

ECH 4905 - Spec Prob in Chem Eng: Pharmaceutical Bioengineering

ECH 4905 Section 22439

Class Periods: M,W,F | Period 5 (11:45 AM - 12:35 PM)

Location: LAR 0310

Academic Term: Spring 2019

Overview:

Pharmaceutical Bioengineering is being offered for the first time in the curriculum of Chemical Engineering. This course will introduce you to basic concepts, technologies, engineering, and challenges in the modern pharmaceutical industry and laboratory focused on biologics (drugs derived from living organisms). The basic concepts you learn in this course might be a refresher to you if you have taken biotechnology-related courses. However, you will be introduced to range of latest technologies and associated challenges that you may revisit in finer detail in other courses. Therefore, it is essential that you work hard to master the material, because these basics will lay the foundation if you work or interact with the researchers in the pharmaceutical or biotechnology industry.

You are encouraged to work and study in groups and help each other as much as possible (in compliance with principles of academic honesty; see below).

Instructor:

Piyush K. Jain (Section 12438)

I prefer to be addressed as "Dr. Jain" but feel free to call me "Piyush" or "Prof. Jain" as you like.

E-Mail: jainp@ufl.edu

Office Phone: 352-294-7012 (Email is preferred mode of communication)

Office: Chemical Engineering Building, Room 329A

Office Hours*: W, F (1-2 PM), or by appointment

*Please note that the office hour timings are subject to changes.

Teaching Assistants:

None

Course Description

(3 Credits) – Introduction to concepts, challenges, and technologies focused on pharmaceutical/biotechnology industry and laboratory research.

Course Pre-Requisites / Co-Requisites

ABE 2062 (Biology for Engineers) or BSC 2010 (Integrated Principles of Biology 1)

CHM 2046 (General Chemistry)

Course Objectives

Each lecture will have specific learning objectives that will be announced at the beginning of that lecture. Broadly, at the end of this course, a student should be able to do the following:

- 1) Understand basic structure, function, production, purification, and analysis of biologics including peptides, recombinant proteins, nucleic acids, vaccines, and cell-based therapies.
- 2) Define and understand physicochemical, pharmacokinetics, and pharmacodynamics parameters and apply them in the context of peptides and proteins based drugs.
- 3) Understand and analyze the common challenges such as manufacturing bioequivalence, stability, drug delivery, and immunogenicity associated with different biologics and propose creative solution(s) to solve these issues.

In addition to these learning objectives, the assignments and projects will be implemented that will be based on real world problems or case studies and will facilitate following skills:

- 1) Read, interpret, and analyze information from the textbook as well as external literature.
- 2) Use resources to find information beyond the assigned textbook and basic search engines.
- 3) Brainstorm and work in a group in a constructive manner.
- 4) Illustrate and present data and findings in front of the class.

Materials and Supply Fees

None

Professional Component (ABET):

- a. Specific outcomes of instruction
 - The students will be able to understand the basic structure, function, production, purification, and analysis of biologics including peptides, recombinant proteins, nucleic acids, vaccines, and cell-based therapies. This will be a lifelong learning.
 - The student will be able to understand the basics concepts of charge, size, pH, pKa, binding, entropy, enzyme kinetics, pharmacokinetics, pharmacodynamics and apply it for solving problems.
 - The student will be able to read the literature, analyze the data and design experiments.
 - The student will be able to recognize the health and safety issues in pharmaceutical industry and will be able to understand the regulatory affairs.
 - The student will be able to work in a multidisciplinary team and propose solutions to key challenges in bioengineering or biotechnology.
 - The student will be able to communicate effectively in front of the class by preparing and presenting graphical slides and/or videos.
 - The student will be able to use a software Chimera by UCSF to analyze molecular structures.
- b. Student outcomes addressed by the course

Outcome (a): an ability to apply knowledge of mathematics, science, and engineering.

Outcome (d): an ability to function on multi-disciplinary teams.

Outcome (g): an ability to communicate effectively.

Relation to Program Outcomes (ABET):

Outcome	Coverage*
a. Apply knowledge	High
b1. Conduct experiments	Low
b2. Statistical design of experiments	
c. Design	Medium
d. Function on teams	High
e. Solve problems	Low
f. Professional and ethical responsibility	
g. Communicate	Medium
h1. Economic impact	Low
h2. Global, societal, and environmental impact	
i. Lifelong learning	Medium
j. Contemporary issues	
k. Techniques, skills, and tools for degree program	High

*Coverage is given as high, medium, or low. An empty box indicates that this outcome is not part of the course.

