BENG 495
Bioengineering Senior Seminar
Spring 2016

Class Time: Thursdays, 1:30 pm to 2:30 pm.
Location: Lecture Hall 3
Instructor: Nathalia Peixoto, PhD
Office location: 3912 Engineering Building
E-mail: npeixoto@gmu.edu

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 based on the writing project developed throughout the semester.

Schedule and learning objectives:
1. Course overview: good writing practices, grading policy, library search capabilities, topic selection
2. Bioengineering as a career:
   a. Bioengineering jobs in industry, government and academia
   b. Academic career paths in Bioengineering.
3. Regulatory issues (part 1)
   a. Role of the FDA
   b. Regulatory process
4. Regulatory issues (part 2)
   a. Differences between drugs and devices
   b. Role of FDA research laboratories
5. Writing Instruction – feedback and discussion. Sharing of writing exemplars.
6. 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.
7. 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. All materials will be available on Blackboard.

**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 or research proposals to be submitted as part of postgraduate fellowship applications. 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 first paper will be reviewed extensively by instructor and peers, 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/)

**WAVES: Wellness, Alcohol and Violence Education and Services**
WAVES promotes wellness within the Mason community through health education, alcohol/drug assessment and education, and violence awareness, prevention and sexual assault response. We help students make healthy, safe choices and encourage lifelong, thoughtful healthy decision-making through individualized support, creative programming, and evidence-based education and outreach.

**WAVES office 703-993-9999, SUB I, Suite 3200**

24-Hour Sexual and Intimate Partner Violence Crisis Line 703-380-1434 waves.gmu.edu
- 703-360-7273 (Fairfax County Office for Women and Domestic and Sexual Violence Services 25 hotline)
- 703-228-4848 (Arlington County Domestic Violence Services Hotline)
- 703-368-4141 (Prince William County Sexual Assault Victims Advocacy Services (SAVAS) hotline)
- 1-800-838-8238 (Virginia Family Violence and Sexual Assault Hotline)
- 1-800-656-HOPE (Rape, Abuse and Incest National Network) [https://ohl.rainn.org/online/](https://ohl.rainn.org/online/)

**CAPS: Counseling and Psychological Services**
Counseling and Psychological Services (CAPS) provides a wide range of free confidential services to students, faculty, and staff. Services are provided by a staff of professional clinical psychologists, social workers, counselors, learning specialists, and psychiatric providers. CAPS individual and group counseling, workshops, and outreach programs are designed to enhance students' personal experience and academic performance.

Visit us at [caps.gmu.edu](http://caps.gmu.edu) for additional resources.
- For consultation or emergency assistance during office hours call 703-993-2380.
- For assistance during non-office hours, call University Police at 703-993-4357.
- 703-527-4077 (CrisisLink)
- 1-800-273-8255 (National Suicide Prevention Lifeline)
- 1-877-838-2838 (Veterans' Crisis Hotline)

**Student Health Services (SHS) —** Provides confidential health care to enrolled students in emergency and non-emergency circumstances on the Fairfax, Arlington and Prince William campuses. If there is a medical emergency and Student Health Services (SHS) is closed, please contact the free after-hours nurse ((703) 993-2831), a hospital emergency room, an urgent care facility, or call 911.

**SUB I, Suite 2300, 703-993-2831**

**University Police:**
Emergency: 911 Non-Emergency: (703) 993-2810
Reporting a Crime (Crime Solvers Anonymous Tip Hot-Line): (703) 993-4111
Mason Police Website: [http://police.gmu.edu/](http://police.gmu.edu/)
Eric Heath, Chief of Police Phone: (703) 993-3840 E-mail: eheath2@gmu.edu