

## **BIOT 502: Introduction to Biotechnology Manufacturing**

**Fall 2023: Term 1: 08/28/23-10/20/2023**

### **Course Description**

This course provides an introduction to the terminology and practices of the biotechnology industry, with an emphasis on the manufacturing, regulatory, and legal aspects of modern biotechnology. Throughout this course, you will learn about many of the cutting-edge therapeutic strategies currently under development and in use.

### **Instructor**

Mary Q. Stewart, Ph.D. [Mary.stewart@unh.edu](mailto:Mary.stewart@unh.edu)

### **Office Hours**

By appointment and virtual (i.e., via telephone or video conference). We may set up regular open hours that works for all students. I am physically located on the Manchester Campus, room 604 (603-641-4390)

### **Objectives**

- To gain an understanding of the types of modern biotechnology products and how they are manufactured
- To develop a basic knowledge of the science underpinning biotechnology products
- To gain an understanding of basic manufacturing principles
- To develop a basic knowledge of the product development process
- To understand the regulatory framework for determining safety and effectiveness of biotechnology products

### **Textbook**

None. Readings, videos, and other content will be assigned in each online module. No pre-requisites, however, high school biology and chemistry background expected.

### **Course Structure**

This course is an online, asynchronous course. Every week, one module will be activated and you will have approximately one week to complete the assignments contained in that module. The modules will include videos or lectures to watch, articles to read, quizzes, and discussion board posts. There are eight (8) course modules; when the eighth module is complete, the course is over.

### **Assignments**

#### **Weekly Discussion Posts**

Each module includes one or more discussion topics that will reinforce the presented content. You are expected to fully participate by posting a response to the discussion topic(s). Your post will demonstrate your ability to apply what you have learned in the module by crafting a response rooted in your understanding of the module material. Responses need to be your original work supported by the module materials and other outside supportive sources. Sources must be cited appropriately (APA). You are also expected to respond each week to at least two of your classmates' postings with value-added comments and/or follow-up questions.

The initial post(s) (i.e., your response to the discussion topic) is/are due **Fridays, 11:59 PM ET**. The responses to your classmates' postings are due **Sundays, 11:59 PM ET**. Any exceptions to these due dates will be stated in the assigned discussion.

**\*Module 1 Discussion Posts:** This module has no classmate response requirement, therefore, the posts for this module are due **Saturday, September 2<sup>nd</sup>, 2023 11:59 PM ET.**

**\*Module 8 Modifications for the last week:** Since the last module ends on a Friday, the initial discussion post is due on **Wednesday, October 18th**, and the response posts and quiz are due **Friday October 20<sup>th</sup>.**

***Given the online nature of this course, the Academic Honesty Policy (below) is critical. Please do not copy/paste answers from the internet or other sources without proper attribution.***

**Late Penalty:** Any discussion posts or responses submitted after the due date, but within a 24-hour period will receive a 1-point reduction. Any discussion posts or responses submitted one day after the due date will receive a 2-point reduction. Any discussion posts or responses submitted two days after the due date will receive a 4-point reduction. Any discussion posts or responses submitted three days after the due date will receive a zero.

### **Quizzes**

The course includes eight (8) graded, timed, quizzes to assess your learning progress in thecourse. Each quiz consists of multiple-choice, true/false, matching, or fill-in- the-blank questions based on the content in the module. You will have two hours to complete and submit the quiz.

Your work on the quizzes should be your own. Do not discuss your answers with other students before submitting your responses, or before they have submitted theirs.

Quizzes are due **Saturdays, 11:59 PM ET.**

**Late Penalty for Quizzes:** Any quiz submitted one day after the due date will receive a 5-point reduction. Any quiz submitted two days after the due will receive a 10-point reduction. Any quiz submitted three days after the due date will receive a zero.

### **Grading**

Your course grade will be determined based on the percentage of points earned out of the total points. 90% and above will earn A- or better; 80% and above will earn B- or better; 70% and above will earn C- or better; 60% and above will earn D- or better. There will be no extra credit assignments.

### **Course Grade Breakdown (subject to additions/changes)**

Discussion posts are typically 20 points each (see post rubrics below), with the exception of the first module which has a total of 14 points. Each module quizzes will have a range of points depending on the module material.

### **Weekly Discussion Posts**

Discussion posts for Module 1 will be worth 14 total points. Points for this post will be awarded based on effort only; if you complete the posts for Module 1, you will receive all 14 points.

