

BIEN 4801- Pharmaceutical Biotechnology

MW 12:50 – 2:05 PM

JSCBB B115

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Schedule

<i>Week</i>	<i>Date</i>	<i>Subject</i>	<i>Notes</i>
1	Jan 12, 14	Intro to Pharmaceuticals Molecule to Drug Overview – Discovery, Preclinical, Clinical Trials Cost of pharmaceuticals	
2	Jan 21	MLK Day on Monday Thermodynamics of Interfaces Surfaces II- Capillary Thermodynamics/ Gibbs eqn.	Reading: Ch 1, 10 Reading Homework due Wed Jan 21 HW1 due Jan 21 Reading: Handout on Canvas
3	Jan 26, 28	Experimental Measurement of surface tension Protein Solutions: Conformational instability/ Timasheff mechanism Experimental Measurement of Protein Stability	Reading: Ch 2 Reading Homework due Monday Jan 26
4	Feb, 2, 4	Application: Protein Aggregation Kinetics The FDA Regulatory Requirements for Approval	HW 2 due Feb 4 Reading Ch 9 Reading Homework due Monday Feb 2
5	Feb 9,11	IP Considerations Clinical Trial Ethical Issues Case Studies	HW 3 due Feb 11

6	Feb 16, 18	PK ADME PD- Binding constants, ED50, etc. Exam review	
7	Feb 23,25	Animal Models / Allosteric Design Kinetic Models	Reading Ch. 5 Reading Homework due Mon Feb 23 2/25 Exam I
8	Mar 2, 4	Transdermal Delivery Iontophoresis Microneedle Delivery Ultrasound Blood Brain Barrier Ocular Delivery	HWK 4 due Mar 4 Reading Homework due Mon Mar 2 Reading Ch 4
9	Mar 9,11	Pulmonary Delivery Parenteral Delivery Pulmonary Delivery: Exubera case study Nasal / Exotic Delivery	HWK 5 due Mar 11
10	Mar 16, 18	Spring Break	
11	Mar 23, 25	Antibodies Antibody-drug conjugates (ADC's) Antibody Formulation & Delivery Issues	Reading: Ch 7 Reading Homework due Mon Mar 23
12	Mar 30 Apr 1	Vaccines Adjuvants Vaccine Ethics	HWK 6 due Apr 5 Reading Ch 22 Reading Homework due Mon Mar 30
13	April 6, 8	Generics / Biosimilars Immunogenicity Exam II	Reading: Ch 6 Reading Homework due Mon Apr 6
14	April 13, 15	Intro to Nucleation Rate Theory Crystal Growth kinetics Polymorphism / Bioavailability	4/15 Exam II in class
15	April 20, 22	Ostwald Ripening Application: Organ Preservation Lyophilization: Materials Science of Glassy States Heat and Mass transfer in lyophilization	Reading: Ch 4 Reading Homework due Apr 20

16	Apr 24		Last class tba	
Final April 27 4:30			Final Paper	7:30 p.m. turn in final paper

Final Paper
(10-15 pages)

1. Pick a disease

suggestions:

Alzheimers

Malaria

Diabetes

Rheumatoid Arthritis

Cancer (pick one)

Tuberculosis

Multiple Sclerosis

...

2. Describe disease in detail

pathology

progression

mode of transmission

populations affected

morbidity/mortality statistics

challenges for treatment

...

3. Describe current therapies

type of drugs used

estimated costs of treatment

intellectual property

clinical trials underway

Introduction

Pharmaceutical Biotechnology is a course that is designed to acquaint students with the engineering challenges associated with the process of converting molecules into drugs. In this course, we will focus on the engineering principles needed to bring therapeutic products derived from living organisms (e.g., proteins, peptides, DNA, RNA) from the production plant to the patient. We will learn about the challenges of keeping these products “active” as they are stored, shipped, and administered to patients. Specific topics will include:

- Regulatory hurdles for commercial biotechnology-derived pharmaceutical products
- Physical stability of biopharmaceuticals
- Chemical stability of biopharmaceuticals
- Material properties of biopharmaceuticals
- Physics of surface interactions applied to formulation of pharmaceuticals
- Design and interpretation of preclinical animal studies
- Pharmacokinetics
- Pharmacodynamics

Where does this course fit in?

The current course focuses on what happens *after* a biopharmaceutical product is made and purified. The course is designed to use and build on a foundation of chemical engineering science learned in other courses such as thermo, separations/bioseparations, fluids, kinetics and heat transfer.

A note on the schedule

The syllabus should be considered a “work in progress”. Depending on class interest levels, some topics may be added/expanded and others dropped/shortened.

Class Materials: Because much of this material is quite new, some of it hasn’t made its way into a book form. Other parts of the course do appear in other books, but there isn’t a single book that unifies it all, and it seemed rather brutal to make you pay for several books and use only small parts of them. So... what we’ll do is the following. We will use parts of book “Pharmaceutical Biotechnology” by Crommelin et al. Chapters from this book can be downloaded as PDFs or Epub from <https://link.springer.com/book/10.1007/978-3-031-30023-3>. Regulatory information, information on patents and the drug development process in general are covered in the book. We’ll highlight some of the most critical sections in the reading assignments. As you can see from the syllabus, we won’t be approaching the subjects in the same order as the book presents them. For other subjects, many of the references that we’ll work from can be downloaded directly as PDF files from the web via CU library. We’ll either simply put these files up on the class webpage, or post links there to other pages. We suggest creating your own course book by printing out information downloaded from the webpage and assembling it into a course folder.

