

The Hashemite University



Faculty of Pharmaceutical Sciences



الجامعة الهاشمية



كلية العلوم الصيدلانية

Syllabus

Pharmaceutical biotechnology (131701576)

First Semester 2024 /2025

COURSE INFORMATION

Course Name: Pharmaceutical Biotechnology (Face-to-face education) Semester: First Department: Pharmaceutics and Industrial Pharmacy Faculty: Pharmaceutical Sciences	Course Code: 131701576 Section: per semester Core Curriculum: 2013 Study Plan
Day(s) and Time(s): According to HU course timetable/semester Classroom: As per semester	Credit Hours: 2 Prerequisites: 131702221 and 131702458

COURSE DESCRIPTION

The aim of this course is to recognize the students with the importance of biotechnology in our life, the principles of molecular biology and gene technology including restriction enzyme, selection of genes, insertion into vectors, expression, and purification of proteins. In addition to the techniques used in the separation and identification of proteins as SDS-PAGE and Western blot. The course will also discuss the different biologicals synthesized by biotechnology including proteins, glycoproteins and monoclonal antibodies. Furthermore, fermentation processes used in the synthesis of antibiotics, vitamins, as well as pharmaceutical excipients are also studied. And lastly, the formulation of the biopharmaceutical, essential excipients added and guidelines of FDA and EMA for approval of biologicals and biosimilars will be discussed.

DELIVERY METHODS

The course will be delivered through a combination of active learning strategies. These will include:

- PowerPoint lectures and active classroom-based discussion
- Collaborative learning through small groups acting in an interdisciplinary context.
- Relevant films and documentaries
- Video lectures
- E-learning resources: e-reading assignments and practice quizzes through Moodle and Microsoft Teams
- Brain storming.

FACULTY INFORMATION

Name	Dr Iman Mansi
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Name	Dr. Ala'a Abuhammad
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Email Address:	new.alaa@ymail.com
Office hour:	As announced per semester

References

Pharmaceutical biotechnology, fundamentals and applications, 2019, edited by
Daan J.A. Crommelin, Robert D. Sindelar, Bernd Meibohm, 5th ed, Springer Cham, ISBN-hard copy: 978-3-030-00709-6

DOI: <https://doi.org/10.1007/978-3-030-00710-2>

Pharmaceutical Biotechnology: Drug Discovery and Clinical Applications, 2012, Oliver Kayser and Heribert Warzecha, Wiley VGH, ISBN: 978-3-527-32994-6

DOI: <https://doi.org/10.1002/9783527632909>

Website, HU moodle

Journal of pharmaceutical biotechnology

Course Objectives

1. Demonstrate a good awareness of the uses of biotechnology.
2. Emphasize the main concepts regarding the methodologies of genetic engineering and their application in the manufacturing of biopharmaceuticals and biomedical research.
3. Understand the manufacturing, pharmacology, formulation, storage conditions and the proper route of administration of commonly used biopharmaceuticals.
4. Gain Knowledge in manufacturing enzymes, vitamins, biopolymers and antibiotics using fermentation biotechnology.
5. Self-learn how to identify and manage manufacturing-related problems of biopharmaceuticals.

Intended Learning Outcomes

A. Foundational knowledge:

- A.1 Gain basic knowledge in the different methodologies of molecular biology and how to use in the manufacturing of biopharmaceuticals.
- A.2 Explain how different antibiotics and monoclonal antibodies can be synthesized, the obstacles in their production and the structural modifications made.
- A.3 Know the pharmacist role in the formulation, handling, and correct storage of the biopharmaceuticals and the guidelines developed by the FDA and EMA for the approval of biological drugs and biosimilars

B. Essential for Practice and Care (Intellectual Skills):

- B.1 Identify troubleshooting in molecular biology techniques during production of biopharmaceuticals.
- B.2 Summarize the basic sources of information in scientific literature related to production and problem solving in pharmaceutical biotechnology.

C. Approach to Practice and Care (competencies)

- C.1 Design a plan to produce a biopharmaceutical starting from the collection of DNA information to the therapeutic protein.
- C.2 Recognize manufacturing problems and being able to develop better methods to improve yield and decrease cost
- C.3 Communicate effectively with patients, caregivers, peers, and other healthcare providers about the proper use, side effects, storage, and administration of biopharmaceuticals.
- C.4 Demonstrate creative solutions of troubleshooting in molecular biology

ACADEMIC SUPPORT

It is The Hashemite University policy to provide educational opportunities that ensure fair, appropriate and reasonable accommodation to students who have disabilities that may affect their ability to participate in course activities or meet course requirements. Students with disabilities are encouraged to contact their instructor to ensure that their individual needs are met. The University through its Special Need section will exert all efforts to accommodate for individual's needs.

