

North Carolina State University
BME 451 & 452: Biomedical Engineering Senior Design

Overview

Senior design is a two-semester required course designed to help students prepare for the workplace and/or graduate studies. The course uses a Design Control Process based on the FDA's Quality System Regulations to move student teams from a Needs Assessment through Product Development and Testing. Each team progresses through 5 phases, completing about 30 controlled deliverables, and maintains a Design History File.

The aim of the courses is to provide the opportunity for senior biomedical engineering students to both integrate and continue to grow their engineering knowledge by accomplishing “real world” engineering design projects. In addition to project activity, students are provided educational resources addressing ethics and professionalism, manufacturing and standards, and intellectual property.

Instructor

Andrew J. DiMeo, Sr., Ph.D.

4202C Engineering Building 3 - 919-515-6720 - ajdimeo@ncsu.edu

Office Hours

Students are encouraged to communicate questions and comments freely and frequently. E-mail is a convenient way and its use is encouraged when possible. Instructor responsibilities are taken very seriously and every effort will be made to provide in person consultation. However, whenever possible (both for your convenience and for that of the instructor) please make appointments for consultation. You are, of course, welcome to call or “stop by” at anytime, but please understand that other responsibilities may make it impossible for the instructor to visit with you when you do so unannounced.

Class Hours and Location

Lecture: Section 001, Monday and Wednesday 12:50 to 1:40 PM, 4201 Engineering Building III
Lab: Section 201, Wednesday 1:50 to 3:40 PM, 4201 Engineering Building III

[Note: Lab sections are scheduled to provide time for practical instruction, demonstrations, experimentation, and part of the project work. There will be occasional formal class meetings during the year for design reviews. The remaining lab times should be used for project work and are times when access to the instructor for consultation can be assured.]

Prerequisites

Each student must have completed 12 hours of BME courses at the 300 level or above and must be within 36 credit hours of degree completion.

Important Dates

In addition to class meeting time and formal lab meeting times, as the project teamwork gears up during the first month of the semester, each team will establish work schedules and deadlines appropriate with the team’s project and consistent with course requirements. These schedules

and deadlines become **very important dates!** Project presentations (design reviews) will be held during class and lab hours on scheduled dates throughout the semester, including possibly the last week of classes, reading days, or exam week. All dates are posted on the course calendar located at:

www.google.com/calendar/embed?src=kl3sd31qlhosqqkp63211vt084%40group.calendar.google.com&ctz=America/New_York

Also see www.ncsu.edu/reg_records/calendars/index.html for university deadlines and holidays

BME 451 COURSE DESCRIPTION

Project Proposal and Design Concepts, including: individual pre-proposals, team proposals, project planning, scheduling, needs assessment, product requirements, competitive landscape and patent review, business risks, design concepts, and phase reviews.

BME 452 COURSE DESCRIPTION

Continuation of BME 451, Design for Manufacturing, Manufacturing, and Qualification, including: detailed manufacturing specifications, biomaterials review, supplier identification, product feasibility, issues tracking, manufacturing planning, bill of materials, product risks, qualification protocol, IP disclosure, process validation planning, regulatory review, design history file audit, lessons learned, and phase reviews.

STUDENT LEARNING OUTCOMES

The purpose of BME 451/2, Biomedical Engineering Senior Design I & II, is to offer senior students an opportunity to learn by becoming involved in the solution of problems of current interest to biomedical engineering.

After completing this course, students will be able to:

- a) Design a system, component, or process to meet desired needs, including
 - 1) Further developing proficiency in engineering graphics
 - 2) Exploiting and developing their talents as creative design engineers
 - 3) Assess engineering design problems with an inquisitive mind and keen eye for details
 - 4) Analyze relatively complex engineering design problems and propose creative solutions
 - 5) Formulate the optimum solution from among several possible alternatives
 - 6) Develop detailed engineering design proposals including proposed project schedules
 - 7) Schedule the design project tasks and manage the design process
 - 8) Design, build and test the selected engineering design solution
 - 9) Produce a potentially publishable written report and accompanying poster
 - 10) Produce and present a professional presentation report on the selected design solution
- b) Function on multidisciplinary teams, including:
 - 1) Acquire and develop the skills to work effectively as members of an engineering team with emphasis on listening, speaking, evaluating, and being evaluated
- c) Communicate effectively, including
 - 1) Writing and speaking effectively on engineering topics
 - 2) Maintaining a design engineering notebook
 - 3) Giving presentations to a diverse audience

REQUIRED TEXTS AND MATERIALS

No Text. Class discussions are supplemented by recommended readings of instructor-prepared materials and various published references. Students are responsible for all material in recommended readings. Each team will maintain a project notebook known as a Design History File (DHF). It is typically a 3-inch 3-ring binder. Each student will maintain a bound (stitched or glued) design engineering notebook with numbered pages.

