

Syllabus: BioE4010 Bioengineering Design Theory, Fall 2021

COURSE TITLE: Biomedical Design Theory

COURSE NUMBER: BioE4010

SECTIONS: Section 01: 8:00 – 9:15 am TTH
Section 02: 12:30 – 1:45 pm TTH

TERM: Fall 2020

LOCATION: Section 01: Rhodes Annex 111
Section 02: Rhodes Annex 111

INSTRUCTORS: **John D. DesJardins, Ph.D.**
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PREREQUISITES: BIOE 3020 or BIOE 3200 or BIOE 3700

OPTIONAL

TEXT BOOK(S):

Biodesign: The process of Innovating Medical Technologies, 2nd Ed.
Zenios S., Makower, J., Yock, P.; 2015.

Design of Biomedical Devices and Systems, 3rd Ed. King, P., Fries, R.,
Johnson, A.; 2014. (Dr. DesJardins & Dr. Mercuri; personal copies in
204 and 313 Rhodes)

*The Quality System Compendium: GMP Requirements & Industry
Practice, 2nd Ed.*, Associate for the Advancement of Medical
Instrumentation (AAMI) (Dr. Mercuri; personal copy in 313 Rhodes)

COURSE CATALOG DESCRIPTION:

3 Credits. Introduces principles of engineering design and applies them to the design of medical devices. Covers materials selection, fabrication processes, performance standards, cost analysis, and design optimization. Students defend a design project proposal in written and oral form before a faculty jury. Preq: BIOE 3020 or BIOE 3200 or BIOE 3700.

COURSE OBJECTIVES & OVERVIEW:

The primary objective of BIOE4010 (Biomedical Design Theory) is to familiarize bioengineering students with key concepts and techniques which underlie the design and product development process typically utilized by entrepreneurs and corporations within the medical device industry. Moreover, this course aims to employ the student's current body of knowledge gained throughout their undergraduate bioengineering curriculum towards communicating and solving real-world clinically relevant biomedical engineering problems. Additionally, students will ultimately be challenged to develop solutions that are both technically feasible and commercially viable.

Topics to be covered in this class include, an overview of basic design theories and techniques, needs finding and screening tools, the ideation process, concept screening, design documentation, an overview of the medical device industry corporate structure and internal interactions necessary for device development, market analysis, regulatory considerations, reimbursement strategy, and the intellectual property landscape. All of these topics will all be discussed in the context of the medical device design process. All of these concepts will be used in the development and delivery of both written materials and oral communication during presentations.

This course will be organized around formal lectures aligned with the device design process itself and will include guest speakers and various in-class team-based exercises which will provide the students the opportunity to put into practice what they are learning via relevant

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examples of challenges typically incurred during the medical device design process. Additionally, students will be divided into design teams which will focus on identifying and assessing clinical needs (as determined via their interaction with local clinicians) and to ultimately develop, present and defend a design proposal related to the identified needs. Finally, this course will prepare the students to move on to BIOE4030 (Applied Biomedical Design) in which they will apply both bioengineering and design principles towards developing solutions to the clinically relevant need identified by their respective groups in BIOE4010.

INSTRUCTIONAL MODALITY:

As of August 18th, this course is schedule to be taught in person. Decisions about the online, asynchronous or in-person options and modalities will be communicated to the students in a timely fashion. Regardless, asynchronous content will also be available and possibly assigned. In-lab access will be scheduled and allowed in accordance with university policies.

GRADING:

Homework [†]	10%
Midterm Oral Presentations and Written content (3 of these)* [†]	30%
Oral Presentation of Gates and Written content (1 and 2)* [†]	30%
End of Semester Design Report [†]	15%
Semester Design Symposium Poster and Oral Presentation* [†]	10%
Semester Design Symposium Attendance	5%

[†] Late penalty for materials that are due: 50% if not turned in on time (usually through a digital process) when due; 25% penalty/each 24 hours thereafter. * An unexcused absence at a team presentation or gate will result in a zero for the presentation portion for that individual student.

A (90-100%) **B** (80-89.9%) **C** (70-79.9%) **D** (60-69.9%) **F** (<60%)

Teams & Team Grading

Team participation is valued and will be assessed in this class. Teams should produce work equivalent to the number of people in that team. In other words, a team of 4 individuals needs to produce work worthy of 4 A's in order for each member to receive an A for that work. A team of 5 individuals needs to produce work worthy of 5 A's in order for each member to receive an A for that work. In other words, the more people on your team, the better that collective work should be.

