

PHAR 6766: Biotechnology-Derived Drugs



Course Syllabus Fall 2020
1.0 Credits

This course adheres to the College of Pharmacy Central Syllabus. Please see the following link for this information:
https://docs.google.com/a/umn.edu/document/d/1artQ5e1rbzxe8lEtWo7BE8k8snZAEgMMz_QcW8yJ-II/edit?pli=1

Course Web Site: <https://canvas.umn.edu/courses/199133>
Term: Fall PD3
Dates: Tuesday, August 25 to Tuesday, December 8, 2020.

Day	Time	Duluth Room (except as indicated)	Twin Cities Room (except as indicated)
Tuesday (8/25 – 12/08)	1:25 – 2:15	Lib410 (remote instruction)	WDH 7-135 (remote instruction)

Course Instructional Team: Directors: Nam Chul Kim and W. Thomas Shier

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Teaching Assistants:

G.T.A. (Duluth): Michael Williams(will2086@d.umn.edu)
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Overview of the course

Course content:

In 2019, eight of the top ten drugs by sales were biotechnology-derived drugs. Sales numbers are not as important to pharmacies as number of scripts filled, but they do matter, because that is where the pharmaceutical industry is going to make its investments going forward. The pipeline for biotechnology drugs isn't empty, so we can expect more of these agents will be brought to market in the future. Pre-filled syringe formulations are bringing more and more of these drugs into community pharmacies. Biotechnology-derived drugs are key participants in several important clinical areas, such as arthritis, kidney diseases and oncology, and more penetration into other fields can be expected. Biotechnology-derived drugs are where the future is, and pharmacy students need to understand how they are made, how they act and what special considerations are involved. This course will provide the **basic knowledge** necessary to understand, recommend and counsel patients on current biotechnology-derived drugs and provide **the basis for self-education** needed to appreciate the biotechnology- derived drugs of the future.

The material covered in this course will provide valuable background information about drugs used in strategically aligned modules/courses, including the diabetes clinical module; dermatology; genetics; immunology; cardiovascular; neurology (multiple sclerosis); oncology; infectious diseases; and inflammatory diseases (arthritis).

Course format

Class will meet virtually for 50-minute sessions, once a week, for the entire semester. Class time will be used for **lectures** and various types of **in-class learning activities** (discussion, problem-solving). Students should plan to spend 2 hours outside of class for every 1 hour in class for this course.

Prerequisites

Successful completion of Integrated Biochemical Sciences, Principles of Medicinal Chemistry, Principles of Pharmacology, Immune System and Infectious Disease, Cellular Metabolism and Nutrition, and Integrated Endocrinology.

Course Materials

There is no required textbook at this time. If a suitable, focused text in the subject appears, it will be considered for adoption.

Computer/Technology Requirements

- Canvas: This course will use Canvas to distribute learning materials. See <https://canvas.umn.edu/courses/199133>
- E-Textbooks: There are no E-Texts at this time. You will access these through the course Canvas site, if they become available.
- E-Mail: Course instructors may communicate through email about course administrative issues. You should check your U of M email daily.

Student-response systems: Discussions may use Turning Point or other adopted audience response system software.

Course Goals & Objectives

Concepts/Goals/Objectives
Concept 1: Biotech-derived drugs are different from other drugs. <i>Course goal 1: Explain ways in which biotech-derived drugs differ from other drugs.</i>
Learning Objective (LO) 1a: Compare and contrast properties of biotechnology-derived drugs (protein, antibody, nucleic acid) and properties of small-molecule drugs; and describe how the differing properties affect drug storage, preparation, and administration methods.
LO 1b: Describe how to make biotechnology-derived drugs (protein, antibody, nucleic acid).
LO 1c: Detail the mechanisms of action for some important biotechnology-derived drugs.
LO 1d: Understand the pharmacokinetics of biotechnology-derived drugs.
LO 1e: Explain how the pharmacokinetics of biotechnology-derived drugs (mostly protein drugs) can be improved to make second generation drugs by the following: (i) pegylation; (ii) altering glycosylation; (iii) altering the molecular weight and (iv) altering solubility
LO 1f: Describe the concepts of antibody-drug conjugates, gene therapy, and cell therapy.
LO 1g: Describe the legal and economic considerations for the production of generic biotechnology-derived drugs (biosimilars).
Concept 2: Biotechnology drugs are important to pharmacy. <i>Course goal 2: Explain how and why biotechnology drugs are important to pharmacy.</i>
LO 2a: List clinically important drugs that have been discovered.
LO 2b: Understand the localization techniques used to diagnose disease with monoclonal antibody-based imaging diagnostics.
LO 2c: Understand diagnostic methods for viral infection.
Concept 3: Biotechnology-specific clinical skills are needed for practice. <i>Course goal 3: Apply knowledge of biotech-derived drugs to patient care.</i>
LO 3a: Explain who, how and why erythropoietin, growth hormone and sometimes insulin are abused.
LO 3b: Outline the potential and limitations of gene and cell-based therapies and what limits their use.
LO 3c: Explain the high cost of biotechnology-derived drugs, and how that cost affects reimbursement, inventory practice and counterfeiting.
LO 3d: Describe the qualities of a biosimilar drug, approval process and cost implications
LO 3e: Analyze the ethical issues around the use of biotechnology drugs

Attendance Policy

Students are expected to attend every class for which they are registered. Students are expected to attend classes on the campus where they are enrolled (**All lectures will be delivered online due to COVID19**). Although instructors may choose to take attendance, it is recognized that sometimes students will need to attend to other obligations, and on those occasions they will listen to the recorded version of the lecture on their computer.

