

UNIVERSITY OF NEW HAMPSHIRE MANCHESTER
Biotech Products & Regulation
BIOT 825 | Fall 2025

SYLLABUS & STUDENT GUIDE

Wednesdays 6:10 - 9:00 pm UNHM PANDRA P380

INSTRUCTORS

Katrina Wells, RAC – kwells@armiusa.org

DESCRIPTION

The biopharmaceutical industry begins with foundations in basic science and works through various stages to turn ideas into marketable therapies. The business, clinical, and regulatory steps that are required to bring a product to market are important to understand in order to maximize one's effectiveness in any department in a biopharmaceutical setting. This course draws upon field experts to help deliver the content and tackle important discussions about the processes involved in drug development.

PURPOSE

Over the course of study in Industrial and Biomedical Sciences, students will become familiar with the scientific and technical details of cutting-edge biotech therapeutics and the research done to develop and test them. This course seeks to broaden students' knowledge of medical product development by familiarizing them with the regulatory processes involved in bringing therapies to market.

COURSE OBJECTIVES

This course will cover this process from discovery to FDA approval and the meetings, submissions, and testing in between. By the end of this course, students will have a basic understanding of how the FDA reviews and regulates human medical products, FDA organizational structure and authority, types and definitions of human medical products, product jurisdiction, and FDA regulatory pathways.

PRE- OR CO-REQUISITE – Not required.

COURSE READING LIST – Materials required for this course will be provided in a digital format.

GRADING DISTRIBUTION

In-class Participation and Projects – 10%

Weekly Quizzes – 10%

First Hour Exam – 20%

Second Hour Exam – 20%

Third Hour Exam- 20%

Final Exam – 20%

COURSE FORMAT

This course will be in-person with a mix of lectures and projects. Additional online assignments and activities to be completed outside of class are curated through Canvas (UNH MyCourses). You will be responsible for reviewing any pre-lecture content before class and come prepared for discussion.

Weekly Learning Plans. Each week you will be presented with a learning plan within the Module for the week (published prior to class in Canvas [UNH MyCourses]). Each module will include the relevant slides, learning objectives, assignments, links to additional supplemental materials, and quizzes. Each module is designed to give organized access to all materials needed during the week and for review.

Independent Study. You will be independently responsible for understanding the course objectives for each week and completing assignments on time. There will be supplementary material to guide your understanding and ample opportunity to ask clarifying questions in-person and over email/Canvas.

Quizzes. A weekly online quiz will be provided through Canvas (UNH MyCourses). There is no time or attempt limits for quizzes. Correct answers will be shown after each attempt. Questions are drawn from the lectures, supplemental materials, and in-person sessions and are intended to drive home the take-aways from the previous class.

PROFESSIONALISM AND COMPORTMENT

Students are expected to conduct themselves at all times in accordance with the professional expectations required. Students are reminded that representatives of the University of New Hampshire when involved with course-related activities inside and outside the classroom. Professional conduct is essential to successful course experience and a successful career.

GENERAL EXPECTATIONS

The key to this course is to take responsibility for your own learning. I am here to support your learning. The following are my expectations for you:

- Abide by the class policies below. In particular, review the sections on Academic Honesty and Plagiarism.
- Actively participate in course discussions and engagement with course material.
- Contact me in a timely manner if circumstances arise which hinder your progress in the course.
- Use time management and backward planning to ensure all deadlines are met.
- Keep backups of any assignments submitted for this course in case of technology mishaps.
- Activate notifications and check in regularly for correspondence from your classmates and me.

Expectations for the Instructors

- I will check my email regularly. I will reply as soon as possible, within 24 hours when possible.
- I will return feedback on submitted assignments within a reasonable period of time.
- I will maintain high expectations for you and your level of achievement while providing as much support as I can to encourage you and help your development.

ACADEMIC HONESTY

The Biology Program at UNH Manchester will strictly adhere to the University policy on academic honesty, as published in the UNH Student Rights, Rules, and Responsibilities Handbook (<http://unh.edu/vpsas/handbook/academic-honesty>). By turning in any piece of work in this course, students declare that they have read and understood the policy and that they did not engage in any form of academic dishonesty as defined in the Handbook.

Academic dishonesty in any form will not be tolerated. Examples of academic dishonesty include falsification or forgery of academic documents, applications, clinical evaluations, or lab evaluations.

AI/LLM (ChatGPT, Gemini, etc.) use is allowed for preliminary research or brainstorming within the Program. However, it is important to note that academic

citation and source generation by AI tools is particularly problematic given evidence that these tools often invent citations even when they claim they are not doing so.

