CHBE 457/ENMA425 Design and Processing of Polymers for Biomedical Devices Spring 2019
Mondays & Wednesdays, 4:00-5:15pm, AJC 2132

Course Description:
This course will provide an overview to the design and processing of polymers used in medical applications. Following a discussion of the physical and mechanical properties of polymers, important classes of polymeric biomaterials will be surveyed, discussing material synthesis, processing techniques and equipment, as well as properties and performance in biomedical applications. Topics will include silicone elastomers, hydrogels, ultra-high molecular weight polyethylene, polyurethanes, polyureas, polyesters, degradable and resorbable polymeric biomaterial designs used in surgery and drug delivery, polymers for ophthalmologic and orthopedic applications, and biopolymers such as silks and collagen. Glass transition and Crystallization: Influence of morphology on polymer structure, function, and properties. Finally, the design of polymer processing equipment will be covered as it applies to the manufacturing of biomedical devices and the fundamentals of extrusion, calendering, coating, fiber spinning, film blowing, and injection molding.

Instructor: Peter Kofinas; Professor and Chair, Chemical and Biomolecular Engineering
kofinas@umd.edu; Office: Bldg. 090 Room 2113

Office hours: Group homework/team learning community: MW 5:15 -6:00 (AJC 2132). Please feel free to stop by my office at any time, I will either meet with you then, or set up a mutually agreeable time. You can also arrange another appointment date and time by emailing me.

Teaching Assistant:
Kyle Ludwig, kludwig2@umd.edu
Office: Kim Building Room 1124
Office Hours: TBD

Pre-requisites
MATH246; and CHEM231; and (CHBE301, ENMA461, or BIOE232).

Recommended Textbooks:

1. Biomaterials Science – An Introduction to Materials in Medicine, 3rd Edition, edited by Buddy Ratner et al., Academic Press 2013. ISBN 978-0-12-374626-9
   This book is available as a free download accessible from the UMD libraries
   https://umaryland.on.worldcat.org/search?databaseList=&queryString=Biomaterials+Science&umdlib= - /oclc/819506978

2. Essentials of Polymer Science and Engineering, Paul C. Painter, Michael M.Coleman, DEStech Publications, 2009. ISBN-13: 978-1932078756

COURSE MECHANICS AND POLICIES

You are expected to comply with all University of Maryland Policies for Undergraduate Students listed on this website http://www.ugst.umd.edu/courserelatedpolicies.html

Course logistics, documents, and announcements will be posted on Canvas (login at http://elms.umd.edu/). Updates to the syllabus and other documents will be made as needed during the semester, and the current version will always be available in the files section on Canvas.

Lectures and Participation

Lecture outlines will be posted online prior to each lecture. During lecture, many students find it useful to print these outlines for taking notes or annotate electronic versions. An updated version of the lecture outline may be posted after the lecture is delivered, please check Canvas for updated files. Regular attendance for this class is expected. In the event that a class must be missed due to an illness, and are absent on a day when a test or other major assignment is due, you must notify your instructor *in advance*. Upon returning to class, you must bring documentation of the illness signed by a health care professional. If you miss class, *even if it is an excused absence*, you are responsible for all information covered that day.

Honor Code and Academic Fraud in this class

You are absolutely free to

1. Work with groups of any size to prepare for class
2. Look things up on your computer or in a book, out of class, using any source. When requested, you will be encouraged to access web resources in class.

However, if during a graded quiz/exam we observe you using text chat or any electronic messaging software, we will assume that you are cheating. You will (at minimum) receive no credit for the quiz, and your case will be turned over to the Honor Council. You will be similarly penalized if we see you looking at someone else's screen/paper during a quiz/exam.

Homework and other Assignments

Homework and other assignments will be posted online and will be due at the specified date and time listed on the assignment. Some assignments will be turned in during class, and must be handed in at the beginning of lecture on the due date. Other assignments will be submitted on Canvas. In all cases, the *dates and instructions on the specific assignment are the information students should adhere to*. Late assignments will not be accepted. Homework keys will be posted on Canvas. All submitted work should be neat and easily legible. You are not being graded on how little paper you can use or how small you can write. We reserve the option to return work ungraded or deduct points if it does not meet these basic requirements. There is no stapler provided in class.

Exams

Two in-class exams will be given. Exams may cover material from all aspects of the course including lectures, discussion sessions, readings, and assignments. Exam 1 will cover material through approximately the first half of the course. Exam 2 will cover mostly the second half. We will be continually building on earlier topics so there may be times when students must draw on content from earlier points in the semester to do well in Exam 2. In the event the University dismisses classes on a day in which an examination is scheduled, then the exam will be given during the very next class session. **No make-up exams will be administered**; however, students with university-approved absences will be accommodated according to university policy. Any requests for re-grading in homeworks and exams must be submitted in writing within ten business days of the assignment/exam deadline.

