

Course Syllabus

- **Course Information**

Course Number/Section: BMEN 4360.001 – Biomaterials and Medical Devices

Term: Spring 2022

Days & Times: Class will meet on Mondays and Wednesdays from 10:00 AM - 11:15 AM CT.

Classroom: AD 2.232 (This is on hold until further university instructions)

Days & Times: Class will meet online via Microsoft Teams Platform at regular lecture times on Mondays and Wednesdays from 10:00 AM - 11:15 AM CT.

- **Instructor Information**

Instructor: Dr. Danieli Rodrigues

Office Phone: 972-883-4703

Office: BSB 12.929

E-mail: danieli@utdallas.edu

Office hours: Mondays/Wednesdays from 1:30-2:30 PM. Held virtually via Microsoft Teams Platform. (please call instructor via Teams during the assigned time block).

Teaching Assistant: Diana Yaghmour

E-mail: diana.yaghmour@utdallas.edu

Office hours: Tuesdays/Thursdays from 10:00-11:00 AM. Held virtually via Microsoft Teams Platform. (please call TA via Teams during the assigned time block).

- **Class Participation**

Students who fail to participate in class regularly are inviting scholastic difficulty. A portion of the grade for this course may be directly tied to your participation in this class. It also includes engaging in group or other activities during class that solicit your feedback on homework assignments, readings, or materials covered in the lectures. Successful participation is defined as consistently adhering to University requirements, as presented in this syllabus. Failure to comply with these University requirements is a violation of the [Student Code of Conduct](#).

- **Class Recordings**

The instructor may record meetings of this course. Any recordings will be available to all students registered for this class as they are intended to supplement the classroom experience. Students are expected to follow appropriate University policies and maintain the security of passwords used to access recorded lectures. Unless the Office of Student AccessAbility has approved the student to record the instruction, students are expressly prohibited from recording any part of this course. Recordings may not be published, reproduced, or shared with those not in the class, or uploaded to other online environments except to implement an approved Office of Student AccessAbility accommodation. If the instructor or a UTD school/department/office plans any other uses for the recordings, consent of the students identifiable in the recordings is required prior to such use unless an exception is allowed by

law. Failure to comply with these University requirements is a violation of the [Student Code of Conduct](#).

- **Covid-19 Guidelines and Resources**

The information contained in the following link lists the University's COVID-19 resources for students and instructors of record. Please see <http://go.utdallas.edu/syllabus-policies>.

- **Course Description**

Introduction to the field of biomaterials used in the design of medical devices and to augment/replace soft and hard tissues. Discussion of bulk properties, clinical applications, 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. Overview of regulatory compliance and performance requirements for commercialization of medical devices.

Students will become familiar with several classes of biomaterials and their bulk and surface properties. Lectures will discuss design and performance requirements of implants, structure-property relationships for synthetic and biological materials, and static and dynamic properties of biomaterials.

- **Course Learning Objectives:**

- **CLO1:** Report contemporary challenges with the design and development of artificial implants using current literature (SO: 3).
- **CLO 2:** Assess the performance of biomaterials and their interactions with the biological environment (SO: 1).
- **CLO 3:** Understand the regulatory environment governing development, performance and commercialization of medical devices (SO: 4).
- **CLO 4:** Recognition of professional responsibility through evaluation of clinical cases and by researching standard testing procedures and their relationships to US and European regulations (SO: 4).

- **Suggested Textbook**

Biomaterials Science: An Introduction to Materials in Medicine. Willian Wagner et al. 2021, 4th edition.

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

Introduction to Biomaterials: Basic Theory and Engineering Applications. C. Mauli Agrawal, Joo L. Ong, Mark R. Appleford, Gopinath Man. Cambridge University Press 2014, 1st Edition.

Biomaterials: A Basic Introduction. Qizhi Chen and George Thouas. CRC Press, 2014, 1st Edition.

Note that the acquisition of a textbook is not required. Lecture notes, articles, and handouts will be distributed via eLearning. Lectures will use a combination of materials from several books, articles and other sources.

- **Class Materials**

The Instructor will provide class materials that will be made available to all students registered for this class as they are intended to supplement the classroom experience. These materials can be downloaded during the course, however, these materials are for registered students' use only. Classroom materials may not be reproduced or shared with those not in class, or uploaded to other online environments except to implement an approved Office of Student AccessAbility accommodation. Failure to comply with these University requirements is a violation of the [Student Code of Conduct](#).

- **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/>

- **Technical Requirements**

In addition to a confident level of computer and Internet literacy, certain minimum technical requirements must be met to enable a successful learning experience. Please review the important technical requirements on the [Getting Started with eLearning](#) webpage.

- **Course Access and Navigation**

This course content can be accessed using your UT Dallas NetID account on the [eLearning](#) website. Please see the course access and navigation section of the [Getting Started with eLearning](#) webpage for more information. To become familiar with the eLearning tool, please see the [Student eLearning Tutorials](#) webpage. UT Dallas provides eLearning technical support 24 hours a day, 7 days a week. The [eLearning Support Center](#) includes a toll-free telephone number for immediate assistance (1-866-588-3192), email request service, and an online chat service.

- **Communication**

This course utilizes online tools for interaction and communication. Some external communication tools such as regular email and a web conferencing tool may also be used during the semester. For more details, please visit the [Student eLearning Tutorials](#) webpage for video demonstrations on eLearning tools. Student emails and discussion board messages will be answered within 2 working days under normal circumstances.

- **Distance Learning Student Resources**

Online students have access to resources including the McDermott Library, Academic Advising, The Office of Student AccessAbility, and many others. Please see the [eLearning Current Students](#) webpage for more information.

