

SURG 5100 Biopharmaceutical Drug Development: From Target to Product

Section A · Fall 2026 · CRN 96270 · University of Vermont

Meets: Tuesday & Thursday, 11:40 a.m. – 12:55 p.m. HSRF 200 (Sep 17 – Oct 8 in HSRF 400 — see schedule).

Term: August 31 – December 11, 2026

Credits: 3 credits. Elective credit for most departments (ask your advisor). Open to undergraduate and graduate students.

Instructors: Dev Majumdar, PhD, Larner College of Medicine and Biomedical Engineering (Dev.Majumdar@uvm.edu); Matt Whelihan, PhD, Research and Development, Prolytix Technologies (Matthew.Whelihan@uvm.edu).

Office hours: By arrangement. Email either instructor; we will find a time within two business days.

Prerequisites: Introductory biochemistry, genetics, or cell and molecular biology — for example MMG 2010, MMG 2040, or BCOR 2300 — or permission of the instructors. Graduate students in any life-science, engineering, or chemistry program may enroll without further prerequisite.

Cross-listing: Cross-listing with Chemistry, Biomedical Engineering, and Microbiology & Molecular Genetics is in progress.

Description

Biopharmaceutical Drug Development provides a practical overview of the end-to-end process of bringing a therapeutic from concept to clinic and market. The course covers target identification, lead optimization, preclinical development, formulation, clinical trial design, regulatory strategy, and manufacturing. Emphasis is placed on translational science, risk management, and decision-making across development stages, and on how scientific, regulatory, and commercial factors intersect in both small- and large-molecule programs.

Format

The course follows a single molecule's path from target to market. Each week takes one stage of the development pipeline, in the order a real program encounters it, and each stage is taught the same way: a lecture that frames the decision, a critical reading of the primary literature, and three real companies measured against that stage — two that failed there and one that survived because of it.

The sequence is deliberately the company's order rather than the learner's. You will spend eight weeks on discovery, manufacturing, and safety before the first clinical trial, because that is the order in which the money is committed and the mistakes are made.

Learning objectives

By the end of the course you will be able to:

1. Describe the end-to-end drug development lifecycle from discovery to product release.
2. Explain the roles of CMC, GxP, quality systems, and regulatory oversight in drug development.
3. Evaluate analytical assays for fitness, validation, and decision-making.
4. Interpret preclinical and toxicology data in the context of IND-enabling studies.
5. Distinguish the phases of clinical development and the key trial design considerations of each.

6. Understand the structure and purpose of FDA regulatory submissions.
7. Apply industry perspectives to career paths in biopharma and regulatory science.

Expectations by level

Undergraduate and graduate students share the schedule, the readings and the classroom. The assessed work differs as follows. Graduate students are expected to work from primary sources and to state the limits of their own arguments.

Component	Undergraduate	Graduate
Final report	8–10 pages tracing one development program of your choice through the eleven stages, naming the stage that decided its outcome.	15–20 pages, as at left, plus an explicit counterfactual: the earliest decision that would have changed the outcome, what it would have cost, and the evidence available at the time.
Seminar leadership	Participate in the critical reading discussion each week.	Lead the critical reading discussion for one week, including a one-page briefing circulated in advance.
Quizzes	Interpretation of data presented in class and in the assigned reading.	As at left, with one additional question per quiz drawn from the primary literature.

Assessment

Component	Undergrad	Graduate
Active participation and preparation	30%	30%
Weekly quizzes (five minutes, start of class)	30%	25%
In-class midterm examination	15%	15%
Final report	25%	30%

Our grading philosophy is that if more than half the class answers a question correctly, the question was fair and we taught the material adequately. If fewer than half do, the problem is more likely the question or our coverage of it. Each item carries a stated point value, but the deduction for an incorrect element scales with how many classmates answered it correctly. Graded components sum to a maximum of 100 points.