Required Textbooks and Software

- Title: Pharmaceutical Biotechnology: Fundamentals and Applications
- Author: Crommelin, Dann J. A., Sindelar, Robert D., Meibohm, Bernd
- (Preferred edition) Year, Edition, ISBN-13: 2019, 5th edition, 978-3030007096
- (Acceptable edition, see details below) Year, Edition, ISBN-13: 2013, 4th edition, 978-1461464853

Note: Students are encouraged to use the 4th edition of the textbook until the 5th edition is released. An electronic version of the 4th edition may be obtained from the library at no charge. However, once the 5th released, it is recommended to obtain and use the 5th edition. You can continue to use the 4th edition for the entire semester but keep in mind that is your responsibility (and your responsibility alone!) to ensure that the assigned readings/concepts are accessible to you and are up to date.

Recommended Materials

- Title: Voigt's Pharmaceutical Technology
- Author: Alfred Fahr, Gerrit L. Scherphof (Translator)
- Publication date and edition: 2018, 12th Edition
- ISBN number: 978-1118972625

Course Schedule

Wk	Begins	# Hours	Concepts	Reading (4 th Edition)	Assignments Due
1	01/07	3	Intro to Pharmaceutical Biotechnology: Cells, nucleic acids, and proteins	Syllabus, Chapters 1, 2	None
2	01/14	3	Protein structure, analysis, charge, size, pH, Pka, binding, entropy	Chapter 2, notes may be provided	None
3	01/22	2	Protein production, purification and formulation	Chapter 3, 4	HW 1
4	01/28	3	Enzyme Kinetics, Pharmacokinetics (PK) & Pharmacodynamics (PD) of protein therapeutics	Chapter 5, notes may be provided	Quiz 1
5	02/04	3	Immunogenicity, Monoclonal antibody and their applications	Chapter 6, 7, 17, 19, 20	HW 2
6	02/11	3	Omic technologies and personalized medicine	Chapter 8	HW3
7	02/18	3	Handling, dispensing, economic and regulatory consideration of biologics	Chapter 9, 10, 11	Quiz 2
8	02/25	3	Course and exam review	Flex/Catch-up	Midterm Exam
9	03/04	0	Spring Break	-	None
10	03/11	3	Recombinant proteins in the market	Chapters 12-16, 18	HW 4

11	03/18	3	Vaccines	Chapter 22	None
12	03/25	3	Oligonucleotides, Antisense, siRNA, miRNA, Ribozymes	Chapter 23	HW 5
13	04/01	3	Gene editing and genome engineering	Notes may be provided	None
14	04/08	3	Gene therapy	Chapter 24	Quiz 3
15	04/15	3	Stem cell technology, project presentations	Chapter 25	Team Project
16	04/22	2	Course and exam review	Review/Catch-Up	None
17	04/29	0	-	Exam Week	Final Exam

Attendance Policy, Class Expectations, and Make-Up Policy

You are required to attend all lectures, but it is on the honor system and I will not record attendance. Absences will be excused if (and only if) you notify your instructor in advance of your absence via email, your reason for absence is consistent with the UF attendance policy. The excused absences must be consistent with university policies in the undergraduate catalog (<https://catalog.ufl.edu/ugrad/current/regulations/info/attendance.aspx>) and require appropriate documentation.

Cell phones, laptops and other electronics are allowed as educational devices only. Please do not distract others by using electronics for other purposes during class.

Make-up policy

Make-up work will be considered on a case-by-case basis, commensurate with your circumstances in a manner that is fair to you and your classmates. There will be no make-up assignments for unexcused absences.

Evaluation of Grades

Assignment	Total Points	Percentage of Final Grade
Homework Sets (5)	10 each	10%
Quizzes (3)	50 each	30%
Midterm Exam	100	20%
Final Exam	100	20%
Group Project/Presentation	100	20%
	500	100%

Exams: 2 Total, 200 points; 100 Points Each

Each exam will be 100 points, with a total time limit of two hours. Exam questions are meant to assess your ability to understand and analyze problems. During the exam, you are permitted to use a calculator (any model without communication ability; you may not share), but are not permitted to refer to books or notes.