Exam 1: Wednesday March 6
Exam 2: Monday April 22
Final Exam: TBA

You are required to submit any documentation regarding religious observances and disability to kofinas@umd.edu by the end of the schedule adjustment period.

CourseEvalUM: Your participation in the evaluation of courses through CourseEvalUM is a responsibility you hold as a student member of our academic community. Your feedback is confidential and important to the improvement of teaching and learning at the University. CourseEvalUM will be open for you to complete your evaluations sometime towards the end of the semester. Please go directly to the website (www.courseevalum.umd.edu) to complete your evaluations. By completing all of your evaluations each semester, you will have the privilege of accessing online, at Testudo, the evaluation reports for the thousands of courses for which 70% or more students submitted their evaluations.

Grading:

20% Exam 1
20% Exam 2
25% Final Exam (comprehensive)
10% Laboratory Assignment
15% Design Project
10% Homework – graded for completion

During the final grade calculation, additional points may be assigned to individuals who regularly attend and participate during class.

In general, reported earned grades will follow the following guidelines

- A+, A, A- denotes excellent mastery of the subject and outstanding scholarship
- B+, B, B- denotes good mastery of the subject and good scholarship
- C+, C, C- denotes acceptable mastery of the subject
- D+, D, D- denotes borderline understanding of the subject, marginal performance, and it does not represent satisfactory progress toward a degree
- F denotes failure to understand the subject and unsatisfactory performance

You must achieve a grade of C- to demonstrate satisfactory academic progress since this is a technical course.

Course outcomes:

Polymer biomaterials selection and design requires a synthesis of knowledge ranging from chemistry, biology, and properties of materials, to a thorough understanding of the clinical problems that are to be solved (or caused) by materials. Upon conclusion of this course you should be able to:

1. Understand how polymeric biomaterials interact with and are recognized by cells and tissues.
2. Analyze how the physical and chemical properties of polymeric biomaterials lend themselves to specific clinical applications.
3. Understand the clinicians concerns and the design criteria that lead to the choice of material for a particular biomedical device.
4. Synthesize knowledge to use polymer materials in novel ways for the engineering of biomedical devices.

Strategies for Success: Students should *read the text(s)* and attend all course meetings. The experience gained through completion of the homework assignments will be needed to do well on exams and to master the material that future courses (and your careers) will build on. Assignments and exams will be continually building on earlier topics so there may be times when students must draw on content from earlier points in the semester to do well in future examinations.

My objective is that everyone understands the material covered in this class and will use concepts taught in class in their future career. If you come see me during office hours or other scheduled appointment with the intent of being spoonfed the answer to a homework problem or finding out what specifically to avoid studying for an exam, you will be out of luck. If you however show me how you approached a problem that you were unable to solve, I will guide you to a strategy that should lead you to the answer. I am also happy to review material that you did not understand, which will help you solve the homework or do well on the exam.

Courtesies: You can help make the classroom conducive to learning if you:
1. Arrive for class on time
2. Do not prepare to leave until the instructor indicates the lecture is over
3. Silence your cell phone
4. Do not eat or drink, except for coffee, tea, or water

You will not chat with your peers, text, or electronically chat during class *except* by permission of the instructor, and you must provide a defensible educational reason. While this is not an Honor Code violation, we do consider it a form of non-participation. You will be warned once. After that, you will lose 1% of your grade per violation.

Topics Covered

The topic schedule is preliminary and subject to change through the course of the semester. Class notes and homeworks will become available on Canvas as the material is covered.

1. What are Biomaterials?
2. Composition of Materials: Types of Bonds, Microstructure
3. Bulk Mechanical Properties
4. Surface Properties
5. Polymers: Molecular Weight and Characterization of Molecular Weight Distributions
6. Glass Transition and Crystallization: Impact on Biomaterial Design
7. Polyurethanes, Polyesters, and Polyureas - Step Polymerization
8. Silicones and Network Hydrogels - Multifunctional Polycondensation
9. Drug Delivery, Bone Cement, Contact Lenses and Implants - Radical Polymerization
10. Microparticles and Nanoparticles
11. Stents, Orthopedic, and Dental Biomaterials
12. Blood Contacting Polymer Biomaterials
13. Processing of Polymer materials for Biomedical Devices
14. The Path from Biomaterial Conception to Clinical Product

Lab:

Teams will collaborate to gather data using the polymer characterization equipment in the Functional Macromolecular Laboratory (Room 1211, KEB). Relevant theory will be covered in lecture. A class will be held in Room 1211 to familiarize students with the equipment, a gel permeation chromatography (GPC) column and a differential scanning calorimeter (DSC). Experimental protocol will be described in a handout before the lab. The lab report will focus on the degradation of poly(lactic acid), a polymer commonly used in biodegradable sutures and drug delivery devices.