All assignments that are completed by a team should include clear documentation of who contributed to the assignment, and when necessary who contributed to what parts of the assignment. All team assignments will have a coversheet (distributed by instructor or TA) that should be used to list the team and include a listing of percentage contributions or a designation of who completed specific sections. This completed coversheet needs to be signed by all team members before the assignment is turned in. These assessments will be reviewed when the

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instructor assigns grades. Due to possible online submissions of materials, an organized method of obtaining digital signatures from all teammates should be arranged within each team. No digital signatures are allowed to be used without permission from that team member for that specific assignment.

If at any time a team feels that one of its members is seriously delinquent in his or her responsibilities, effort or attitude, the team has the right to petition the instructor for remediation. Initial concern with teammate performance should be discussed as soon as possible with the instructor. Direct attempts will be made to mediate and resolve the problem.

Consistent class attendance is in your best interest. There is not a required textbook for the course and assignments are based on material covered in class and resource material provided. Students are responsible for material posted on CANVAS so check it regularly.

Any questions pertaining to grading or requests for re-consideration of grading must be made in writing within 1 week of when the graded assignment is returned to the student. Requests for re-consideration of a grade, must include a copy of the graded assignment. These considerations will be processed in a timely fashion, and written feedback and grade adjustment (higher, lower or not at all) will be completed, and returned to the student. Verbal requests for re-consideration of grading are not actionable.

Classroom Policies:

Design Laboratory Use and Access

The department has given us dedicated access to an undergraduate design laboratory, located in Rhodes Annex 312. This lab will be outfitted with design critical instrumentation, supplies, books and computers. It will also serve as your design team meeting space, if needed. This laboratory will be used extensively during BioE4030, but may also be used for BioE4010. This lab will have key code access. You will be required to complete safety training before you are allowed use of this facility. You will be required to sign off on any SOP's that are needed to operate any of the equipment. Specific COVID-19 Policies are being set up for use of this lab space. These will be detailed in a separate document.

Academic Integrity

“As members of the Clemson University community, we have inherited Thomas Green Clemson’s vision of this institution as a ‘high seminary of learning.’ Fundamental to this vision is a mutual commitment to truthfulness, honor, and responsibility, without which we cannot earn the trust and respect of others. Furthermore, we recognize that academic dishonesty detracts from the value of a Clemson degree. Therefore, we shall not tolerate lying, cheating, or stealing in any form.”

The Honor Code for the College of Engineering and Science/Clemson University will be applied to individuals when these individuals are expected to complete tests, projects, and reports on their own, and to teams when these teams complete work together (<http://www.clemson.edu/cecas/current-students/honor-code.html>).

Waiting for Instructor

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If the instructor or any TA's for the class do not show up within 15 minutes of the scheduled beginning of class, students are free to leave and the class should be considered to be canceled for that class period. Any scheduled assignments or assignments given digitally for that class remain in force.

Attendance Policy

Students will get more out of this course if they attend every class and presentation. There will be two types of activities during this course; Lectures and Team Presentations.

For Team Presentations, attendance by all team members for scheduled team presentation is required. Failure of an individual to attend and participate with your team in that presentation will result in a zero for that individual's presentation grade. The remaining students in that team are expected to compensate for any missing teammate (excused or otherwise), and cover any materials that were the responsibility of the absent student. Excused absences will be taken into consideration, and a make-up assignment will be required. There is an expectation that expected absences be communicated to the instructor such that scheduled team presentations do not conflict with these out of class conflicts. Presentation times are usually flexible, and advanced communication with the professor (at least 2 weeks prior) is expected.

Attendance during scheduled lectures is not required, and there will be no grade penalties for not attending class. However, if you attend, there will occasionally be in-class bonus points, towards your final grade. These bonus points will be recorded in a googlesheet, and logged in Canvas. If you miss class due to an excused absence, you will not be given an extra opportunity to earn these bonus points. Any attempt to communicate the in-class poll/quiz materials to someone that is not in class will be considered a cheating offense, and reported to the university as an academic offense.

If a student is expected to miss class, it is common courtesy to let his/her teammates and the instructor know. Course materials and information that was covered in class can be accessed via the course online materials.

UNIVERSITY ADVISED WORDING

Specific COVID-19 related information:

For a student who reports testing positive or is being asked to quarantine/isolate because of exposure to the virus, it will be up to the student to inform the instructor that they will be moving to online only instruction for at least the next two weeks. Students are directed to use the Notification of Absence link in Canvas to initiate this notification, which can be found under the "Help" button on the left navigation. (For courses where Canvas is not used, the direct link to the Notification of Absence form can be found through the Division of Student Affairs site.) Additional communication via email is encouraged; students should follow up with their instructor to develop a continued plan of study for each course. Students cannot be penalized in their grade for needing to move to online instruction.