- **Server Unavailability or Other Technical Difficulties**

The University is committed to providing a reliable learning management system to all users. However, in the event of any unexpected server outage or any unusual technical difficulty which prevents students from completing a time sensitive assessment activity, the instructor will provide an appropriate accommodation based on the situation. Students should immediately report any problems to the instructor and also contact the online [eLearning Help Desk](#). The instructor and the eLearning Help Desk will work with the student to resolve any issues at the earliest possible time.

- **Pre-requisites/Core-requisites**

BMEN 2320, CHEM 1312

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

01/19, 01/24, 01/26

1. Course Overview and Introduction

- 1.1. Course objectives and expectations
- 1.2. Introduction to biomaterials science
- 1.3. Brief history of biomaterials: surgeon-era to engineered biomaterials
- 1.4. Overview of current clinical applications: cardiovascular devices and stents, dental restoration, dental implants, neural prosthesis, ophthalmology, orthopedic implants, renal, skin applications.
- 1.5. Overview of the current medical device industry

01/31, 02/02, 02/07, 02/09

2. Basic Properties of Biomaterials

- 2.1. Bonding, interatomic, intermolecular, surface interactions
- 2.2. Bulk properties: microstructure, strength, deformation, failure, fracture
- 2.3. Surface properties: hydrophilic and hydrophobic interactions, surface charges

02/14

Exam 1

02/16-04/04

3. Classes of Materials Used in Medicine

02/16, 02/21, 02/23, 02/28

- 3.1. Metallic biomaterials:
 - *general characteristics and desirable properties*
 - *fabrication and processing*
 - *surface: oxide film formation and surface modification techniques*
 - *characterization: bulk and surface*

- *main metallic alloys used in implantable devices: Ti, SST, Nitinol, CoCr, Mg, Ta*

03/02, 03/07, 03/09

3.2. Ceramic biomaterials:

- *general characteristics and properties*
- *types of bioceramics*
- *fabrication and strengthening*
- *characterization: bulk and surface*
- *applications in the field: calcium phosphates, alumina, zirconia, natural and synthetic hydroxyapatite*

03/21, 03/23, 03/28, 03/30, 04/04

3.3. Polymeric biomaterials:

- *general information*
- *basic principles: molecular and chemical structure, molecular weight and polydispersity*
- *physical behavior*
- *synthesis: addition, free-radical, condensation polymerization*
- *characterization: bulk and surface*
- *selected applications in the field: (device, drug delivery, tissue engineering)*
 - *bioinert polymers: polyethylene, acrylics (PMMA), silicones*
 - *degradable and resorbable biopolymers*
 - *hydrogels*

04/06

Exam 2

04/11, 04/13

5. Biomaterials Degradation in the Biological Environment

- 5.1. Working environment of implants in the body
- 5.2. Chemically assisted degradation
- 5.3. Mechanically assisted degradation
- 5.4. Synergistic failure modes
- 5.5. Review of clinical cases of implant failure (selected fields: cardiovascular, neural, tissue, arthroplasty, dental, etc.)

04/18, 04/20

6. Biocompatibility

- 6.1. Biological response to biomaterials, wound healing, foreign body reaction
- 6.2. Blood-material interactions
- 6.3. Toxicity, hypersensitivity
- 6.4. Tumors associated with biomaterials and implants
- 6.5. Biofilms

04/25, 04/27

7. Special Considerations for Implantable Devices and Biomaterials

- 7.1. Sterility and patient safety
- 7.2. Device failure mode analysis
- 7.3. Design standards and regulatory compliance
- 7.4. Clinical trials and market approval

05/02

Final exam review section

05/04

Open day – Final exam (Exam 3) to be scheduled

- **Grading Policy**

- **Exam 1:** 25%
- **Exam 2:** 25%
- **Exam 3:** 25%
- **Quizzes and participation:** 15%
- **Analysis of selected journal articles, or clinical case (group activity):** 10%

%	100-93.0%	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%-67.0%	66.9%-63.0%	62.9%-60.0%	≤59.9
Letter Grade	A	A-	B+	B	B-	C+	C	C-	D+	D	D-	F

- **Course Assessment**

- **Exams:** Three exams will be given this semester. Each exam will cover prior chapters learned in class or as instructed. Final exam (Exam 3) is not cumulative as will follow the same structure as Exams 1 and 2. The lowest grade from the three exams will be dropped in the calculation of the final average.
- **Quizzes:** will be given in a weekly basis following lectures or discussion of clinical/device application cases. Quizzes can be done in an individual basis or in teams of 2 students. Quizzes are meant to prepare students for exams and will contain a variety of questions. Students will receive a completion grade for each quiz activity. Detailed answer keys for each quiz will be uploaded on eLearning. The answer key will go over each question providing answers and additional study materials. Quizzes and answer keys are prepared to guide students through the material and for practice of class related contents. Students are highly encouraged to spend time working on these assignments in a weekly basis.
- **Analysis of journal articles/clinical cases/device applications:** students will form teams of 2 and will select one clinical application of interest from the list of the most implanted medical devices that will be discussed in class. Each group will research and find a recently published journal article or clinical case related to the topic selected for review. Groups will prepare a 3-page long critical review on the article. Submission dates and paper instructions will be posted on eLearning.

- **Course & Instructor Policies**

- **Make up exams:** Students are expected to take exams on posted dates 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. Unavoidable conflicts must be communicated to the instructor ahead of time. **PLEASE FOLLOW SCHEDULES AS POSTED.**
- **Class attendance:** Class attendance is expected as this is a fast paced and highly interactive course. The instructor encourages questions from students during lectures. Please access eLearning on a weekly basis for lecture slides, activities including quizzes, and assignments submission.
- **Classroom citizenship:** Each student is expected to participate in quizzes and associated discussions. Instructor will mark student participation in class during lecture/discussions.

- **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.