ECH 4905 - Spec Prob in Chem Eng: Pharmaceutical Bioengineering
ECH 4905  Sections 28491, 28889
Class Periods: M, W, F | Period 6 (12:50 PM – 1:40 PM)
Location: Zoom/Canvas. Click here to join the zoom
Academic Term: Spring 2021

Instructor:
Piyush K. Jain
I prefer to be addressed as “Dr. Jain” but feel free to call me “Prof. Jain” or “Piyush”.
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 (1:50-3:30 PM) via zoom
Sections 28491 (80-99% Online): Online classes/office hours. In-person hours arranged by appointment.
Section 28889 (100% Online): Online classes/office hours.
*Please note that the office hour timings are subject to changes.

Teaching Assistant/Peer Mentor/Supervised Teaching Student:
Please contact through the Canvas website
  •  None

Course Description
(3 Credits) – Introduction to concepts, challenges, and technologies focused on pharmaceutical/biotechnology industry and laboratory research. Pharmaceutical Bioengineering is being offered for the second 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. While the class sessions and office hours will be online, 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).

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

Relation to Program Outcomes (ABET):
The table below is an example. Please consult with your department’s ABET coordinator when filling this out.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. An ability to identify, formulate, and solve complex engineering</td>
<td>Low</td>
</tr>
<tr>
<td>problems by applying principles of engineering, science, and mathematics</td>
<td></td>
</tr>
<tr>
<td>2. An ability to apply engineering design to produce solutions that</td>
<td>Low</td>
</tr>
<tr>
<td>meet specified needs with consideration of public health, safety, and</td>
<td></td>
</tr>
<tr>
<td>welfare, as well as global, cultural, social, environmental, and</td>
<td></td>
</tr>
<tr>
<td>economic factors</td>
<td></td>
</tr>
<tr>
<td>3. An ability to communicate effectively with a range of audiences</td>
<td></td>
</tr>
<tr>
<td>4. An ability to recognize ethical and professional responsibilities</td>
<td>Medium</td>
</tr>
<tr>
<td>in engineering situations and make informed judgments, which must</td>
<td></td>
</tr>
<tr>
<td>consider the impact of engineering solutions in global, economic,</td>
<td></td>
</tr>
<tr>
<td>environmental, and societal contexts</td>
<td></td>
</tr>
<tr>
<td>5. An ability to function effectively on a team whose members together</td>
<td>High</td>
</tr>
<tr>
<td>provide leadership, create a collaborative and inclusive environment,</td>
<td></td>
</tr>
<tr>
<td>establish goals, plan tasks, and meet objectives</td>
<td></td>
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<tr>
<td>6. An ability to develop and conduct appropriate experimentation,</td>
<td>Medium</td>
</tr>
<tr>
<td>analyze and interpret data, and use engineering judgment to draw</td>
<td></td>
</tr>
<tr>
<td>conclusions</td>
<td></td>
</tr>
<tr>
<td>7. An ability to acquire and apply new knowledge as needed, using</td>
<td>High</td>
</tr>
<tr>
<td>appropriate learning strategies</td>
<td></td>
</tr>
</tbody>
</table>

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

Required Textbooks and Software
None

Recommended Materials
- Pharmaceutical Biotechnology: Fundamentals and Applications
  - Authors: Crommelin, Dann J. A., Sindelar, Robert D., Meibohm, Bernd
  - ISBN: 978-3030007096
- Methods in Biotechnology
  - Authors: Seung-Beom Hong, M. Bazlur Rashid, Lory Z. Santiago-Vázquez
• Biomedical Engineering- Bridging Medicine and Technology
  o **Authors:** W. Mark Saltzman
  o **Year, Edition:** 2015, 2nd Edition
  o **ISBN:** 9781107037199

• Lehninger Principles of Biochemistry
  o **Authors:** David L. Nelson; Michael M. Cox
  o **ISBN:** 9781464187957 (8th Edition: 9781319322342)

