

BEC (CHE) 577: ADVANCED BIOMANUFACTURING AND BIOCATALYSIS

Spring 2026: Tuesdays 6:00 PM – 8:45 PM (EB3 02213)

Class will also run concurrently on Zoom. Students enrolled through EOL (and in special circumstances with instructor permission, students in the on-campus section) will have the option to join the class via Zoom. If you do join over Zoom, **I request that you keep your cameras on. Participation in breakout rooms will be expected for those who join on Zoom.** All lecture content will be posted online; Zoom session will also be recorded and posted online)

Zoom Link:

<https://ncsu.zoom.us/j/97421389507?pwd=dXeWdAwmXLLtTU7OaGQQELRJALDET.N.1&jst=2>

Note: Only authenticated NC State users can join the Zoom meeting.

Instructor: Bala Rao (bmrao@ncsu.edu)

Office Hours: Please schedule time over email.

TA: Siddharth Parekh (sgparekh@ncsu.edu)

Office Hours: Please schedule time to meet over email.

Recorded lectures will be available at

<https://ncsu.hosted.panopto.com/Panopto/Pages/Sessions/List.aspx?folderID=9322962e-c847-46f1-87f6-b3af01447863>

Important note regarding instructor/TA contact

- 1) *If you need help or clarification on a HW or other class material, as far as possible, please post your questions on the class forum (on Moodle).* Chances are several others will have the same question or will find the discussion useful. Students are welcome – and strongly encouraged – to participate in the discussions on the forum and answer questions.
- 2) If an email is addressed individually to the instructor or TA, we will do our best to respond within 24 hours during weekdays (typically much faster).

Prerequisites: Graduate standing in engineering or life science graduate program or consent of instructor. Previous coursework in microbiology, cell biology, microbial biochemistry or molecular biology will be helpful.

Student Learning Objectives:

1. Explain the scientific basis underlying the use of products relevant to advanced biomanufacturing, including antibody and antibody-like products, vaccines, and cell and gene therapies.

2. Evaluate methods used in advanced biomanufacturing for production of therapeutic proteins, vaccines, cell and gene therapies, and other industrially relevant biochemicals. Identify methods and processes that are most suitable for a product.
3. Evaluate the effect of intellectual property considerations and regulation by the US Food and Drug Administration (FDA) on development of products and biomanufacturing strategy.

Course materials

There is no textbook required for this course. All course resources will be available on the course Moodle site.

Course content and structure

This course is organized into four modules that focus on important classes of products that are relevant to advanced biomanufacturing. The modules are:

- 1) Antibodies and antibody-like proteins
- 2) Vaccines
- 3) Cell and gene therapies
- 4) Other products (focus this year will be on alternative proteins/cultured meat)

In each module, we will examine various aspects of biomanufacturing that are relevant to that class of product such as choice of recombinant host for protein expression and role of intellectual property and FDA regulation.

Grading

Class attendance, participation and peer reviews (5%)

Class participation and engagement is a vital part of the course. Attendance will be recorded. For those taking this course through distance education, access to course materials/videos will be used to track **engagement**. Additionally, we expect that students will participate in discussion on the discussion forum online (as prompted by the instructor), and complete peer review assignments. We do realize that people sometimes have real reasons to be absent (illness, emergencies, interviews, etc.) ***We assure you that we will accommodate your needs.*** Please inform the instructor as soon as possible.

Homework (75%; 11 HW)

Homework is due at **5 PM on Tuesday**. Homework will largely focus on reading that is assigned in the previous class. We permit (and even encourage) use of AI tools (see details in AI policy) Since “solutions” for the HW will be discussed on the day HW is due, **no credit can be assigned for late HW submission.**

Technology brief (20%)

Students will work on a concise paper that discusses a technology solution to a contemporary biomanufacturing problem. Students can choose from one of 4-6 topics selected by the instructor. The technology brief will be a 10-page paper (single spaced, Times New Roman 12

pt. font, 1" margins; figures included within page limit; references/bibliography does not count towards page limit).

Peer evaluation of technology brief and oral presentation.

Each student will be required to peer-review the final paper and up to 3 HWs and provide feedback using an instructor-assigned format. Up to 75% of the class participation grade will be based on these peer reviews.

Grading scale

The following grading scale will be used for this course. This grading scale may be adjusted; however, any adjustment will result in a grade that is higher than that calculated using the grading scale below.