Discussion posts for Modules 2-7 will be worth a total of 20 points. You can receive a total of 12 points for the initial discussion post and 8 points for the two responses to your classmates' posts. **Note** that the due date for the discussion in Canvas is the date that the initial post is due, but that response posts due dates are not able to be integrated into Canvas separately, so be sure to complete according to the syllabus.

The rubric forgrading of the discussion posts is stated below:

<b>Initial Post</b>	
6 points	Posted a response to the discussion topic
2 points	Posted response addresses most of the discussion topic and includes a reference (if applicable)
2 points	The included reference is from a primary source (i.e., a published journal article, standard, guidance document, or guideline) (if applicable)
2 points	The posted response provides insightful commentary that demonstrates an understanding of the topic and the module content
<b>12 points</b>	<b>Total Points Possible</b>

<b>Response Posts</b>	
2 points	Posted response to one classmate's post
2 points	Posted response to a second classmate's post
4 points	Posted response(s) to classmates provide insightful commentary that supports your position of agreement or disagreement. Responses go beyond surface level and superfluous comments that comment on other student's effort rather than the discussion points they are making. Responses should NOT look like: "nice job" or "I agree". Responses should look like deep thinking such as "I agree/disagree because..." (supported by evidence from the content presented) or "I wonder if..." (applying an idea to a new application or scenario).
<b>8 points</b>	<b>Total Points Possible</b>

### Academic Integrity

The Biology and Biotechnology Programs at UNH Manchester will strictly adhere to the University policy on academic honesty, as published in the UNH Student Rights, Rules, and Responsibilities Handbook (<https://catalog.unh.edu/srrr/>), specifically section <https://catalog.unh.edu/srrr/university-policies-regulations/academic-integrity/>)

By submitting any piece of work in this course, you declare that you have read and understand the policy, and that you did not engage in any form of academic dishonesty as defined in the Handbook.

Plagiarism can take many forms, such as: submitting someone else's work—in whole or in part—as your own; collaborating on answers for individual assignments, or allowing your own work to be used by another student; copying information from a website or other text without proper documentation; buying a pre-written paper or lab report.

Cheating is mainly concerned with copying on exams or in lab, bringing crib notes into an exam or referring to notes or the textbook or any other source such as a programmable calculator, tablet, or cell phone during an exam. All electronic devices must be turned off and put away for the duration of any quiz or exam. Ear buds are not permitted.

Unless otherwise specified, the use of Automated Writing Tools, including chatGPT and similar artificial intelligence (AI) tools, is strictly prohibited in this course, even when properly attributed. The use of automated writing tools is considered plagiarism (as defined by UNH's Academic Integrity Policy) and will be handled in accordance with existing policy.

Any instances of cheating or plagiarism will result in consequences that can range from a failing grade on the assignment for all students involved to dismissal from the University, as defined in the UNH Student Rights, Rules, and Responsibilities Handbook.

### Absences/Accommodations/Disabilities

If you are dealing with an unexpected, extenuating circumstance that will significantly affect your performance in this course, reach out to Lisa Enright, Assistant Dean of Student Success, at [lisa.enright@unh.edu](mailto:lisa.enright@unh.edu) to request a letter be sent to all your faculty.

While no significant weather issues are expected during Term 1 that might impact your network/computer access, if you lose internet access for this online course for a significant amount of time that would impact your ability to access the material and submit assignments, please contact the instructor as soon as possible.

If you have a documented disability that will need accommodations for this course, according to the Americans with Disabilities Act (as amended, 2008), each student with a disability has the right to request services from UNH to accommodate his/her/their disability. If you are a student with a documented disability or believe you may have a disability that requires accommodations, please contact Student Accessibility Services (SAS) located on the Manchester campus in the Student Services Suite (Office 405A). Accommodation letters are created by SAS with the student. Please follow-up with your instructor as soon as possible to ensure timely implementation of the identified accommodations in the letter. Faculty have an obligation to respond once they receive official notice of accommodations from SAS but are under no obligation to provide retroactive accommodations.

For more information refer to [www.unh.edu/sas](http://www.unh.edu/sas) or contact SAS at 603.862.2607, 711 (Relay NH) or [sas.office@unh.edu](mailto:sas.office@unh.edu).