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**Course Schedule**

<table>
<thead>
<tr>
<th>Wk</th>
<th>Begins</th>
<th># Hours</th>
<th>Concepts</th>
<th>Assignments Due</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>01/11</td>
<td>3</td>
<td>Syllabus, Intro to biopharmaceuticals</td>
<td>None</td>
</tr>
<tr>
<td>2</td>
<td>01/18</td>
<td>2</td>
<td>Proteins and nucleic acids structure</td>
<td>None</td>
</tr>
<tr>
<td>3</td>
<td>01/25</td>
<td>3</td>
<td>Charge, size, pH/pKa, binding</td>
<td>HW 1</td>
</tr>
<tr>
<td>4</td>
<td>02/01</td>
<td>3</td>
<td>Protein production, purification and formulation</td>
<td>Quiz 1</td>
</tr>
<tr>
<td>5</td>
<td>02/08</td>
<td>3</td>
<td>Enzyme kinetics, pharmacokinetics (PK) &amp; pharmacodynamics (PD)</td>
<td>HW 2</td>
</tr>
<tr>
<td>6</td>
<td>02/15</td>
<td>3</td>
<td>Antibodies and their applications</td>
<td>HW3</td>
</tr>
<tr>
<td>7</td>
<td>02/22</td>
<td>3</td>
<td>Course review, molecular visualization using Chimera</td>
<td>None</td>
</tr>
<tr>
<td>8</td>
<td>03/01</td>
<td>3</td>
<td>Biomolecular technologies</td>
<td>Quiz 2</td>
</tr>
<tr>
<td>9</td>
<td>03/08</td>
<td>3</td>
<td>Recombinant proteins, Vaccines</td>
<td>HW 4</td>
</tr>
<tr>
<td>10</td>
<td>03/15</td>
<td>3</td>
<td>Nucleic acids, antisense, siRNA, miRNA, ribozymes</td>
<td>HW 5</td>
</tr>
<tr>
<td>11</td>
<td>03/22</td>
<td>2</td>
<td>Gene therapy, stem cell technology</td>
<td>None</td>
</tr>
<tr>
<td>12</td>
<td>03/29</td>
<td>3</td>
<td>Gene editing and genome engineering</td>
<td>Quiz 3</td>
</tr>
<tr>
<td>13</td>
<td>04/05</td>
<td>3</td>
<td>Regulatory consideration of biologics</td>
<td>None</td>
</tr>
<tr>
<td>14</td>
<td>04/12</td>
<td>3</td>
<td>Project presentations</td>
<td>Team Project</td>
</tr>
<tr>
<td>15</td>
<td>04/19</td>
<td>2</td>
<td>Course and exam review</td>
<td>None</td>
</tr>
<tr>
<td>16</td>
<td>04/26</td>
<td>0</td>
<td>Exam Week</td>
<td>Final Exam: 04/28 (12:30-2:30 PM)</td>
</tr>
</tbody>
</table>
**Online Course Recording**
Our class sessions may be audio visually recorded for students in the class to refer back and for enrolled students who are unable to attend live. Students who participate with their camera engaged or utilize a profile image are agreeing to have their video or image recorded. If you are unwilling to consent to have your profile or video image recorded, be sure to keep your camera off and do not use a profile image. Likewise, students who un-mute during class and participate orally are agreeing to have their voices recorded. If you are not willing to consent to have your voice recorded during class, you will need to keep your mute button activated and communicate exclusively using the "chat" feature, which allows students to type questions and comments live. The chat will not be recorded or shared. As in all courses, unauthorized recording and unauthorized sharing of recorded materials is prohibited.