Special Needs Section:

Tel: 00962-5-3903333 Extension: 4209 Location: Students Affairs
Deanship/ Department of Student Welfare Services Email: amalomoush@hu.edu.jo
amalomoush@staff.hu.edu.jo

COURSE REGULATIONS

Participation

Class participation and attendance are important elements of every student's learning experience at The Hashemite University, and the student is expected to attend all classes. A student should not miss more than 15% of the classes during a semester. *Those exceeding this limit of 15% will receive a failing grade regardless of their performance.* It is a student's responsibility to monitor the frequency of their own absences. **Attendance record begins on the first day of class irrespective of the period allotted to drop/add and late registration. It is a student's responsibility to sign-in; failure to do so will result in non-attendance being recorded.**

In exceptional cases, the student, with the instructor's prior permission, could be exempted from attending a class provided that the number of such occasions does not exceed the limit allowed by the University. The instructor will determine the acceptability of an absence for being absent.

A

student who misses more than 25% of classes and has a valid excuse for being absent will be allowed to withdraw from the course.

On average, students must spend 10 hrs of study and preparation weekly. At the beginning of the lectures, be on time and don't leave before the end of the lecture without an accepted excuse. **If you missed a class, you must find out about any announcements or assignments you missed.** For any clarification, please communicate with your instructor at her posted office hour by appointment. Listen well to the lecture, if you have a question, ask your instructor. You will find the course material at the course team after the lecture.

Sharing of course materials is forbidden. No course material including, but not limited to, course outline, lecture hand-outs, videos, exams, and assignments may be shared online or with anyone outside the class. Any suspected unauthorized sharing of materials, will be reported to the university's Legal Affairs Office. If a student violates this restriction, it could lead to student misconduct procedures.

Plagiarism

Plagiarism is considered a serious academic offence and can result in your work losing marks or being failed. HU expects its students to adopt and abide by the highest standards of conduct in their interaction with their professors, peers, and the wider University community. As such, a student is expected not to engage in behaviours that compromise his/her own integrity as well as that of The Hashemite University.

Plagiarism includes the following examples, and it applies to all student assignments or submitted work:

- **Use of the work, ideas, images or words of someone else without his/her permission or reference to them.**
- **Use of someone else's wording, name, phrase, sentence, paragraph or essay without using quotation marks.**
- **Misrepresentation of the sources that were used.**

The instructor has the right to fail the coursework or deduct marks where plagiarism is detected

Late or Missed Assignments

In all cases of assessment, students who fail to attend an exam, class project or deliver a presentation on the scheduled date without prior permission, and/or are unable to provide a medical note, will automatically receive a fail grade for this part of the assessment.

- Submitting a term paper on time is a key part of the assessment process. Students who fail to submit their work by the deadline specified will automatically receive a 10% penalty. Assignments handed in more than 24 hours late will receive a further 10% penalty. Each subsequent 24 hours will result in a further 10% penalty.
- In cases where a student misses an assessment on account of a medical reason or with prior permission; in line with university regulations an incomplete grade for the specific assessment will be awarded and an alternative assessment or extension can be arranged.

Missed Assessments

In all cases of assessment, students who fail to attend an exam on the scheduled date without prior permission, and/or are unable to provide a medical note, will automatically receive a failure grade for this part of the assessment

- In cases where a student misses an assessment on account of a medical reason or with prior permission; in line with university regulations an incomplete grade for the specific assessment will be awarded and an alternative assessment or extension can be arranged.

Cheating

Cheating, academic misconduct, fabrication and plagiarism will not be tolerated, and the university policy will be applied. Cheating policy: The participation, the commitment of cheating will lead to

applying all following penalties together:

- Failing the subject, he/she cheated at
- Failing the other subjects taken on the same course
- Not allowed to register for the next semester
- The summer semester is not considered as a semester

Student Complaints Policy

Students at Hashemite University have the right to pursue complaints related to faculty, staff, and other students. The nature of the complaints may be either academic or non-academic. For more information about the policy and processes related to this policy, you may refer to the students' handbook.