Note: Make-up exams will be considered on a case-by-case basis for documented, excused absences or emergencies. However, once you begin an exam, you may not be granted an excused absence for any reason.

Quizzes: 4 Total, 100 points; 25 Points Each

Each quiz will occur during lecture time, and will consist of a few multiple choice, true/false, or short answer questions, totaling 50 points. During quizzes, you are not permitted to use a calculator (no complex calculations included), books, or notes.

Quiz questions will be easier (generally) and more conceptual than exam questions, and will assess your comprehension of lecture material and ensure that you keep up-to-date. Therefore, they may be announced or unannounced but you will be able to get a rough idea from the schedule as listed.

Homework: 5 Total, 50 points; 10 points Each

Homework will be assigned approximately once per week, and will consist of 4-5 problems to submit. The submitted problems will be graded on the following basis:

- Not attempted – 0 points
- Attempted but not completed – 2 points
- Completed but incorrect – 5 points
- Completed and correct – 10 points

You should plan to spend at least 3 hours per week on homework (if not more). You are permitted to discuss the problems and problem-solving strategies with your colleagues, but you may not breach the Academic Honesty Course Policy (see below).

Homework is to be completed on the assignment document (see Canvas page) in neat handwriting (without excessive erasures or cross-outs) or typed in word on standard-size (8.5" x 11") paper, without frayed edges, folds or excessive wrinkling. Homework can be uploaded on Canvas using a scanner software or an app. You are responsible to making sure that the homework is uploaded on Canvas.

Homework is due at 5 PM on Mondays of the week. To incentivize you to finish homework assignments early, homework submissions by 5 PM on the Friday before the due date will receive **two automatic bonus points**. However, your total homework score may not exceed 50 points. You may also submit homework via e-mail any time prior to the due date, however, Canvas is preferred. **Late homework will not be accepted without prior documentation and approval.**

Team-Based Project: 100 Points

In the class project, you will work in groups of three to four to determine a challenge in the pharmaceutical biotechnology process of your choice and propose solution(s). You will prepare a short Power Point or video presentation and present it in front of the class. Groups will be assigned, but you might get an option to choose one of your teammates. Topics will be claimed on a first-come, first served basis, and no duplicate topics are allowed.

More details will be given when the project is assigned at the end of March.

Extra Credit: 20 Points Possible

You will have the opportunity to earn a maximum of 20 extra-credit points by selecting a published article relevant to the in-class concepts and writing a report analyzing the data presented in the article (maximum of 10 points) and drafting a question and providing the solution from the article (maximum of 10 points). By submitting these questions, you authorize me to use them in subsequent years (or, if the question is good enough, this year!).

The deadline to turn in extra-credit is one week prior to the last lecture (i.e. you cannot submit extra credit after you see your final exam grade). More details will be provided in April.

Point Value	Percent Value (%)	Letter Grade
470-500	94-100	A
460-469	92-93.9	Gray
445-459	89-91.9	A-
435-444	87-88.9	Gray
425-434	85-86.9	B+
420-424	84-84.9	Gray
405-419	81-83.9	B
395-404	79-80.9	Gray

Point Value	Percent Value (%)	Letter Grade
380-394	76-78.9	B-
370-379	74-75.9	Gray
350-369	70-73.9	C+
335-349	67-69.9	Gray
310-334	62-66.9	C
300-309	60-61.9	Gray
275-299	55-59.9	C-
0-274	0-54.9	D/F (Gray)

More information on UF grading policy may be found at:
<https://catalog.ufl.edu/ugrad/current/regulations/info/grades.aspx>

Regrades:

Regrade challenges will be considered for exams and quizzes only (i.e. homework, the team project, extra credit, etc. is not eligible for regrade challenges). There will be a two-point penalty assessed to each regrade challenge that is not overturned, and your entire assignment may be regraded as a result.

Regrade requests for simple addition mistakes or systematic grading errors may be submitted without risk of penalty or whole regrades.

To submit a regrade: On a separate sheet of paper (titled “regrade request”), briefly and clearly state the reason for your request and attach it to the front of the assignment. **DO NOT WRITE ANYTHING DIRECTLY ON ANY PAGE OF YOUR ASSIGNMENT.** You must hand-deliver your regrade request to me (in my office or after class) within one week of the date the assignment was returned to the class.

