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
None

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

Required Textbooks and Software
- Title: Pharmaceutical Biotechnology: Fundamentals and Applications
- Author: Crommelin, Dann J. A., Sindelar, Robert D., Meibohm, Bernd
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**

<table>
<thead>
<tr>
<th>Wk</th>
<th>Begins</th>
<th># Hours</th>
<th>Concepts</th>
<th>Reading (4th Edition)</th>
<th>Assignments Due</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>01/07</td>
<td>3</td>
<td>Intro to Pharmaceutical Biotechnology: Cells, nucleic acids, and proteins</td>
<td>Syllabus, Chapters 1, 2</td>
<td>None</td>
</tr>
<tr>
<td>2</td>
<td>01/14</td>
<td>3</td>
<td>Protein structure, analysis, charge, size, pH, Pka, binding, entropy</td>
<td>Chapter 2, notes may be provided</td>
<td>None</td>
</tr>
<tr>
<td>3</td>
<td>01/22</td>
<td>2</td>
<td>Protein production, purification and formulation</td>
<td>Chapter 3, 4</td>
<td>HW 1</td>
</tr>
<tr>
<td>4</td>
<td>01/28</td>
<td>3</td>
<td>Enzyme Kinetics, Pharmacokinetics (PK) &amp; Pharmacodynamics (PD) of protein therapeutics</td>
<td>Chapter 5, notes may be provided</td>
<td>Quiz 1</td>
</tr>
<tr>
<td>5</td>
<td>02/04</td>
<td>3</td>
<td>Immunogenicity, Monoclonal antibody and their applications</td>
<td>Chapter 6, 7, 17, 19, 20</td>
<td>HW 2</td>
</tr>
<tr>
<td>6</td>
<td>02/11</td>
<td>3</td>
<td>Omic technologies and personalized medicine</td>
<td>Chapter 8</td>
<td>HW3</td>
</tr>
<tr>
<td>7</td>
<td>02/18</td>
<td>3</td>
<td>Handling, dispensing, economic and regulatory consideration of biologics</td>
<td>Chapter 9, 10, 11</td>
<td>Quiz 2</td>
</tr>
<tr>
<td>8</td>
<td>02/25</td>
<td>3</td>
<td>Course and exam review</td>
<td>Flex/Catch-up</td>
<td>Midterm Exam</td>
</tr>
<tr>
<td>9</td>
<td>03/04</td>
<td>0</td>
<td>Spring Break</td>
<td></td>
<td>None</td>
</tr>
<tr>
<td>10</td>
<td>03/11</td>
<td>3</td>
<td>Recombinant proteins in the market</td>
<td>Chapters 12-16, 18</td>
<td>HW 4</td>
</tr>
<tr>
<td>11</td>
<td>03/18</td>
<td>3</td>
<td>Vaccines</td>
<td>Chapter 22</td>
<td>None</td>
</tr>
<tr>
<td>12</td>
<td>03/25</td>
<td>3</td>
<td>Oligonucleotides, Antisense, siRNA, miRNA, Ribozymes</td>
<td>Chapter 23</td>
<td>HW 5</td>
</tr>
</tbody>
</table>
Gene editing and genome engineering

Notes may be provided

None

Gene therapy

Chapter 24

Quiz 3

Stem cell technology, project presentations

Chapter 25

Project

Course and exam review

Review/Catch-Up

None

Course and exam review

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. Excused absences must be consistent with university policies in the Graduate Catalog (http://gradcatalog.ufl.edu/content.php?catoid=10&navoid=2020#attendance) and require appropriate documentation.

**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 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>10 each</td>
<td>10%</td>
</tr>
<tr>
<td>Quizzes (3)</td>
<td>50 each</td>
<td>30%</td>
</tr>
<tr>
<td>Midterm Exam</td>
<td>100</td>
<td>20%</td>
</tr>
<tr>
<td>Final Exam</td>
<td>100</td>
<td>20%</td>
</tr>
<tr>
<td>Project/Presentation</td>
<td>100</td>
<td>20%</td>
</tr>
<tr>
<td></td>
<td>500</td>
<td>100%</td>
</tr>
</tbody>
</table>

**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 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 can 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.**

**Project: 100 Points**

In the class project, you will work alone or may be paired with another student to determine a challenge in the pharmaceutical biotechnology process of your choice and propose solution(s). You will prepare a short Power Point and/or video presentation and present it in front of the class. 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.

**Grading Policy**

<table>
<thead>
<tr>
<th>Point Value</th>
<th>Percent Value (%)</th>
<th>Letter Grade</th>
<th>Point Value</th>
<th>Percent Value (%)</th>
<th>Letter Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>470-500</td>
<td>94-100</td>
<td>A</td>
<td>380-394</td>
<td>76-78.9</td>
<td>B-</td>
</tr>
<tr>
<td>460-469</td>
<td>92-93.9</td>
<td>Gray</td>
<td>370-379</td>
<td>74-75.9</td>
<td>Gray</td>
</tr>
<tr>
<td>445-459</td>
<td>89-91.9</td>
<td>A-</td>
<td>350-369</td>
<td>70-73.9</td>
<td>C+</td>
</tr>
<tr>
<td>435-444</td>
<td>87-88.9</td>
<td>Gray</td>
<td>335-349</td>
<td>67-69.9</td>
<td>Gray</td>
</tr>
<tr>
<td>425-434</td>
<td>85-86.9</td>
<td>B+</td>
<td>310-334</td>
<td>62-66.9</td>
<td>C</td>
</tr>
<tr>
<td>420-424</td>
<td>84-84.9</td>
<td>Gray</td>
<td>300-309</td>
<td>60-61.9</td>
<td>Gray</td>
</tr>
</tbody>
</table>
More information on UF grading policy may be found at:
http://gradcatalog.ufl.edu/content.php?catoid=10&navoid=2020#grades

**Regrades:**
Regrade challenges will be considered for exams and quizzes only (i.e. homework, thproject, 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 “ECH6937” (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

<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 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](https://lss.at.ufl.edu/help.shtml).

**Career Resource Center**, Reitz Union, 392-1601. Career assistance and counseling.  
[https://www.crc.ufl.edu/](https://www.crc.ufl.edu/).

**Library Support**, [http://cms.uflib.ufl.edu/ask](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/](https://teachingcenter.ufl.edu/).

**Writing Studio, 302 Tigert Hall**, 846-1138. Help brainstorming, formatting, and writing papers.  
[https://writing.ufl.edu/writing-studio/](https://writing.ufl.edu/writing-studio/).