### Student Resources

Your academic success and overall mental health are very important. If, during the semester, you find you are experiencing emotional or mental health issues, please utilize the resources below:

In partnership with The Mental Health Center of Greater Manchester, UNH Manchester offers consultation visits on a walk-in basis and through telehealth appointments. Services include:

- Free confidential screening & consultation with a licensed mental health therapist.
- Referrals to mental health or substance misuse treatment. And assistance in understanding how to afford additional treatment (with or without insurance!) or find free services.

You may email: [unhm.wellness@unh.edu](mailto:unhm.wellness@unh.edu) to make an appointment to meet with a counselor by clicking [here](#) or by using the QR codes below.

For in person appointments please scan this code



For remote appointments please scan this code



If you would like to connect to counseling services directly, you may do so by contacting The Greater Manchester Mental Health Center at (603) 668 - 4111.

The National Suicide Prevention Lifeline provides 24/7, free and confidential support via phone or chat

for people in distress, resources for you or your loved ones, and best practices for professionals. Call (800) 273-TALK (8255).

**Basic Needs Support:** Food, Housing, Financial. <https://www.unh.edu/dean-of-students/getting-help/housing-food-financial-basic-needs-support>

**Library:** The UNH Manchester librarians are available to assist you with your research. You can contact a librarian by calling 603-641-4173 or by emailing [unhm.library@unh.edu](mailto:unhm.library@unh.edu).

The following online resources provide information about library resources and services:

**UNH Manchester Library webpage:** <https://cps.unh.edu/library>

**Online Research Guides:** <https://libraryguides.unh.edu/index.php?b=s>

**Access Library Resources Remotely:** <https://libraryguides.unh.edu/remoteaccess>

**Reserve a study room for Zoom classes:** <https://libraryguides.unh.edu/remoteaccess/studyrooms>

**Center for Academic Enrichment:** The Center for Academic Enrichment (CAE) professionals and peers are available to support all UNH Manchester students in maximizing their learning potential through individual in-person and online tutoring, in-class workshops, and study groups in math, writing, course content, study skills, time management, and personal statements. All students registered for UNH Manchester courses are entitled to one hour of individual tutoring, per course, per week. Appointments are available at <https://caetutor.unh.edu>; for more information, contact the CAE at (603) 641-4113, or [unhm.cae@unh.edu](mailto:unhm.cae@unh.edu).

**Food Pantry** The UNH Manchester Food Pantry, located in room 437 is open Monday through Friday from 8:00am- 9:30pm. Any UNH Manchester community member can take what they need. If you have any questions please email [UNHM.Foodpantry@unh.edu](mailto:UNHM.Foodpantry@unh.edu)

**Sexual Harassment and Rape Prevention Program (SHARPP):** Provides free and confidential advocacy and direct services to survivors. UNH Manchester's SHARPP Office Hours during Fall & Spring Semesters are Mondays 9am-4pm in Room 471. Zoom Appointment Availability year round is Mon-Fri 9am-4pm  
24/7 Crisis Line: 603-862-SAFE (7233)

Main Office: 603-862-3494

<https://www.unh.edu/sharpp/>

UNH Manchester students can also contact the YWCA of New Hampshire – 603-668-2299 (24hour), 72 Concord St. Manchester, NH, for crisis or emergency services.

The University of New Hampshire at Manchester and its community are committed to assuring a safe and productive educational environment for all students. Title IX makes it clear that violence, harassment, and discrimination based on sex and gender are Civil Rights offenses subject to the same kinds of accountability and the same kinds of support applied to offenses against other protected categories such as race, national origin, and ability.

If you or someone you know has experienced sexual or relationship violence, and/or stalking and harassment, you can find the appropriate resources below:

Reporting On Campus:

- Title IX Deputy Intake Coordinator: Lisa Enright 603-641-4336. Lisa's office is located on the fourth floor in Room 439.
- UNH Manchester Security: 603-641-4124 or located in the second floor foyer

Reporting Off Campus:

- Manchester Police Department - 603-668-8711, 405 Valley St. Manchester, NH
- or your local police department

For emergencies dial 911.

**Confidential Support Resources:**

- YWCA, NH – 603-668-2299(24hour), 72 Concord St. Manchester, NH
- Sexual Harassment and Rape Prevention Program (SHARPP): 603-862-7233(24hour), 8 Ballard Street, Wolff House, Durham NH 03824
- The Mental Health Center of Greater Manchester: See contact information and hours above
- 24 Hour NH Sexual Violence Hotline: 1-800-277-5570
- 24 Hour NH Domestic Violence Hotline: 1-866-644-3574

**Name Coach**

We have a new tool in Canvas, NameCoach, that will help us all to pronounce each other's names properly. Please join me in making our learning environment as inclusive as possible by recording your name (instructions [here](#)) and taking advantage of the opportunity to respectfully learn how to pronounce each other's names.