Expectations

You are expected to participate actively in your own education while in the College of Pharmacy. This will prepare you to be a lifelong learner.

Assessments and Grading

The following graded assessments will count toward your final grade for this course in the following amounts:

#	Date	Title Brief description	Assessment Goal (required to link to domain)	Points	% of final grade
1	10/19	Exam 1 (Lectures 1-7)	Learning Objective 1-2, 3a	59	29.5%
2	Finals Week	Exam 2 (Lectures 8 - 15)	Learning Objective 1-3	63	31.5%
3	Each Week	Weekend Quiz	All Learning Objectives	44	22%
4	11/30	Biotechnology case assignment	Learning Objective 3c-e	27	13.5%
5	12/10	Ethics In-Class Discussion Attendance and Participation	Learning Objective 3e	5	2.5%
6	Last Week	Complete a course evaluation		2	1%

You will complete two written exams (**2 hr each, 24 hours window**). The dates of these exams are announced in the course schedule.

- Weekend Quiz: Canvas
- Exam 1 and 2: ExamSoft

All exam answers must be written in ink. No regrade requests will be accepted for exams answered with pencil.

REGRADE POLICY

All exams submitted for regrade must have a written explanation attached detailing the need for the exam to be regraded. The request must be submitted to the instructor within one week of receiving the graded exam. No changes will be made in the final grade without the consent of the course faculty. Regrading exams may also result in point deductions, if overlooked grading errors are found.

MAKE-UP EXAM POLICY

Under no circumstances will make-up exams or in-class discussion sessions be scheduled for unexcused absences. Excused absences include 1) illness verified by a physician's letter, 2) serious family emergency, and 3) a University-sponsored event, verified by a note from the leader of the sponsoring institution. Notification of the course director must occur in advance of the regularly scheduled exam.

HONOR CODE

Each student is bound by the following specific provisions as part of the Code: Academic misconduct is any unauthorized act which may give a student an unfair advantage over other students, including but not limited to: falsification, plagiarism, misuse of test materials, receiving unauthorized assistance and giving unauthorized assistance. Each student will be asked to sign a cover sheet on tests that reaffirms the honor code as it applies to this course. Specifically, each student will be required to do their own work on all tests, quizzes and any written

assignments. For written assignments, students are allowed to discuss the assignment with other students, but all written material must be their own work and not the result of group discussions.

Grading Information

Grades will be assigned at the end of the term and will be based on the total number of points out of a maximum of 200 points. See the grades table below. To pass the course you must obtain 60% of the total points.

Incomplete grades will be given only by prior arrangement approved by the course director.

Quiz and Exam Policies

- All written exams will be given open book online in ExamSoft during scheduled times. You will have a **24 hour** window to complete exams during a defined time-limited period.
- Exams will not be graded on a curve.
- The final percentage will be rounded off to the nearest unit place to determine the final grade. For example, 92.4% will be rounded to 92% (A-) while 92.5% will be rounded to 93% (A).
- Exams will be comprehensive and will build on previous content. Standard analyses of composite class responses for all exam questions will be conducted by the authors of those exams prior to releasing the scores.
- An opportunity to request an exam regrade is provided for all exams system.
- Grades will not be given out over the telephone or by email.

Course Letter Grades

Grade	Percentage
A	93 - 100
A-	90 - 92
B+	87 - 89
B	83 - 86
B-	80 - 82
C+	77 - 79
C	73 - 76
C-	70 - 72
D	60 - 69
F	0 - 59

Detailed Course Outline & Schedule*

- Subject to change at course director's discretion.

Date	Day	Lecture #	Topic	Weekend Quiz	Instructor
8/25/20	Tue	1	Introduction (Market & Tech)	O	Kim
9/1/20	Tue	2	Refresher to proteins, nucleic acids and associated techniques	O	Kim
9/8/20	Tue	3	Nucleic acid-based drugs	O	Kim
9/15/20	Tue	4	Monoclonal antibodies and antibody drug conjugates	O	Shier
9/22/20	Tue	5	Pharmacokinetics of antibodies and antibody drug conjugates	O	Elmquist
9/29/20	Tue	6	Diagnostics	O	Kim
10/6/19	Tue	7	Pharmacology of biotechnology derived drugs	O	Shier
10/19/20	Mon		Exam 1 (covers lectures #1-7)		tentative
10/20/20	Tue	8	Second generation biotech drugs	O	Shier
10/27/20	Tue	9	Vaccines	O	Shier
11/3/20	Tue	10	Novel therapies - cell and gene therapies	O	Shier
11/10/20	Tue	11	Cost of Biotech drugs	O	Schondelmeyer
11/17/20	Tue	12	Biosimilars	X	Jacobson
11/24/20	Tue	13	Case discussion biotechnology derived drugs	X	Jacobson
12/1/20	Tue	14	Case discussion biotechnology derived drugs	X	Jacobson
12/8/20	Tue	15	Ethics of Biotechnology drugs	X	Stratton/ Jacobson
Finals Week	TBD		Exam 2 (covers lectures #8-15)		

- **11/30/20 Biotechnology derived drug case assignment due (Dr. Jacobson)**
- **12/10/20 Ethics Questions & Group Vote due (Dr. Stratton)**

Additional Policy Sources:

[University of Minnesota and College of Pharmacy Policy Reference \(Centralized Syllabus\)](#)

[This page includes all required UMN and CoP policies, e.g., Academic Freedom; Copyright; Course Evaluations; Disability Accommodations; FERPA, etc.]