Because you don't have the advantage of a textbook that covers everything, and because some of the material is difficult, don't let yourselves get lost. Ask questions! We have plenty of flexibility to make sure everyone is able to understand the material.

What background is required of me?

The real world doesn't neatly separate into subjects- so there may be pieces that some of you haven't seen before. Don't worry, ask questions!

Grading

We will have two types of homework: one based on reading chapters of the book, and one based on the lectures. It is expected that the "reading" homework can be answered essentially by using material in the book. Please turn in the "reading" homework" individually; typically it will be due at the beginning of class on Mondays. The "lecture" homework may require you to look up data, read articles from the literature, and recall concepts and methods you've seen in previous classes (material & energy balances, thermos, kinetics, chemistry, biochemistry, fluids...). There will be a "lecture" homework set due roughly every week. "Lecture" homework can be turned in in groups of no more than three people.

Each group of three will present one 10-15 minute current event topic. We'll discuss timing, topics and format once we are a couple of weeks into the course.

We will also have two midterm exams and a final report.

The weighting will be:

Class Presentation- current event 5%

Homework (lecture) – 20%

Homework (reading) - 5%

Midterm Exams - 25% each

Group report final - 20 %

Semester grades will be based on student's total weighted score. The semester grades will be assigned so that a median total weighted score corresponds to ~ B.

IMPORTANT NOTE- The class Canvas website provides an estimate of your overall grade- but this may not be appropriately weighted and scaled, so it should not be relied on. Canvas should be good for checking your scores on the individual items (homework, exams, etc.) but not for the grade they imply!

The fine print:

Honor Code

All students enrolled in a University of Colorado Boulder course are responsible for knowing and adhering to the [Honor Code](#). Violations of the Honor Code may include but are not limited to: plagiarism (including use of paper writing services or technology [such as essay bots]), cheating, fabrication, lying, bribery, threat, unauthorized access to academic materials, clicker fraud, submitting the same or similar work in more than one course without permission

from all course instructors involved, and aiding academic dishonesty. Understanding the course's syllabus is a vital part of adhering to the Honor Code.

All incidents of academic misconduct will be reported to Student Conduct & Conflict Resolution: StudentConduct@colorado.edu. Students found responsible for violating the Honor Code will be assigned resolution outcomes from Student Conduct & Conflict Resolution and will be subject to academic sanctions from the faculty member. Visit [Honor Code](#) for more information on the academic integrity policy.

Accommodation for Disabilities, Temporary Medical Conditions, and Medical Isolation

If you qualify for accommodations because of a disability, please submit your accommodation letter from Disability Services to your faculty member in a timely manner so that your needs can be addressed. Disability Services determines accommodations based on documented disabilities in the academic environment. Information on requesting accommodations is located on the [Disability Services website](#). Contact Disability Services at 303-492-8671 or DSinfo@colorado.edu for further assistance. If you have a temporary medical condition, see [Temporary Medical Conditions](#) on the Disability Services website.

If you have a temporary illness, injury or required medical isolation for which you require adjustment, contact the professor to work out any needed arrangement.

Accommodation for Religious Obligations

Campus policy requires faculty to provide reasonable accommodations for students who, because of religious obligations, have conflicts with scheduled exams, assignments, or required attendance. Please communicate the need for a religious accommodation in a timely manner.

In this class, please let me know as soon as possible by email if you have any such conflicts.

See the [campus policy regarding religious observances](#) for full details.

Preferred Student Names and Pronouns

CU Boulder recognizes that students' legal information does not always align with how they identify. If you wish to have your preferred name (rather than your legal name) and/or your preferred pronouns appear on your instructors' class rosters and in Canvas, visit the [Registrar's website](#) for instructions on how to change your personal information in university systems.

Classroom Behavior

Students and faculty are responsible for maintaining an appropriate learning environment in all instructional settings, whether in person, remote, or online. Failure to adhere to such behavioral standards may be subject to discipline. Professional courtesy and sensitivity are especially important with respect to individuals and topics dealing with race, color, national origin, sex, pregnancy, age, disability, creed, religion, sexual orientation, gender identity, gender expression, veteran status, marital status, political affiliation, or political philosophy.

Additional classroom behavior information

- [Student Classroom and Course-Related Behavior Policy.](#)
- [Student Code of Conduct.](#)
- [Office of Institutional Equity and Compliance.](#)
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Sexual Misconduct, Discrimination, Harassment and/or Related Retaliation

CU Boulder is committed to fostering an inclusive and welcoming learning, working, and living environment. University policy prohibits [protected-class](#) discrimination and harassment, sexual misconduct (harassment, exploitation, and assault), intimate partner abuse (dating or domestic violence), stalking, and related retaliation by or against members of our community on- and off-campus. The Office of Institutional Equity and Compliance (OIEC) addresses these concerns, and individuals who have been subjected to misconduct can contact OIEC at 303-492-2127 or email OIEC@colorado.edu. Information about university policies, [reporting](#)

[options](#), and [OIEC support resources](#) including confidential services can be found on the [OIEC website](#).

Please know that faculty and graduate instructors are required to inform OIEC when they are made aware of incidents related to these concerns regardless of when or where something occurred. This is to ensure the person impacted receives outreach from OIEC about resolution options and support resources. To learn more about reporting and support a variety of concerns, visit the [Don't Ignore It page](#).

Mental Health and Wellness

The University of Colorado Boulder is committed to the well-being of all students. If you are struggling with personal stressors, mental health or substance use concerns that are impacting academic or daily life, please contact [Counseling and Psychiatric Services \(CAPS\)](#), located in C4C, or call (303) 492-2277, 24/7.