BENG 495
Bioengineering Senior Seminar
Spring 2015

Class Time: Thursdays, 12:30pm-1:30pm
Location: Engineering 2608
Instructor: Nathalia Peixoto, PhD
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Office Hours: Thursdays, 11am to 12pm.

Course Description: This seminar course familiarizes students with a variety of responsibilities of bioengineers. Examples of topics include dealing with biomedical ethics, regulatory requirements, global considerations, and health care costs. Speakers will include faculty, as well as invited guests from industry, government, and academia. Students are required to explore and then present technical material themselves. Student performance in this course will be based on the quality of two term papers to be submitted in fulfillment of the Mason Writing Intensive Requirements. There are quizzes throughout the semester and one final exam.

Course Objectives: After successfully completing this course, the student will be able to:

• Describe the ethical issues involved in Bioengineering research and development.
• Explain regulatory requirements for Bioengineering related technology.
• Describe the roles and responsibilities of stakeholders in health care.
• Discuss challenges in life sciences and opportunities for innovation through Bioengineering.

Course Organization: Students will attend seminars throughout the semester. Lectures on FDA regulatory issues, clinical trials, and technical subjects will be interspersed with seminars. At the end of the semester students will give an oral presentation on the writing project developed throughout the semester.

Schedule and learning objectives:
1. Course overview - good writing practices and grading policy, library search capabilities, topic selection
2. Regulatory issues (part 1)
   a. Role of the FDA
   b. Regulatory process
3. Regulatory issues (part 2)
   a. Differences between drugs and devices
   b. Role of FDA research laboratories
5. Clinical trials (revised paper #2 due)
   a. Design and implementation of device and drug clinical trials of trials.
   b. Case study of a clinical trial that includes efficacy, ethical, and cost considerations.
6. Cost issues in health care:
   a. Cost dependence on viewpoint. Individual, insurance, and societal views.
   b. Case studies of medical devices
7. Bioengineering as a career:
8. Student Presentations – Paper #2 due

Textbook: Selected reading assignments will be provided. In some cases, electronic copies of articles will be available, or references will be given to material on the web.

Grading:

This course fulfills in part the Writing Intensive requirement in the Bioengineering major. Students will be required to write two term papers, each being an extension of topics discussed in the seminars. The papers will be at least 2,000 words long, approximately 8 standard double-spaced pages. The topic will be chosen by the student, although the instructor may provide suggestions. At least one of the lectures will be devoted to the review of good writing practices, as well as to explaining grading policies.

The instructors will evaluate the first paper extensively, and they will provide detailed feedback to the student. Each paper will be “marked up” to indicate major issues of grammar, technical content, and style; an overall evaluation will be also provided. The grade will include equal consideration of technical content and writing. Students will be given the opportunity to rewrite the paper if they wish to secure an improved grade. In case of severe problems, the student will be also referred to the Writing Center.

The second paper will be also evaluated extensively. Grading, once again, will depend both on content and quality of writing. Since this second paper is likely to be completed close to the end of the semester, typically students will not be invited to rewrite. The grade in the course will be determined by attendance at the seminars (15%), student presentation (10%), two term-papers (40%), quizzes (15%), and final exam (25%). Letter grades are mapped to numeric intervals as follows: A (90-100), B (80-89), C (70-79), D (60-69), F (below 60).

Notes:

- Failure to attend seminar sessions will result in penalties. If you must miss a session, notify the instructor by e-mail as soon as possible stating the reason for your absence. If you must miss more than one session for medical reasons, please contact the instructor for alternative arrangements.
- Successful attendance to the seminar requires being there on time, being prepared and actively participating in discussions.
- Assignments submitted late will be penalized 20% for every day of delay. In case of a documented medical emergency that does not allow you to submit an assignment on time, please notify the instructor.

Academic Integrity: All George Mason University students have agreed to abide by the letter and the spirit of the Honor Code. You can find a copy of the Honor Code at academicintegrity.gmu.edu. All violations of the Honor Code will be reported to the Honor Committee for review.

Mason Email Accounts: Students must use their MasonLIVE email account to receive important University information, including messages related to this class. See http://masonlive.gmu.edu for more information.
Office of Disability Services: If you are a student with a disability and you need academic accommodations, please see the instructor and contact the Office of Disability Services (ODS) at 993-2474. All academic accommodations must be arranged through the ODS. [http://ods.gmu.edu](http://ods.gmu.edu)

Student conduct office: [http://studentconduct.gmu.edu/](http://studentconduct.gmu.edu/)