Course Syllabus

- **Course Information**

  Course Number/Section: BMEN 6342.001 – Biomaterials and Medical Devices
  Term: Spring 2017
  Days &Times: Class meets in CB3 1.304 on Mondays and Wednesdays, 11:30 AM – 12:45 PM

- **Instructor Information**

  Professor: Dr. Danieli Rodrigues
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  Office hours: Mondays and Wednesdays from 3:00-4:00 PM

- **Course Description**

  Advanced discussion of biomaterials used in the design of medical devices and tissue replacement. Overview of current challenges and successes with implantable devices, biomaterials properties, clinical requirements, clinical applications and cases, and *in-vivo* behavior of different classes of natural and synthetic materials. Analysis of biological response and biocompatibility, degradation and failure processes of implantable biomaterials/devices. Students will become familiar with several classes of biomaterials and their current clinical applications.

- **Course Learning Objectives:**

  1. Summarize clinical problems at the interface of engineering, medicine, biology, and physiology (SO: a).
  2. Assess the performance of biomaterials and their interactions with the biological environment (SO: k).
  3. Evaluate contemporary designs of implantable biomaterials and devices using current literature (SO: j).
  4. Recognition of professional responsibility through evaluation of clinical cases and regulations (SO: f).

- **Suggested Textbook**

  Please note that purchase of a textbook is not required for this class. Lectures will use a variety of books, journal articles, class notes and slides. All class materials will be made available for study. The list of main books that will be used in the preparation of lectures include:

  - **Biomaterials Science: An Introduction to Materials in Medicine**. Buddy D. Ratner et al. 2012, 3rd edition or 2nd edition 2004.

- **Essential Biomaterials: Cambridge Texts in Biomedical Engineering**. David Williams 2014, 1st edition.

- **Websites**

Course Materials (power point lectures, updated syllabus, handouts, project guidelines and information) will be available on eLearning.utdallas.edu.

- Other important resources:
- *FDA*:
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm
- *Testing standards for devices and biomaterials can be found at*:
  http://www.iso.org/iso/home.html
  http://www.astm.org/

- **Course Content Outline and Tentative Schedule:**

01/09
Course introduction
- Goals and class learning objectives
- Class overview
- Project discussion

01/09, 01/11, 01/18
Chapter 1. Background: the clinical need of biomaterials and devices in the twenty-first century
- Materials in clinical practice
- The biomaterials concept
- The evolution of biomaterials science and the changing concepts
- Requirements of materials in clinical medicine
- Class and applications of biomaterials used in the body
- Overlook of the current medical device industry
- **Paper review 1 and group discussion (Group 1)**

01/23, 01/25, 01/30, 02/01, 02/06, 02/08, 02/13, 02/15
Chapter 2. Essential materials science
- Introduction
- Basic materials model
- Atoms, molecules, interatomic, intermolecular bonds
- The organization of atoms and molecules: state of matter, crystalline and amorphous
- Practical materials: metals, alloys, synthetic polymers, biopolymers, ceramics, natural composites
- **Paper 2 review and group discussion (Group 2)**
- Surface properties of materials
- Physical properties of materials
- Mechanical properties of materials
- Corrosion and degradation mechanisms
- Synthesis, fabrication, manufacturing and sterelization considerations
- Special considerations: environmental responsiveness, nanoparticles, injectable materials, self-assembly, bio-mimetic materials

- **Paper 3 review and group discussion (Group 3)**

02/20, 02/22

Chapter 3. Biocompatibility pathways

- Introduction
- The fundamental biocompatibility paradigm
- Biocompatibility scenarios
- Systemic or remote site biocompatibility
- Specific clinical examples of biocompatibility phenomena
- Influence of bacteria, fungi, viruses, prions and endotoxins
- Clinical and patient variables
- **Paper 4 review and group discussion (Group 4)**

02/27

Project proposal presentations: all groups

03/01, 03/06, 03/08, 03/20, 03/22, 03/27, 03/29, 04/03, 04/05

Chapter 4. Contemporary and future biomaterials

- Classification of biomaterials
- Metallic systems
- Ceramic systems
- **Paper 5 review and group discussion (Group 5)**
- Polymeric systems
- Carbon materials
- Composite materials
- Engineered biological materials (TBD)
- **Paper 6 review and group discussion (Group 6)**

04/10

Exam assessment

Chapter 5. Characterization of biomaterials

Chapter 5 is a handout summarizing some of the most important characterization techniques, this chapter also involves visit to lab facility and take-home activity:

- Contact angle
- Infrared spectroscopy
- X-ray photoelectron spectroscopy (XPS)
- Atomic force microscopy (AFM)
- Scanning electron microscopy (SEM)
- X-ray diffraction (XRD)
- Chromatography
- Thermal analysis (DSC, TGA, DMA)
- Mechanical testing (quasi-static, dynamic)

04/12-04/17

Chapter 6. Surface modification of biomaterials

- Abrasive blasting
- Plasma glow discharge
- Thermal spraying
- Physical vapor deposition
- Chemical vapor deposition
- Grafting

- **Paper 7 review and group discussion (All groups)**

04/19, 04/24
Chapter 7. Selected clinical applications of medical devices
- Orthopedics
- Dentistry, maxillofacial and craniofacial tissues
- The cardiovascular system
- Neural prosthesis
- Eyes and ears
- Skin applications
- **Paper 8 review and applications (All groups)**

04/24, 04/26 – (This lecture may be given earlier in the semester depending on invited speaker schedule, TBD)
Chapter 8. Infrastructure of the biomaterials industry
- Principles of medical device regulations
- Guidelines
- Clinical trials and post-market surveillance
- Product liability litigation in medical technology

05/03, 05/05
Project presentations and final report due.