Clemson University Title IX (Sexual Harassment) Statement

Title IX Policy: Clemson University is committed to a policy of equal opportunity for all persons and does not discriminate on the basis of race, color, religion, sex, sexual orientation, gender, pregnancy, national origin, age, disability, veteran's status, genetic information or protected

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activity (e.g., opposition to prohibited discrimination or participation in any complaint process, etc.) in employment, educational programs and activities, admissions and financial aid. This includes a prohibition against sexual harassment and sexual violence as mandated by Title IX of the Education Amendments of 1972.

The University is committed to combatting sexual harassment and sexual violence. As a result, you should know that University faculty and staff members who work directly with students are required to report any instances of sexual harassment and sexual violence, to the University's Title IX Coordinator. What this means is that as your professor, I am required to report any incidents of sexual harassment, sexual violence or misconduct, stalking, domestic and/or relationship violence that are directly reported to me, or of which I am somehow made aware.

There are two important exceptions to this requirement about which you should be aware: Confidential Resources and facilitators of sexual awareness programs such as "Take Back the Night and Aspire to be Well" when acting in those capacities, are not required to report incidents of sexual discrimination.

Another important exception to the reporting requirement exists for academic work. Disclosures about sexual harassment, sexual violence, stalking, domestic and/or relationship violence that are shared as part of an academic project, a research project, classroom discussion, or course assignment, are not required to be disclosed to the University's Title IX Coordinator.

This policy is located at <http://www.clemson.edu/campus-life/campus-services/access/title-ix/>. Ms. Alesia Smith is the Executive Director for Equity Compliance and the Title IX Coordinator. Her office is located at 223 Holtzendorff Hall, phone number is 864.656.3181, and email address is alesias@clemson.edu.

Accessibility Policy:

Clemson University values the diversity of our student body as a strength and a critical component of our dynamic community. Students with disabilities or temporary injuries/conditions may require accommodations due to barriers in the structure of facilities, course design, technology used for curricular purposes, or other campus resources. Students who experience a barrier to full access to this class should let the professor know, and make an appointment to meet with a staff member in Student Accessibility Services as soon as possible. You can make an appointment by calling 864-656-6848, by emailing studentaccess@lists.clemson.edu, or by visiting Suite 239 in the Academic Success Center building. Appointments are strongly encouraged – drop-ins will be seen if possible, but there could be a significant wait due to scheduled appointments. Students who receive Academic Access Letters are strongly encouraged to request, obtain and present these to their professors as early in the semester as possible so that accommodations can be made in a timely manner. It is the student's responsibility to follow this process each semester. You can access further information here: <http://www.clemson.edu/campus-life/campus-services/sds/>.

Requests for SDS accommodations must be submitted 1 week prior to expected implementation.

COVID-19 Related Expectations for Face Coverings to Include in Syllabus

Specific COVID-19 related information for in-person classes:

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While on campus, face coverings are required in all buildings and classrooms. Face coverings are also required in outdoor spaces where physical distance cannot be guaranteed. Please be familiar with the additional information on the Healthy Clemson website, such as the use of wipes for in person classes. If a student does not have a face covering or refuses to wear an approved face covering without valid accommodation, the instructor will ask the student to leave the academic space and may report the student's actions to the Office of Community & Ethical Standards as a violation of the Student Code of Conduct. If the student's actions disrupt the class to the extent that an immediate response is needed, the instructor may call the Clemson University Police Department at 656-2222.

Animal Use

If your course includes the use of animals, the following policy and link must be included in the

syllabus: <http://www.clemson.edu/research/compliance/iacuc>

Human Subjects

Any human subjects research should comply with campus IRB regulations, see:

<http://www.clemson.edu/research/compliance/irb/>

Emergency Procedures

Clemson University is committed to providing a safe campus environment for students, faculty, staff, and visitors. As members of the community, we encourage you to take the following actions to be better prepared in case of an emergency:

- A. Emergency procedures have been posted in all buildings and on all elevators. Students should review these procedures for their own safety and understanding.
- B. Ensure you are signed up for emergency alerts (<https://www.getrave.com/login/clemson>)
- C. Download the Rave Guardian app to your phone (<https://www.clemson.edu/cusafety/cupd/rave-guardian/>)
- D. Learn what you can do to prepare yourself in the event of an active threat (<http://www.clemson.edu/cusafety/EmergencyManagement/>)

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