COURSE ORGANIZATION AND SCOPE

BME 451 is a required course of the Biomedical Engineering curriculum and consists of a series of lectures, site visits, and the first phase of major team projects that the students will complete in BME 452. Class meetings for senior design consist of two lecture meetings per week plus a two-hour lab session. The lecture periods are devoted to topics related to the engineering teamwork, the design process, manufacturing processes and standards, professionalism intellectual property law, and case studies on engineering ethics. The lab period is occasionally used for group discussions, demonstrations, or design reviews, but in general will be available for team effort on the design project.

Course Content

See web site, www.bme.ncsu.edu/seniordesign/class/index.html

Course Locker Space

Individual, group (team), and common locker space is provided as follows:

Path	
Windows	J:\eos\lockers\workspace\bme\bme451\001
Unix	/afs/eos.ncsu.edu/lockers/workspace/bme/bme451/001

The space is configured as follows:

Locker Type	Space	Access Rights	
		Student	Instructor
Individual	250 MB	Read/Write	Read/Write
Group (Team)	750 MB	Read/Write	Read/Write
Common	750 MB	Read	Read/Write

Please note that at the end of the fall semester the materials in individual student course lockers and team lockers will be required to be moved to new space for BME 452 (that is just how the system works). The addresses in the above tables will change, substituting “452” for “451.”

Grading Policy:

Timeliness: Assignments are to be submitted on time. The grade of all late submissions will be automatically reduced 25% of maximum credit. No credit will be given for work submitted after an assignment is returned to the rest of the class, except by explicit and special arrangement made with the course instructor.

For detailed information on how assignments are turned in, please reference:

www.bme.ncsu.edu/seniordesign/class/documents/References/Turn-in-References.html

Completeness: Students are held responsible for completion of all work assigned, in whole and in part. If the students do not understand what is expected or required, it is their responsibility to obtain clarification (i.e., ask either the instructor or TA) and then complete the work.

Quality of Presentation: A major portion of this course is about learning to communicate engineering work in a clear and logical manner. Organization and clarity of presentation will be considered in all evaluations. Students are expected to become proficient at making written, graphic, and oral engineering presentations.

Format: Unless otherwise indicated, all written assignments are to be submitted electronically in a form amenable for printing (For example Times-Roman 12 point font with a one inch margin on all four sides).

Culture of Evaluation: There will be intensive and frequent evaluation in the course including evaluation by instructors and sponsors as well as peer evaluation among students. Formalized ways of providing for anonymous peer evaluation are provided, and participation in such evaluation is required.

Academic Integrity: Some assignments in this course are individual in nature. That is, the work submitted for evaluation is the result of the student's own thought and study and produced without assistance from another person. Any sources of assistance or reasons for similarity of submissions must be acknowledged and explained. The content of team assignments is assumed to be the combined efforts and responsibility of all team members. For a more complete explanation of academic integrity as it applies to this course, the student is encouraged to consult: www.ncsu.edu/student_affairs/osc/AIpage/acaintegrity.html

Grading: The student's grade will primarily depend on the group design project. Other factors, such as homework assignments and tests may also be considered. An **estimated** percentage contributing to the final grade is given below:

- Individual Contributions to the Design Project (50%)
 - o Individual Team Evaluations 15%
 - o Homework, Tests, Other* 10%
 - o Notebook 10%
 - o Attendance 10%
 - o Presentations 5%
- Group Contributions to the Design Project (50%)
 - o Phase 0 & 1 Deliverables* 45% (BME 451)
 - o Phase 2 Deliverables 15% (BME 452)
 - o Phase 3 Deliverables 15% (BME 452)
 - o Phase 4 Deliverables 15% (BME 452)
 - o Presentations 5%

*Individual pre-proposals and lessons learned deliverables are part of the individual contribution, not part of the Phase Deliverables

For the individual and team projects, such factors as the quality of the problem-solving approach, the amount of work done, apparent understanding of the problem, evidence of good engineering analysis, the quality of the written and oral reports, and the completeness of the design will be considered in establishing the grade. Other factors such as cooperation and collegiality, resourcefulness, creativity, and participation in class discussion will also contribute to the grade.