E-mail:

In order to ensure a timely response, put “ECH4905” (formatted exactly; all caps, no spaces) in the subject line. You must also use proper e-mail etiquette and professionalism.

Students Requiring Accommodations

Students with disabilities requesting accommodations should first register with the Disability Resource Center (352-392-8565, <https://www.dso.ufl.edu/drc>) by providing appropriate documentation. Once registered, students will receive an accommodation letter which must be presented to the instructor when requesting accommodation. Students with disabilities should follow this procedure as early as possible in the semester.

Course Evaluation

Students are expected to provide feedback on the quality of instruction in this course by completing online evaluations at <https://evaluations.ufl.edu/evals>. Evaluations are typically open during the last two or three weeks of the semester, but students will be given specific times when they are open. Summary results of these assessments are available to students at <https://evaluations.ufl.edu/results/>.

University Honesty Policy

UF students are bound by The Honor Pledge which states, “We, the members of the University of Florida community, pledge to hold ourselves and our peers to the highest standards of honor and integrity by abiding by the Honor Code. On all work submitted for credit by students at the University of Florida, the following pledge is either required or implied: “On my honor, I have neither given nor received unauthorized aid in doing this assignment.” The Honor Code (<https://www.dso.ufl.edu/sccr/process/student-conduct-honor-code/>) specifies a number of behaviors that are in violation of this code and the possible sanctions. Furthermore, you are obligated to report any condition that facilitates academic misconduct to appropriate personnel. If you have any questions or concerns, please consult with the instructor or TAs in this class.

Software Use

All faculty, staff, and students of the University are required and expected to obey the laws and legal agreements governing software use. Failure to do so can lead to monetary damages and/or criminal penalties for the individual violator. Because such violations are also against University policies and rules, disciplinary action will be taken as appropriate. We, the members of the University of Florida community, pledge to uphold ourselves and our peers to the highest standards of honesty and integrity.

Student Privacy

There are federal laws protecting your privacy with regards to grades earned in courses and on individual assignments. For more information, please see: <http://registrar.ufl.edu/catalog0910/policies/regulationferpa.html>

Campus Resources:

Health and Wellness

U Matter, We Care:

Your well-being is important to the University of Florida. The U Matter, We Care initiative is committed to creating a culture of care on our campus by encouraging members of our community to look out for one another and to reach out for help if a member of our community is in need. If you or a friend is in distress, please contact umatter@ufl.edu so that the U Matter, We Care Team can reach out to the student in distress. A nighttime and weekend crisis counselor is available by phone at 352-392-1575. The U Matter, We Care Team can help connect students to the many other helping resources available including, but not limited to, Victim Advocates, Housing staff, and the Counseling and Wellness Center. Please remember that asking for help is a sign of strength. In case of emergency, call 9-1-1.

Counseling and Wellness Center: <http://www.counseling.ufl.edu/cwc>, and 392-1575; and the University Police Department: 392-1111 or 9-1-1 for emergencies.

Sexual Assault Recovery Services (SARS)

Student Health Care Center, 392-1161.

University Police Department at 392-1111 (or 9-1-1 for emergencies), or <http://www.police.ufl.edu/>.

Academic Resources

E-learning technical support, 352-392-4357 (select option 2) or e-mail to Learning-support@ufl.edu.
<https://lss.at.ufl.edu/help.shtml>.

Career Resource Center, Reitz Union, 392-1601. Career assistance and counseling. <https://www.crc.ufl.edu/>.

Library Support, <http://cms.uflib.ufl.edu/ask>. Various ways to receive assistance with respect to using the libraries or finding resources.

Teaching Center, Broward Hall, 392-2010 or 392-6420. General study skills and tutoring.
<https://teachingcenter.ufl.edu/>.

Writing Studio, 302 Tigert Hall, 846-1138. Help brainstorming, formatting, and writing papers.
<https://writing.ufl.edu/writing-studio/>.

Student Complaints Campus: https://www.dso.ufl.edu/documents/UF_Complaints_policy.pdf.

On-Line Students Complaints: <http://www.distance.ufl.edu/student-complaint-process>.