**MyCourses (Canvas) and E-mail**

Check MyCourses every day. Non-urgent announcements will be posted on MyCourses. Urgent/time-sensitive announcements will be sent, when possible, via e-mail. Be sure that you have your email properly set up within canvas to ensure that you receive urgent announcements and updates.

**Class and Assignment Schedule (subject to change)**

Module	Assignment	Due Date
<b>Module 1- Introduction to Manufacturing and Biotechnology Medical Products</b>		<b>Week One Module Opens 08/28/23</b>
	Complete all module readings and videos	
	Discussion post-“Introductions”	Saturday, 9/2, 11:59 PM ET
	Discussion post-“Reflection”	Saturday, 9/2, 11:59 PM ET
	Quiz 1	Saturday, 9/2, 11:59 PM ET
<b>Module 2- Manufacture of Monoclonal Antibodies and Therapeutic Proteins</b>		<b>Week Two Module Opens 09/1/23</b>
	Complete all module readings and videos	
	Discussion post(s) Look to see if there is more than one discussion required.	Friday, 9/8, 11:59 PM ET
	Response posts-2 posts for <b>each</b> discussion	Sunday, 9/10, 11:59 PM ET
	Quiz 2	Saturday, 9/9, 11:59 PM ET
<b>Module 3- Manufacture of Cell Therapies</b>		<b>Week Three Module Opens 09/08/23</b>
	Complete all module readings and videos	
	Discussion post(s) Look to see if there is more than one discussion required.	Friday, 9/15, 11:59 PM ET
	Response posts-2 posts for <b>each</b> discussion	Sunday, 9/17, 11:59 PM ET
	Quiz 3	Saturday, 9/16, 11:59 PM ET
<b>Module 4 – Manufacture of Gene Therapies</b>		<b>Week Four Module Opens 09/15/23</b>
	Complete all module readings and videos	
	Discussion post(s) Look to see if there is more than one discussion required.	Friday, 9/22, 11:59 PM ET

	Response posts-2 posts for <b>each</b> discussion	Sunday, 9/24, 11:59 PM ET
	Quiz 4	Saturday, 9/23, 11:59 PM ET
<b>Module 5 – Manufacture of Regenerative Medicine Products</b>		<b>Week Five Module Opens 09/22/23</b>
	Complete all module readings and videos	
	Discussion post(s) Look to see if there is more than one discussion required.	Friday, 9/29, 11:59 PM ET
	Response posts-2 posts for <b>each</b> discussion	Sunday, 10/1, 11:59 PM ET
	Quiz 5	Saturday, 9/30, 11:59 PM ET
<b>Module 6 – Current Good Manufacturing Practices (cGMPs) and Standards</b>		<b>Week Six Module Opens 09/29/23</b>
	Complete all module readings and videos	
	Discussion post(s) Look to see if there is more than one discussion required.	Friday, 10/6, 11:59 PM ET
	Response posts-2 posts for <b>each</b> discussion	Sunday, 10/8, 11:59 PM ET
	Quiz 6	Saturday, 10/7, 11:59 PM ET
<b>Module 7 – Biotechnology Product Development: From R&amp;D to the Market</b>		<b>Week Seven Module Opens 10/06/23</b>
	Complete all module readings and videos	
	Discussion post(s) Look to see if there is more than one discussion required.	Friday, 10/13, 11:59 PM ET
	Response posts-2 posts for <b>each</b> discussion	Sunday, 10/15, 11:59 PM ET
	Quiz 7	Saturday, 10/14, 11:59 PM ET
<b>Module 8 – Getting a Biotechnology Product to Market</b>		<b>Week Eight Module Opens 10/13/23</b>
	Complete all module readings and videos	
	Discussion post(s) Look to see if there is more than one discussion required.	<b>Wednesday, 10/18, 11:59 PM ET</b>
	Response posts-2 posts for <b>each</b> discussion	<b>Friday, 10/20, 11:59 PM ET</b>
	Quiz 8	<b>Friday, 10/20, 11:59 PM ET</b>