COURSE ASSESSMENT

Students will be graded through the following means of assessment and their final grade will be calculated from the forms of evaluation as listed below with their grade weighting taken into account. The criteria for grading are listed at the end of the syllabus

Students will be graded through the following means of assessment:

Course Assessment Plan						
Assessment	Grade Weighting	Deadline Assessment	CILOs			
			A	B	C	D
First Exam	25%	3rd-14 th Nov.2024	A	B	C	
Second Exam	25%	15-26 th Dec.	A	B	C	
Final Exam	50%	12-23 th Jan.2025	A	B	C	

Description of Exams

Test questions will predominately come from material presented in the lectures and the lectures themselves. Semester exams may be conducted during the regularly scheduled lecture period. Exam may consist of a combination of multiple choice, short answer, match, true and false, and/or descriptive questions.

No make-up exams will be given. Only documented absences will be considered as per HU guidelines. Make-up exams may be different from regular exams in content and format.

Grades are not negotiable and are awarded according to the following criteria:

Letter Grade	Description	Grade Points
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A+	Excellent	4.00
A		3.75
A-		3.50
B+	Very Good	3.25
B		3.00
B-		2.75
C+	Good	2.50
C		2.25
C-		2.00
D+	Pass	1.75
D	Pass	1.50
F	Fail	0.00
I	Incomplete	-

WEEKLY LECTURE SCHEDULE AND CONTENT DISTRIBUTION

“Lecture hours and weeks are approximate and may change as needed”

Note: For Chem 101 sections with 2 lecture periods per week (S/T, M/W or T/R), one lecture period covers 1. lecture hours (60 minutes). The course content specifies the sections in chapters 1-10 of the textbook that will be included in quizzes, homework and exams.

“Lecture hours and weeks are approximate and may change as needed”

Note: For the 2 lecture periods per week (S/T, M/W), one lecture period covers 1 lecture hours (60minutes). The course content specifies chapters of the textbook that will be included in exams.

Week Number	No. of Hours	CILOs	Subject	Delivery Methods	Assessment Methods
1	2	A	Introduction to biotechnology	PowerPoint Lectures Active Classroom-Based Discussions	Exams
2	2	A, B, C	Molecular biology Restriction enzyme Polymerase chain reaction	PowerPoint Lectures Active Classroom-Based Discussions	Exams
3	2	A, B, C	Polymerase chain reaction Klenow enzyme reaction	PowerPoint Lectures Active Classroom-Based Discussions	Exams
4	2	A, B, C	Plasmids and vectors	PowerPoint Lecture Active Classroom-Based Discussions	Exams
5	2	A, B, C	Ligation and transformation into bacterial cells White-blue selection and DNA purification	PowerPoint Lecture	Exams
6	2	A, B, C	Sequencing of DNA	PowerPoint Lectures Relevant Videos	Exams

7	2	A, B, C	Western Blot	PowerPoint Lectures	Exams
8	2	A, B, C	Cell lines and protein expression Protein expression into bacterial cells, Plant and animal cell lines	Active Classroom-Based Discussions Relevant Videos	Exams
9	2	A, B, C	Protein drugs Insulin, growth hormone, erythropoietin, interferons, tPA and other protein drugs Enzyme technology	Active Classroom-Based Discussions Relevant Videos	Exams
10	2	A, B, C	Protein drugs Insulin, growth hormone, erythropoietin, interferons, tPA and other protein drugs Enzyme technology	Active Classroom-Based Discussions Relevant Videos	Exams
11	2	A, B, C	Monoclonal antibodies Antibodies and antibody fragments in treatment of cancer, autoimmune diseases and allergy	Active Classroom-Based Discussions Relevant Videos	Exams
12	2	A, B, C	Monoclonal antibodies Antibodies and antibody fragments in treatment of cancer, autoimmune diseases and allergy Fermentation Synthesis of primary and secondary metabolites (antibiotics)	Active Classroom-Based Discussions Relevant Videos	Exams
13	2	A, B, C	Fermentation Synthesis of primary and secondary metabolites (antibiotics)	Active Classroom-Based Discussions	Exams

			Gene therapy Introduction to gene therapy		
14	2	A, B, C	Stem cells Stem cells in disease treatment Formulation of biopharmaceuticals EMA and FDA regulations	Active Classroom-Based Discussions Relevant Videos	Exams
15-16			University Final Exam		