

**Designing Biological Therapeutics**  
BME 4931/6938 #25300  
**Class Periods:** MWF, period 6, 12:50-1:40PM  
**Location:** Black Hall 315  
**Academic Term:** Spring 2025

**Instructor:**

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(352)273-9326  
Office Hours: By appointment

**Teaching Assistant/Peer Mentor/Supervised Teaching Student:**

- None

**Course Description**

3 credit hours. In this course, students will be introduced to the design and development of biologic therapeutics. Students will learn the types of biologic therapeutics, which includes cells and proteins, and the methods used to produce them. Students will gain an appreciation for the history of biologic therapeutics and their regulation by the FDA. Finally, case studies will highlight successes, failures, and emerging challenges in this rapidly growing field. This course is likely to be of interest to students with a background in biochemistry, molecular biology, cell biology, biomaterials, and regenerative medicine.

**Course Pre-Requisites / Co-Requisites**

BME 3060 – BME Fundamentals  
BME 4311 – Molecular Biomedical Engineering

**Course Objectives**

In this course students will (1) learn to distinguish between a drug and a device according to FDA guidelines, (2) learn the engineering principles underlying upstream and downstream processing of biological therapeutics, and (3) gain experience in the design approach for developing biological therapeutics, which includes identifying drug targets and disease indications, identifying drug candidates, developing a bioprocess production workflow, and moving a drug from the laboratory to the regulatory pipeline and/or market.

**Materials and Supply Fees**

None

**Professional Component (ABET):**

None

**Relation to Program Outcomes (ABET):**

Outcome	Coverage*
1. An ability to identify, formulate, and solve engineering problems by applying principles of engineering, science, and mathematics.	
2. An ability to apply both analysis and synthesis in the engineering design process, resulting in designs that meet desired needs.	

3. An ability to develop and conduct appropriate experimentation, analyze and interpret data, and use engineering judgment to draw conclusions.	
4. An ability to communicate effectively with a range of audiences	
5. An ability to recognize ethical and professional responsibilities in engineering situations and make informed judgments, which must consider the impact of engineering solutions in global, economic, environmental, and societal contexts.	
6. An ability to recognize the ongoing need for additional knowledge and locate, evaluate, integrate, and apply this knowledge appropriately.	
7. An ability to function effectively on teams that establish goals, plan tasks, meet deadlines, and analyze risk and uncertainty	

### ***Required Textbooks and Software***

None, reading materials will be identified in the course notes or posted on the course website.

### ***Recommended Materials***

- None

### ***Course Schedule***

Week 1:	General Overview
Week 2:	Regulatory Pipeline – drug versus device
Week 3:	Intellectual Property
Week 4:	Fundamentals of Bioprocessing – <b>Quiz 1, Monday, February 3 (in class)</b>
Week 5:	Engineering considerations – biochemistry, molecular biology, and cell growth
Week 6:	Upstream and Downstream Manufacturing
Week 7:	Quality Considerations – <b>Quiz 2, Wednesday, February 24 (in class)</b>
Week 8:	Protein Therapeutics
Week 9:	Protein Therapeutics
Week 10:	<b>Team Design Presentations – round 1</b>
Week 11:	Nucleotide Therapeutics – <b>Quiz 3, Monday, March 31 (in class)</b>
Week 12:	Vaccines
Week 13:	Autologics
Week 14:	<b>Team Design Presentations – round 2</b>
Week 15:	Future directions – <b>Quiz 4, Wednesday, April 23 (in class)</b>

### ***Attendance Policy, Class Expectations, and Make-Up Policy***

-You must let me know AS SOON AS POSSIBLE if you will be ABSENT on the SCHEDULED DATE of ANY quiz or presentation. Where possible, a make-up MUST be taken **PRIOR TO** the date listed in the syllabus. **No make-up quizzes or exams will be given for unexcused absences.** Excused absences are consistent with university policies in the undergraduate catalog (<https://catalog.ufl.edu/ugrad/current/regulations/info/attendance.aspx>) and require appropriate documentation.