Grading scale

A+ 97–100 · A 93–96 · A– 90–92 · B+ 87–89 · B 83–86 · B– 80–82 · C+ 77–79 · C 73–76 · C– 70–72 · F below 70

Weekly schedule

Rooms follow the registrar's assignment: HSRF 200, except September 17 through October 8, which are in HSRF 400. There is no class on Thursday, November 26 (Thanksgiving recess). This is a projected schedule and may shift slightly.

Wk	Dates	Room	Topic and sessions	Due
1	Sep 1 · Sep 3	HSRF 200	Introduction: the pipeline and where programs	Quiz 1

Wk	Dates	Room	Topic and sessions	Due
			die Course map and attrition data · What drives pharmaceutical innovation in the United States	
2	Sep 8 · Sep 10	HSRF 200	Drug discovery Target identification and candidate selection · State of the art: DNA-encoded libraries and computational screening	Quiz 2
3	Sep 15 · Sep 17	HSRF 200 / 400	Chemistry, manufacturing and controls What CMC is and why the process is the product · Case studies in scale-up failure	Quiz 3
4	Sep 22 · Sep 24	HSRF 400	GxP and the role of quality assurance Quality systems and the FDA · Invited quality assurance expert	Quiz 4
5	Sep 29 · Oct 1	HSRF 400	Analytical assay design and validation The seven elements of validation · Case studies of assay failure	Quiz 5
6	Oct 6 · Oct 8	HSRF 400	Formulation and drug delivery Exposure, not potency: the therapeutic window · Modified release and the promise about rate	Quiz 6
7	Oct 13 · Oct 15	HSRF 200	Toxicology Species selection and first-in-human dose setting · Case study session	Quiz 7
8	Oct 20 · Oct 22	HSRF 200	Preclinical trials The IND-enabling package · Chemotype liabilities and study duration	Midterm exam
9	Oct 27 · Oct 29	HSRF 200	FDA regulatory submissions The Common Technical Document · Accelerated approval and its obligations	Quiz 8
10	Nov 3 · Nov 5	HSRF 200	Clinical development Phases as questions, not calendar blocks · Adaptive and expandable designs	Report proposal due
11	Nov 10 · Nov 12	HSRF 200	Clinical trials: design, endpoints and statistics What randomization buys · Surrogates, endpoints and platform trials	Quiz 9
12	Nov 17 · Nov 19	HSRF 200	Roles and jobs in the food chain The organization as a detection system · Careers panel with industry guests	Quiz 10
13	Nov 24 · Nov 26 (no class)	HSRF 200	Drug product release and program maintenance Release decisions and specifications · Lifecycle management and post-approval change	Quiz 11

Wk	Dates	Room	Topic and sessions	Due
14	Dec 1 · Dec 3	HSRF 200	Careers in industry Functions, transferability and the job market · Guest speaker panel	Report draft due
15	Dec 8 · Dec 10	HSRF 200	Course conclusion Synthesis: the recurring failure modes · Final report presentations	Final report due

Guest speakers and site visits

Guest speakers from industry present throughout the term, including company founders and chief executives, quality assurance leads, toxicologists, and regulatory scientists who prepare FDA submissions. Optional site visits to Vermont pharmaceutical and biotechnology operations are scheduled outside class hours; attendance is encouraged but never required, and no assessment depends on attending one.

Attendance

Attendance is expected and folds into the participation grade. We assume everyone will miss up to three classes in a semester for illness, interviews, or travel; points come off only after more than three absences. Attendance at a scientific conference is an excused absence and does not count toward that total. If you must miss a session with a graded component, tell us before it happens.

Use of generative AI

Why the policy exists. Large language models are useful tools, and you will use them in your career. They create two problems in this course. The pedagogical problem is that you are here to learn to reason about biomedical science and to express that reasoning precisely; outsourcing either defeats the purpose of enrolling. The functional problem is that much of the assessed work turns on interpreting data, including hypothetical and deliberately altered cases, where a language model is likely to produce confident and wrong answers.