- **Grading Policy**

  - Exam assessment: 25%
  - Quizzes: 20%
  - Journal article discussion and participation in class: 10%
  - Project: 45%
    - Proposal and problem presentation: 5%
    - Report: 20%
    - Final presentation: 20%

%	97+	96.9%-93.0%	92.9%-90.0%	89.9%-87.0%	86.9%-83.0%	82.9%-80.0%	79.9%-77.0%	76.9%-73.0%	72.9%-70.0%	69.9%-60.0%	≤59.9
Letter Grade	**A+**	**A**	**A-**	**B+**	**B**	**B-**	**C+**	**C**	**C-**	**D**	**F**

- **Course Assessment**

  - **Journal article discussion:** at the end of specific sections (see course schedule) a journal article will be assigned by the instructor or student group. The class is expected to review the material before the next lecture. One of the student groups will be responsible for summarizing and leading the discussion of the article in class. There will be 8 journal articles that will be discussed during the semester. All students are expected to review the material and come prepared with questions for the presenting group. The group reviewing the article will have 10 minutes to discuss the study followed by another 5-10 minutes of Q&A. Groups will be graded by the quality of presentation, preparation and engagement with the class.

- **Quizzes:** will cover materials from lectures and discussions and will substitute homework. It will be done in class, individual or as in group activity, or as take-home activities.

- **Exam assessment:** will cover topics seen until end of chapter 4.

- **Project:** device design problem study focused on a current implantable medical device system. This is a semester long project in which students will use class information for classification, characterization, analysis of properties, review of regulatory environment, review of possible failure modes and mechanical scenario, etc. with a specific implantable device of interest that shows a current challenge. For example: "dental cements used in root canal treatment are not ideal because of the high degree of shrinkage these materials undergo during polymerization. Volumetric shrinkage of the material post-polymerization will create cavities and de-bonding from the tissue walls enabling bacteria to infiltrate and proliferate, which can lead to re-infection of the canal". How can you approach this problem? What kind of materials could be used to potentially mitigate this deleterious shrinkage problem which is a direct result of conversion of monomers to polymers? What kind of properties the material/device would need to have? Biocompatibility? Regulatory pathway? Manufacturing and sterilization steps? Possible failure modes?. All of these critical items need to be identified.

    - **Proposal:** groups are expected to turn in a two-page project proposal after the first month of classes. The proposal will identify the device/biomaterial to be studied, will state the clinical problem with that particular device/biomaterial, and will provide a background on the application and overall characteristics of the device. Groups will perform an extensive literature review during the first month to select the system of interest and will meet with the instructor right after identifying the system to discuss feasibility of the project. The written proposal will be composed of two pages and groups will have 10 minutes to present their proposed projects to the class. **Two-page proposal due date: 02/22**; **Group presentation of proposals: 02/27**.

    - **Report:** the final report is due the day of group presentations (final exam date). It will be composed of multiple sections following guidelines given by the instructor (12 pages, single-spaced, see requirements in the report guideline document to be distributed in class).

    - **Presentation:** groups will have 20 minutes to present projects followed by 5-10 minutes of questions. Presentations will describe the device problem of investigation, identifying all the characteristics (chemical, physical and biomechanical environments) of the device/biomaterials in study as discussed in lectures. Class elements need to be present in the report and presentation, and an in-depth analysis of the device/biomaterials properties is expected, as well as analysis of feasibility of methods proposed, regulatory and commercialization steps. The presentation can follow the sections presented in the report. Reports due date: final exam date; Presentations: final exam date, or in two days.

  - *Device design problem study: The goal of this activity is to identify current problems associated with medical device designs. Students will be separated in teams and will select a specific problem of interest with an implantable device or biomaterial. Each team will give an oral and written presentation of the selected system at the end of the semester defining the clinical problem and proposing alternative materials/design/processing/modifications that could potentially mitigate the risks or "solve the problem" associated with the selected device/biomaterial. Extensive literature review, as well as a proposal, will be required prior to the presentation of the project. Design, development, failure modes, performance requirements*

and regulatory aspects will be addressed for each system selected and should have a separate section in the report.

- **Course & Instructor Policies:**

  Make up exams: All students are expected to take the exams on the dates posted in the class schedule and as announced by the instructor. Unavoidable conflicts must be communicated to the instructor ahead of time. Missed exams without e-mail notification in advance of the absence will result in a grade of zero for the assignment or test.

  Late work: No late work will be accepted.

  Group Presentations: Group members absent on the day of their group presentation will not be awarded credit for the group presentation.

  Class attendance: Class attendance is mandatory. Advance notice for any non-emergency absence to the instructor is expected. Student will lose credit for the day of non-participation in the class activity.

  Quiz(s): No make-up quiz will be offered if a student is absent for reasons other than an emergency situation.

  Classroom citizenship: Each student is expected to participate in the quizzes and associated discussion.

- **UT Dallas Syllabus Policies and Procedures**

  The information contained in the following link constitutes the University's policies and procedures segment of the course syllabus.

  Please go to http://go.utdallas.edu/syllabus-policies for these policies.

The descriptions and timelines contained in this syllabus are subject to change at the discretion of the Professor.