and Privacy Act (FERPA) and UTEP's acceptable-use policy. A recording of class sessions will be kept and stored by UTEP, in accordance with FERPA and UTEP policies. **You may not share recordings outside of this course.** Doing so may result in disciplinary action.

Plagiarism Detecting Software

Some of your course work may be submitted to SafeAssign, a plagiarism detecting software. SafeAssign is used to review assignment submissions for originality.

Copyright Statement for Course Materials

All materials used in this course are protected by copyright law. The course materials are only for the use of students currently enrolled in this course and only for the purpose of this course. They may not be further disseminated.