What is permitted. You may use AI tools for grammar, spelling, and clarity of your own prose, and for locating primary literature that you then read yourself. You may not use them to generate scientific content, analysis, or argument that you submit as your own.

Citation. Any use of an AI system must be disclosed in a one-line note at the end of the assignment stating which tool and for what. Undisclosed use is treated as a citation violation under the Code of Academic Integrity. We will not deduct points for disclosed, permitted use; we will deduct points for confused science regardless of who or what produced it.

Required materials and platforms

No textbook. Primary literature and topical reviews are the reading material and are posted on Brightspace. You will need the ability to produce PDF files. Brightspace is the repository for all course content; there is no Teams page for this course.

University of Vermont standard syllabus components

Technical support for students. Review the student technology checklist at uvm.edu/it/kb/student-technology-resources. For technical problems contact the Helpline at 802-656-2604.

Classroom environment. In this class we work together to build a learning community that is inclusive and respectful, in the spirit of Our Common Ground. Constructive dialogue requires mutual respect, a willingness to listen and open-mindedness toward opposing views. Conduct that substantially or repeatedly disrupts teaching or the ability of others to engage may result in a student being asked to leave the classroom temporarily. See the Classroom Code of Conduct in the Undergraduate Catalogue.

Academic integrity. This course follows the UVM Code of Academic Integrity, which addresses plagiarism, fabrication, collusion and cheating. You may use and interpret data from any source; anything not drawn from the Brightspace environment must be cited appropriately. See also the AI policy above.

Lived name and pronouns. The UVM Directory includes fields for your lived name and your pronouns. Entering your pronouns is strongly encouraged and helps create a more inclusive campus; the information propagates to systems including Microsoft Teams and Brightspace.

Student learning accommodations. Any student with a documented disability interested in using ADA accommodations should contact Student Accessibility Services. SAS works with students and faculty through an interactive process to identify reasonable accommodations, which are communicated to faculty in an accommodation letter. Discuss with us the accommodations you plan to use. SAS: A170 Living/Learning Center, 802-656-7753, access@uvm.edu, uvm.edu/access.

Religious holidays. Students have the right to practice the religion of their choice. Submit to your instructors in writing, as early as possible and at least one week before the observance, the dates of any conflict. Faculty must permit students who miss work or examinations for religious observance to make up that work.

Research and citation help. For help selecting topics, finding information and citing sources, ask a librarian. Dana Medical Library: dana.uvm.edu/help/ask. Howe Library: library.uvm.edu/askhowe.

Course evaluation. Student evaluations are conducted through Blue and completion is expected at the conclusion of the course. Evaluations are anonymous and confidential; they are used primarily to improve the course and also in faculty promotion review.

Intellectual property. Students may not publicly share or sell academic materials they did not author, including the syllabus, outlines, presentations, practice questions or other copyrighted class materials, and may not share assessments. Violations are handled under UVM's Intellectual Property policy and the Code of Academic Integrity.

Other UVM policies. The Code of Student Conduct, FERPA Rights Disclosure, Final Exam Policy, Grade Appeals and Grading policies apply and are available at uvm.edu/policies.

Promoting health and safety. The University's first priority is a healthy and safe community. Center for Health and Wellbeing; Counseling and Psychiatry Services (CAPS), 802-656-3340. If you are concerned about a community member, contact the Dean of Students Office at 802-656-3380 or report anonymously through the C.A.R.E. Team website.

Alcohol and cannabis. Alcohol and cannabis have no place in an academic environment. They impair attention, memory and concentration, degrade how information is processed and stored, and disrupt the sleep patterns that support long-term memory, with effects that can persist for 48 hours or more. We expect you to do everything you can to optimize your learning and participate fully.

Draft prepared for departmental review. Week 6 (Formulation and Drug Delivery) is a proposed topic and is not yet approved. Case material referenced in class is instructor-prepared and pending source verification.