<u>Score (%)</u>	<u>Grade</u>
>97	A+
92-96.99	A
89-91.99	A-
86-88.99	B+
82-85.99	B
79-81.99	B-
76-78.99	C+
72-75.99	C
69-71.99	C-
66-68.99	D+
62-65.99	D
59-61.99	D-
<59	F

Academic integrity

Each student must be familiar with and comply with the NCSU Code of Student Conduct.

Further information is available at:

“http://www.ncsu.edu/provost/academic_regulations/integrity/reg.htm” and

“<http://www.fis.ncsu.edu/ncsulegal/41.03-codeof.htm>”

The student's submission of any HW or other assignment means that the student has materially contributed to the assignment in question and that he/she neither gave nor received unauthorized aid. Authorized aid includes discussing the interpretation of the problem statement with other students, sharing ideas or approaches for solving the problem, and explaining concepts involved in the problem. Any other aid would be unauthorized; it would be treated a violation of the academic integrity policy and will result in zero for that part of the course (e.g., cheat on a Homework and you will receive a zero for the entire Homework grade in the course).

Proper referencing of any source of information you use in your homework is required (e.g., if you use any information from a book, find some information on the Web, you must reference it properly). Also see AI policy.

Students who cheat will be subject to discipline through the Office of Student Conduct.

Use of Turnitin software

In this class, Turnitin is used to help students ensure that they have not plagiarized others in their written assignments. Plagiarism is a serious violation of the Code of Student Conduct; a definition appears below. Students who are found to have plagiarized on their final assignment submissions will have their case referred to Student Conduct for disciplinary proceedings.

Plagiarism is the use or close imitation of the language and thoughts of another and the representation of the other's work as their own. The act of submitting work for evaluation or to meet a requirement is regarded as assurance that the work is the result of the student's own thought and study, produced without assistance, and stated in that student's own words, except as quotation marks, references, or footnotes acknowledge the use of other sources. Any ideas or materials taken from another source for either written or oral use must be fully and correctly acknowledged. Submission of work used previously must first be approved by the faculty member. Plagiarism includes, but is not limited, to the following actions:

- (a) Representing the work of others as his or her own; or
- (b) Submitting written materials without proper attribution or acknowledgment of the source.

AI policy

The AI policy for this course can be found here. Please be sure to read carefully!

<https://docs.google.com/document/d/1Agh5Mf5IH7PTdbmAxlDdSGdluST2FEfVDsENgspmJXY/edit?usp=sharing>

Supporting Students in Distress

As a student you may experience a range of personal issues that can impede learning, such as strained relationships, increased anxiety, alcohol/drug concerns, feeling down, difficulty concentrating and/or lack of motivation. These mental health concerns or stressful events may lead to diminished academic performance and may impact your ability to participate in daily activities. It is very important that you have a support system and that you ask for help when you are struggling. The Counseling Center at NC State offers confidential mental health services for full time NC State students, including same-day emergency services. Please visit <https://counseling.dasa.ncsu.edu/> to get connected.

As members of the NC State Wolfpack community, we each share a personal responsibility to express concern for one another and to ensure that this classroom and the campus as a whole remains a safe environment for learning. Occasionally, you may come across a fellow classmate whose personal behavior concerns or worries you. When this is the case, I would encourage you to report this behavior to the NC State Students of Concern website: <https://ncstatecares.dasa.ncsu.edu/>.

Although you can report anonymously, it is preferred that you share your contact information so they can follow-up with you personally.

Important dates and topics covered (tentative schedule)

#	Date	Topics (tentative range of dates)	Deliverables
1	13 th January	#1 Antibodies and antibody-like proteins	-
2	20 th January		HW1
3	27 th January		HW2
4	3 rd February		HW3 Suggested topics for technology brief posted
5	10 th February	#2 Vaccines	HW4
	17 th February		No class (wellness day)
6	24 th February		HW5
7	3 rd March		HW6
8	10 th March		HW 7 Discuss technical brief outline with instructor by this date
	17 th March	#3 Cell and gene therapies	No class (Spring Break)
9	24 th March		HW7
10	31 st March		HW8
11	7 th April		HW9
12	14 th April		HW10 Detailed draft outline of technical brief
13	21 st April	#4 Other products	
14	28 th April		Technology brief due
	5 th May	Scheduled final exam	HW11 (peer reviews of papers due as part of HW 11)

Notes

- Class does not have a final exam; however, HW11 is due on the scheduled date of the final exam.