



Hashemite University
Faculty of Pharmaceutical Sciences
Department of Pharmaceutics and industrial pharmacy

Semester: First

Year: 2022/2023

Course Information	
Course Title	Pharmaceutical Biotechnology
Course Number	131701576
Credit Hours	2
Prerequisites	131702458

Instructor	
Name	Dr. Iman Mansi
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Office Phone	3444
Office Hours	To be announced
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Course Description
<p>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 guidelines of FDA and EMA for biologicals and biosimilars will be discussed.</p>

Course Objectives
<p>The students are expected to:</p> <ol style="list-style-type: none">1. Demonstrate a good awareness of uses of biotechnology2. Emphasize the main concepts regarding the methodologies of genetic engineering3. Recognize how different biological drugs are manufactured using biotechnology4. Know the microorganisms used in fermentation processes and the synthesis of different antibiotics

Intended Learning Outcomes
<p>A. Knowledge and Understanding:</p> <ol style="list-style-type: none">1. Classify drugs whether they are chemicals or biological drugs2. Know how to use the molecular biology methodologies used in the synthesis of biological drugs3. Explain how different antibiotics can be synthesized by fermentation and the best strain of microorganism that can be used <p>B. Intellectual skills (cognitive and analytical):</p> <ol style="list-style-type: none">1. To apply the biotechnological techniques on gene sequence of certain protein2. Student should be able to prepare the sequence of primers, addition of any sequence

required for cloning purposes.

3. Student should be able to deal with any troubleshooting in any of the techniques
4. Gain knowledge in fermentation and modifications made on penicillins
5. Understand the concept of gene therapy and stem cells

C. Transferable Skills

1. Develop of problem solving and critical thinking skills.
2. Use oral communication to effectively transmit ideas and conclusions to a scientific audience.
3. Be able to read, analyse and discuss any information in biotechnology books

Reading List

1 (textbook)	Pharmaceutical biotechnology, fundamentals and applications, 2008, edited by Daan J.A. Crommelin, Robert D. Sindelar, Bernd Meibohm, 3rd ed, Informa Healthcare USA, Inc, ISBN-13: 978-1-4200-4437-9
2	Pharmaceutical biotechnology,
3	Pharmaceutical biotechnology, CR Kokare, 2010, Nirali Prakashan
	Website, moodle Journals: Journal of pharmaceutical biotechnology Journal of Biological chemistry

Course Contents

Topics	Topic Details	Reference No.	Chapter	Estimated no. of hours	Assessment
Introduction	Introduction to pharmaceutical biotechnology			2	
Molecular biology	Restriction enzyme Polymerase chain reaction Klenow enzyme reaction Plasmids and vectors Transformation into bacterial cells White-blue selection and DNA purification Sequencing of DNA			6	
Cell lines and protein expression	Protein expression into bacterial cells Plant and animal cell lines			2	
Protein drugs	Insulin, growth hormone, erythropoietin and other protein drugs Enzyme technology			4	
Monoclonal antibodies	Antibodies in treatment of cancer, RA and allergy			4	
Fermentation	Synthesis of antibiotics			3	
Gene therapy	Principles of gene therapy			2	
Stem cells	Stem cells in disease treatment			2	

FDA and EMEA guidelines	Guidelines for manufacturing of biological drugs			1	
	Revision				
	Final Exam				

Grade Distribution		
Assessment	Grade	Date
- First Exam	25	The 5 th week
- Second Exam	25	The 11 th week
- Final Exam	50	The 16 th week

Important regulations
<ul style="list-style-type: none"> ◆ On average, students need to spend 4 hrs of study and preparation weekly. ◆ Excellent attendance is expected. According to the university policy, students who miss more than 15% of the lecture hours with or without excuse will be dismissed from the course ◆ 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, it is your responsibility to find out about any announcements or assignments you have missed ◆ For any clarification, please communicate your instructor at his posted office hours or by appointment ◆ Switch off your mobile or keep it silent throughout the lecture ◆ Listen well to the lecture and avoid side discussions, if you have a question, ask your instructor and not your colleague ◆ If you have any information, document your reference, if you didn't, then you broke the intellectual property rights law and the law will be applied <ul style="list-style-type: none"> ○ For more informations, visit the website: <ul style="list-style-type: none"> ○ http://www.plagiarism.org/ ◆ Exams are scheduled to be given three times throughout the semester, your are expected to attend all. If not, make-up exams will be offered for valid reasons. It may be different from regular exams in content and format. ◆ Cheating, academic diconduct, fabrication and plagiarism will not be tolerated, and the university policy will be applied

Last updated on 9/10/2022 by : Dr. Iman Mansi