- Attendance is not required.
- Laptop/tablet use in the classroom is acceptable
- Use of cell phones in the classroom is unacceptable, and will result in your being excused from class immediately

### ***Evaluation of Grades***

<b>Assignment</b>	<b>Total Points</b>	<b>Percentage of Final Grade</b>
Quizzes (4)	15 each	60%
Design Presentations (2)	20	40%
<b>Total</b>		<b>100%</b>

### ***Grading Policy***

<b>Percent</b>	<b>Grade</b>	<b>Grade Points</b>
94 - 100	A	4.00
90.0 - 93.99	A-	3.67
87 - 89.99	B+	3.33
83 - 86.99	B	3.00
80 - 82.99	B-	2.67
77 - 79.99	C+	2.33
73- 76.99	C	2.00
70 - 72.99	C-	1.67
67 - 69.99	D+	1.33
63 - 66.99	D	1.00
60 - 62.99	D-	0.67
0 - 59.99	E	0.00

More information on UF grading policy may be found at:

<https://catalog.ufl.edu/ugrad/current/regulations/info/grades.aspx>

### ***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.ua.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.bluer.com/ufl/>. Summaries of course evaluation results are available to students at <https://gatorevals.ua.ufl.edu/public-results/>.

### ***In-Class Recording***

Students are allowed to record video or audio of class lectures. However, the purposes for which these recordings may be used are strictly controlled. The only allowable purposes are (1) for personal educational use, (2) in connection with a complaint to the university, or (3) as evidence in, or in preparation for, a criminal or civil proceeding. All other purposes are prohibited. Specifically, students may not publish recorded lectures without the written consent of the instructor.

A “class lecture” is an educational presentation intended to inform or teach enrolled students about a particular subject, including any instructor-led discussions that form part of the presentation, and delivered by any instructor hired or appointed by the University, or by a guest instructor, as part of a University of Florida course. A class

lecture does not include lab sessions, student presentations, clinical presentations such as patient history, academic exercises involving solely student participation, assessments (quizzes, tests, exams), field trips, private conversations between students in the class or between a student and the faculty or lecturer during a class session.

Publication without permission of the instructor is prohibited. To “publish” means to share, transmit, circulate, distribute, or provide access to a recording, regardless of format or medium, to another person (or persons), including but not limited to another student within the same class section. Additionally, a recording, or transcript of a recording, is considered published if it is posted on or uploaded to, in whole or in part, any media platform, including but not limited to social media, book, magazine, newspaper, leaflet, or third party note/tutoring services. A student who publishes a recording without written consent may be subject to a civil cause of action instituted by a person injured by the publication and/or discipline under UF Regulation 4.040 Student Honor Code and Student Conduct Code.

### ***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/process/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 varied perspectives and lived experiences within our community and is committed to supporting the University’s core values, including the elimination of discrimination. It is expected that every person in this class will treat one another with dignity and respect regardless of race, creed, color, religion, age, disability, sex, sexual orientation, gender identity and expression, marital status, national origin, political opinions or affiliations, genetic information, and veteran status.

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 Undergraduate Coordinator
- HWCOE Human Resources, 352-392-0904, [student-support-hr@eng.ufl.edu](mailto:student-support-hr@eng.ufl.edu)
- Pam Dickrell, Associate Dean of Student Affairs, 352-392-2177, [pld@ufl.edu](mailto:pld@ufl.edu)
- Toshikazu Nishida, Associate Dean of Academic Affairs, 352-392-0943, [nishida@eng.ufl.edu](mailto: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***

**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](mailto: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:** <https://counseling.ufl.edu>, 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](mailto: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](mailto:Learning-support@ufl.edu).  
<https://elearning.ufl.edu/>.

**Career Connections Center**, Reitz Union, 392-1601. Career assistance and counseling; <https://career.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://sccr.dso.ufl.edu/policies/student-honor-code-student-conduct-code/>; <https://care.dso.ufl.edu>.

**On-Line Students Complaints:** <https://distance.ufl.edu/getting-help/>; <https://distance.ufl.edu/state-authorization-status/#student-complaint>.