**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**

<table>
<thead>
<tr>
<th>Assignment</th>
<th>Total Points</th>
<th>Percentage of Final Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Homework Sets (5)</td>
<td>20 each</td>
<td>20%</td>
</tr>
<tr>
<td>Quizzes (3)</td>
<td>50 each</td>
<td>30%</td>
</tr>
<tr>
<td>Final Exam</td>
<td>100</td>
<td>20%</td>
</tr>
<tr>
<td>Group Project/Presentation</td>
<td>150</td>
<td>30%</td>
</tr>
<tr>
<td></td>
<td>500</td>
<td>100%</td>
</tr>
</tbody>
</table>

**Final Exam: 100 points**
Final 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 granted an excused absence for any reason.

**Quizzes: 3 Total, 150 points; 50 Points Each**
Each quiz will occur during lecture time, and will consist of a few multiple choice, true/false, or short answer questions, and 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 can get a rough idea from the schedule as listed.

**Homework: 5 Total, 100 points; 20 points Each**
Homework will be assigned approximately once per week, and will consist of 3-5 problems to submit. The submitted problems will be graded on the following basis:

- Not attempted – 0% points
- Attempted but not completed – 20% points
- Completed but incorrect – 50% points
- Completed and correct – 100% 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 100 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: 150 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 on zoom. 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 in 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.

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**Grading Policy**

<table>
<thead>
<tr>
<th>Point Value</th>
<th>Percent Value (%)</th>
<th>Letter Grade</th>
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</thead>
<tbody>
<tr>
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<td></td>
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</table>

<table>
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<tr>
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<tbody>
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</tbody>
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*Spec Prob in Chem Eng: Pharmaceutical Bioengineering, ECH 4905*

*Prof. Piyush K. Jain, Spring 2021*
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 who experience learning barriers and would like to request academic accommodations should connect with the disability Resource Center by visiting https://disability.ufl.edu/students/get-started/. It is important for students to share their accommodation letter with their instructor and discuss their access needs, as early as possible in the semester.

Course Evaluation
Students are expected to provide professional and respectful feedback on the quality of instruction in this course by completing course evaluations online via GatorEvals. Guidance on how to give feedback in a professional and respectful manner is available at https://gatorevals.aa.ufl.edu/students/. Students will be notified when the evaluation period opens, and can complete evaluations through the email they receive from GatorEvals, in their Canvas course menu under GatorEvals, or via https://ufl.bluera.com/ufl/. Summaries of course evaluation results are available to students at https://gatorevals.aa.ufl.edu/public-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://sccr.dso.ufl.edu/policies/student-honor-code-student-conduct-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.

**Commitment to a Safe and Inclusive Learning Environment**
The Herbert Wertheim College of Engineering values broad diversity within our community and is committed to individual and group empowerment, inclusion, and the elimination of discrimination. It is expected that every person in this class will treat one another with dignity and respect regardless of gender, sexuality, disability, age, socioeconomic status, ethnicity, race, and culture.

If you feel like your performance in class is being impacted by discrimination or harassment of any kind, please contact your instructor or any of the following:
- Your academic advisor or Graduate Program Coordinator
- Robin Bielling, Director of Human Resources, 352-392-0903, rbielling@eng.ufl.edu
- Curtis Taylor, Associate Dean of Student Affairs, 352-392-2177, taylor@eng.ufl.edu
- Toshikazu Nishida, Associate Dean of Academic Affairs, 352-392-0943, nishida@eng.ufl.edu

**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: https://registrar.ufl.edu/ferpa.html

**Campus Resources:**

**Health and Wellness**

<table>
<thead>
<tr>
<th>U Matter, We Care:</th>
</tr>
</thead>
<tbody>
<tr>
<td>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 <a href="mailto:umatter@ufl.edu">umatter@ufl.edu</a> 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.</td>
</tr>
</tbody>
</table>

**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 Discrimination, Harassment, Assault, or Violence**
If you or a friend has been subjected to sexual discrimination, sexual harassment, sexual assault, or violence contact the Office of Title IX Compliance, located at Yon Hall Room 427, 1908 Stadium Road, (352) 273-1094, title-ix@ufl.edu

**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://care.dso.ufl.edu.