The group design project in this course will be the result of team efforts. By definition, a team is composed of individuals with diverse talents united by a common goal. A team shares its mix of strengths and weaknesses equally among all members. If team members expect to benefit from the talents of its stronger members, it must be willing to compensate for its weaker members. On the other hand, it is the responsibility of each team member to contribute in every possible way to the success of the team.

The instructor will determine at least fifty percent of the student's grade on the group project based on the above factors. The remainder will be determined from input from fellow class members, outside evaluators, and the project sponsor.

Student Responsibilities

Students with Disabilities

Reasonable accommodations will be made for any student with a verifiable disability. In order to take advantage of available accommodations, students must register with Disability Services at 1900 Student Health Center, Campus Box 7509, 515-7653. For more information, see Disability Services for Students:

www.ncsu.edu/provost/offices/affirm_action/dss/

For additional information on NC State's policy on working with students with disabilities, please see the Handbook for Teaching and Advising:

www.ncsu.edu/provost/hat/current/appendix/appen_k.html

Class Participation

Active participation is strongly encouraged, enriches the learning experience, and will be regarded very favorably in the final evaluation. At any time during class, students, either individually or as a group, are subject to be requested to participate in class discussions, demonstrations, and written exercises.

Outside Class Participation

Since a significant part of the courses involves team projects, teams are expected to meet outside of class and lab times. The meeting time and place is generally set by the consent of the team and is often located at a site visit. Each student's regular attendance and participation of team meetings is essential to the success of the group and the individual.

"In College, we expect that you will spend 2 to 3 hours working on a course outside of class for every hour in class."

Referenced on 8/18/09 from www.stat.ncsu.edu/programs/ugrad/incoming.php

Senior Design is a 3-credit course, therefore it is expected that you will be working 6 to 9 hours per week outside of class in addition to the 2 hours of class plus 2 hours of lab. Therefore, on average, you should be spending 10 to 13 hours per week on Senior Design.

Attendance Policy

Students must make regular attendance a top priority. Excuses for anticipated absences must be cleared with the instructor before the absence. Excuses for anticipated or emergency absences will be accepted at the discretion of the instructor and in accordance with university policy on excused absences as defined by the university in NCSU's attendance policy:

www.ncsu.edu/policies/academic_affairs/courses_undergrad/REG02.20.3.php

When an excuse is accepted, an agreement will be reached regarding making up any work missed. When an excuse is not accepted, there is no obligation on the part of the instructor to provide an opportunity for makeup work. Excuses for emergency absences must be reported to the instructor as soon as possible, but not more than one week after the return to class.

Senior Design considers attendance as part of your grade consistent with being present in an actual work setting. Attendance is considered in both peer evaluation (time outside of class) and with an in-class roll. All students are given two free absences whether excused or not. The remaining attendance will be used to calculate that portion of your grade.

Reading Assignments

Copies of important reading assignments will be made available electronically or as hard copies in class.

Class Courtesies

Students are expected to conduct themselves in a professional manner at all times and be prepared for class and ready to begin at the start of the period. Late arrivals create major disruptions. Habitual late arrivals will not be tolerated. Most classes will begin with a lecture/discourse relating directly to subsequent assignments and will include significant interactive discussion.

State, university, and departmental policies prohibit smoking or use of other tobacco products in the classrooms. Eating is allowed in class as long as it does not create a problem.

Safety

The Senior Design Lab is composed of a combination classroom and project work facilities. Certain assignments of this course will require the students to use the facilities and use materials, tools and equipment that may cause injuries if improperly used. Students will be given an individual copy of the Lab Safety Plan and are expected to read and understand every item in this plan prior to using the facility. Students should consult the instructor immediately for clarification of any part of the plan they do not understand. It is the student's responsibility to consult the instructor for safety instructions and potential hazards that may arise that may not be specifically covered in the Lab Safety Plan.

Prior to beginning work in the lab, each student will complete the Safety Training Certification form to signify having received instruction on the proper safety procedures and hazards inherent in working in the Senior Design Lab. The deliberate misuse of tools, materials or equipment in such a way as to place the student or others in danger is a breach of the Student Code of Conduct.

Field Trips

The university will provide transportation for any field trips during the courses. Please note that off site clinical shadowing and any related needs assessment activities are not considered field trips.