Lab dates and lab report due date will be announced later in the semester

Polymer Biomaterial Design Project:

In this project, teams will identify a clinical problem of interest and select an existing, FDA-approved polymer-biomaterial Class III device that addresses this problem. Each team will develop a report on a polymer-based device produced by a specific manufacturer, keeping in mind design constraints, necessary materials and components, appropriate biocompatibility and device performance assessments, and the FDA device approval route. The findings will be documented in a written report, and presented during an oral presentation held on the last two class lectures. As in the real world, there are no exact answers to this project. Reports and presentations will be assessed based on rigor, creativity, ingenuity, logic, and professionalism. *All project materials should be submitted on Canvas*

PROJECT COMPONENT	**GRADE VALUE**
1 page preliminary summary of proposed device	20% of project grade
Project report (**written**)	40% of project grade
Presentation (**submit a copy of PPT**)	40% of project grade

Project report. The Project Report should include a title page with the project title, names of all group members, group ID, and presentation date. The body should have a logical flow from section to section and be professionally formatted using 1" margins with single-spaced 11pt Arial font. Captions for figures and schematics should be 10pt font. The report must also be referenced. The report should include the following information at the level of detail teams feel is appropriate/of interest for the selected application: Problem statement/statement of need, background including existing or competing devices, how the device solves the problem and improves upon previous designs, diagrams and/or structures describing each material/component, rationale for selection of each material/component including an analyses of structure-property relationships, simulations or design calculations, a plan to assess biocompatibility and performance, the proposed route and requirements for FDA approval, and other areas deemed relevant. For more information on what content is expected in the report and how to organize it, please see **General Guidelines** below.

Presentations. Each team will have *15 minutes* to present their project using PowerPoint slides or an equivalent electronic presentation format. Presentations running longer than 15min:15sec will be stopped.

General Guidelines

1. Select a polymer-based Class III biomedical device that addresses the clinical problem you have identified. This should be a specific FDA-approved device, with a known manufacturer and ample documentation to use for research.
2. Present a brief summary: What is the clinical problem the specific device is aiming to address?
3. Identify the various major parts of the device, provide a drawing or illustration and list the materials used. This may involve contacting the manufacturer and/or locating the appropriate information within the patent literature. How is the device packaged? How is it sterilized? Are there any sterilization considerations or concerns?
4. How is the polymer based device used in a clinical setting? What is the history of intervention for such problems? What is the outcome of the intervention when using this device? Why are polymers a major component of the device? If the materials have changed over that time, why?
5. Justify the selection of the materials used with regards to similar successful applications. What are the important physical chemical and mechanical properties of the biomaterial? Here you need to include diagrams and quantitative data. You should address:
    1. Bulk structure and composition
    2. Surface interactions
    3. Chemical structure & properties
    4. Physical / mechanical properties
    5. How are these properties measured experimentally?
    6. Where does the material originate, or how is it synthesized and manufactured?

   7. What is its cost, and are there favorable federal regulations?
6. Biological response: How does the body respond to the biomaterial? What adverse reactions are possible?
7. Provide an FDA approval plan for this device.
8. Provide an alternative biomaterial solution to at least one of the key components used in the device and justify/document your selection. List benefits and drawbacks of the existing components and those of the proposed biomaterial alternative.

All projects must include a thorough statement of the problem and material choice (including diagrams and structure-property relationships), and a testing/FDA approval plan. A well written project report will typically be about 10-15 pages, including figures and tables, but grades are assigned on quality, not how short or long the report is.

ONLINE FDA RESOURCES

Official FDA guidance documents database for assessing existing devices, drugs, and technologies: https://www.fda.gov/RegulatoryInformation/Guidances/default.htm

Searchable FDA database of recognized standards (e.g., ISO 10093) and devices to which the standards apply: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

Grading guidelines for paper (equal weight for a, b and c)

a. Did the paper answer all the applicable questions? Was the paper clear in presentation format and easy to read? Was the line of thought of the paper easy to follow? Was the paper written as a technical manuscript (e.g., should not be written as a novel)? Was correct grammar used? Was the topic area specified clearly? Was enough material covered (either broad or in-depth, not necessarily both)?

b. Did the paper content focus on the polymer biomaterials aspect of the device? Did the aspects of design and use discussed lead toward a discussion of the biomaterial issues? Was the clinical relevance properly addressed? Were future directions in the field noted?

c. Were the references properly cited in the text? Were the references properly formatted at the back of the paper? Were there sufficient references covered, and were these well-chosen? Was too much emphasis put on one or two references? Were tables, charts or figures used when appropriate and properly referenced in the text?