

Designing Biological Therapeutics
BME 4931 Section 3A11
Class Periods: MWF, period 5, 11:45AM-12:35PM
Location: COM C1-103
Academic Term: Fall 2019

Instructor:

Gregory A. Hudalla
ghudalla@bme.ufl.edu
(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 – Quiz 1, Monday, September 9 (in class)
Week 5:	Engineering considerations – biochemistry, molecular biology, and cell growth
Week 6:	Upstream and Downstream Manufacturing
Week 7:	Quality Considerations – Quiz 2, Wednesday, October 2 (in class)
Week 8:	Protein Therapeutics
Week 9:	Protein Therapeutics
Week 10:	Team Design Presentations – round 1
Week 11:	Nucleotide Therapeutics – Quiz 3, Monday, October 28 (in class)
Week 12:	Vaccines
Week 13:	Autologics
Week 14:	Team Design Presentations – round 2
Week 15:	Future directions – Quiz 4, Monday, November 25 (in class)

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

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

Grading Policy

Percent	Grade	Grade Points
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 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 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.bluera.com/ufl/>. Summaries of course evaluation results are available to students at <https://gatorevals.ua.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

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 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://www.dso.ufl.edu/documents/UF_Complaints_policy.pdf.

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