We highly value independent critical thinking and problem-solving skills and thus AI/LLM use is not allowed within the Program to generate answers or complete assignments. All use of AI/LLMs must be disclosed, including grammar polishing. In that case, the original unpolished version of the assignment must also be submitted along with the final version. Use of AI without disclosure is considered plagiarism.

Any instances of cheating, plagiarism, or academic dishonesty 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.

CLASS POLICIES

Use of Personal Electronic Devices During Class. Using personal electronic devices in the classroom setting can hinder instruction and learning, not only for the student using the device but also for other students in the class. Students may use internet-capable devices to take notes or research class-related questions. Students may not use devices for messaging or entertainment during class.

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

- UNH Manchester Library webpage: <https://manchester.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 CAE provides academic support services, including individual tutoring, for all students. Make an appointment through the

CAE My Courses site on your Canvas dashboard. Phone: (603) 641-4113. Email: unhm.cae@unh.edu

Sexual Harassment. "Sexual harassment" means unwelcome sexual advances, requests for sexual favors, and/or other verbal or physical conduct of a sexual nature. Such conduct has the purpose or effect of unreasonably interfering with an individual's work or academic performance or creating an intimidating, hostile, or offensive working or academic environment. Such behavior is not acceptable.

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) 541-4101 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 (24 hours), 72 Concord St Manchester, NH
- Sexual Harassment and Rape Prevention Program (SHARPP): (603) 862-7233 (24 hours), 8 Ballard Street, Wolff House, Durham NH 03824
- The Mental Health Center of Greater Manchester: See contact information and hours below
- NH Sexual Violence Hotline: 1 (800) 277-5570 (24 Hours)
- NH Domestic Violence Hotline: 1 (866) 644-3574

Equity, Diversity, Equal Opportunity, and Affirmative Action. We will provide equal access to and opportunity in this course without regard to race, color, creed, religion, national origin, gender, age, marital status, disability, public assistance status, veteran status, sexual orientation, gender identity, or gender expression.

Disability Accommodations. The University is committed to providing students with documented disabilities equal access to all university programs and facilities. If

you think you have a disability requiring accommodations, you must register with the Student Accessibility Services (SAS) office. The Student Accessibility Coordinator at UNHM is Jenessa Zurek. Please reach out to the SAS office via email at jenessa.zurek@unh.edu for registration information and disability related questions. Jenessa Zurek is available through phone and email Mondays and Wednesdays from 9am-2pm.

Mental Health and Stress Management. In partnership with The Mental Health Center of Greater Manchester, UNH Manchester offers free mental health sessions for students. 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 1 (800) 273-TALK (8255). 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 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



Food Pantry. The campus food pantry is stocked with non-perishable and refrigerated food items for students in room 437. If you have any questions, contact Kattarina.Biss@unh.edu

BIOT 825 Biotech Products and Regulations - Fall 2025 Schedule

Dates	Topics/Activities
Week 1 8/27	<ul style="list-style-type: none">• Introduction to Course and Expectations• Introduction to the US Government and FDA
Week 2 9/3	<ul style="list-style-type: none">• Recap on the US Government and FDA• Product Classification and Jurisdiction
Week 3 9/10	<ul style="list-style-type: none">• FDA Interactions• Special Programs• Introduction to the Regulatory Pathways
Week 4 9/17	FIRST HOUR EXAM
Week 5 9/24	<ul style="list-style-type: none">• Recap on the Regulatory Pathways• Start Device Pathway Activity
Week 6 10/1	<ul style="list-style-type: none">• Complete Device Pathway Activity
Week 7 10/8	<ul style="list-style-type: none">• Biologics Pathway
Week 8 10/15	SECOND HOUR EXAM
Week 9 10/22	<ul style="list-style-type: none">• Quality Systems• Phase-appropriate cGMP, cGLP, cGTP, etc.
Week 10 10/29	<ul style="list-style-type: none">• Challenging the Paradigm
Week 11 11/5	<ul style="list-style-type: none">• Postmarket Surveillance and Enforcement• Reimbursement
Week 12 11/12	THIRD HOUR EXAM
Week 13	<ul style="list-style-type: none">• Enforcement Case Studies

11/19	<ul style="list-style-type: none">• Startup Case Studies
Week 14 11/26	No classes - Thanksgiving holiday
Week 15 12/3	<ul style="list-style-type: none">• Policy Case Studies• Review
Week 16 12/10	FINAL EXAM