The Hashemite University

الجامعـــــــــة الهاشميـــــــــة

Faculty of Pharmaceutical Sciences

Syllabus: Biologic and Biosimilar Drugs (161701591)
Second Semester of the academic year

COURSE INFORMATION	
Course Name: Biologic and Biosimilar Drugs (blended learning) **Semester:** Second **Department:** Department of Pharmaceutics and Pharmaceutical Technologies. **Faculty:** Pharmaceutical Sciences	**Course Code:** 161701591 **Section:** As per the semester **Core Curriculum**: Ellective – 2019 Study plan **JNQF Level:** 7
Day(s) and Time(s): : According to HU courses timetable/semester **Classroom:** As per the semester	**Credit Hours:** 3 **Prerequisites**: Industrial Pharmacy 2 and Biotechnology 131701471 and 131701576

COURSE DESCRIPTION

This course is concerned with biological drugs, their definition, techniques used in their production and purification, and their therapeutic applications. In addition, it discusses the definition of biosimilar and the guidelines developed by different agencies such as the European Medicines Agency (EMA), the World Health Organization (WHO), and the Food and Drug Administration (FDA), as well as the approval requirements and type of testing required for biosimilarity.

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.
- E-learning resources: e-reading assignments and practice quizzes through Model and Microsoft Team

FACULTY INFORMATION

Name	**Dr. Muna Oqal**
Academic Title:	**Assistant Professor**
Office Location:	**Faculty of Pharmaceutical Sciences, 3rd floor, office number: 3438**

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Office Hours:	**As announced per the semester** *Please send an e-mail (munak@hu.edu.jo) to meet at any other time.*

REFERENCES AND LEARNING RESOURCES

Required Textbook

1. The Challenge of CMC Regulatory Compliance for Biopharmaceuticals., John Geigert. BioPharmaceutical Quality Solutions 2019. 3rd edition. https://doi.org/10.1007/978-3-030-13754-0. Spinger, Gewerbestrasse 11, 6330 Cham, Switzerland.ISBN 978-3-030-13753-3.
2. Biosimilar Regulatory, Clinical and Biopharmaceutical Development., Gutka, Harry Yang , and Shefali Kakar. American Association of Pharmaceutical Scientists 2018. Biosimilars, AAPS Advances in the Pharmaceutical. Sciences Series 34, https://doi.org/10.1007/978-3-319-99680-6. Spinger, Gewerbestrasse 11, 6330 Cham, Switzerland. ISBN 978-3-319-99679-0.
3. Introduction to Biologic and Biosimilar Product Development and Analysis., Karen M. Nagel., American Association of Pharmaceutical Scientists 2018. https://doi.org/10.1007/978-3-319-98428-5. Spinger, Gewerbestrasse 11, 6330 Cham, Switzerland 2018. ISBN 978-3-319-98427-8.
4. Cancer Policy: Pharmaceutical Safety, June M. McKoy and Dennis P. Cancer Treatment and Research. 2019. https://doi.org/10.1007/978-3-319-43896-2. Spinger, Gewerbestrasse 11, 6330 Cham, Switzerland, ISBN 978-3-319-43894-8.

Suggested Additional Resources:

1. **Website, moodle Journal of Generics and Biosimilars Initiative. BMJ Journal**

COURSE OBJECTIVES

The students are expected to:

1. Emphasize on the main concepts for the biological and biosimilar drugs.
2. Demonstrate a good knowledge of methodologies used for the production and purification of the biological drugs.
3. Be able to explain the rationale behind the synthesis of biosimilar drugs and to recognize the differences between the biological and biosimilar drugs.
4. Demonstrate a good awareness for regulatory guidelines which developed by different agencies.
5. Be able to describe the approval requirements for testing required for biosimilarity.
6. Be able to describe the therapeutic application of biosimilar and biological drugs and their recent development within the pharmaceutical industry.

COURSE INTENDED LEARNING OUTCOMES (CILOs)

Successful completion of this course should lead to the following learning outcomes:

A. Foundational Knowledge

A.1 Gain the basic understanding of biological drugs and their difference from biopharmaceutical products.
A.2 Distinguish the difference between biological and biosimilar drugs concept.
A.3 Understand the unique biosimilar guidelines and protocols developed by FDA, EMA and WHO.

B. Essentials for Practice and Care

B.1 Gain knowledge in planned manufacturing of biological and biosimilar drugs.
B.2 Describe the therapeutic role of the biological and biosimilar drugs in clinical therapeutic plan development for the patients

C. Approach to Practice and Care

C.1 Acquire ability to read, analyse and discuss any information in the book cover biologic and biosimilar drugs.

D. Personal and Professional Development

D.1 Develop problem solving and critical thinking skills.
D.2 Use oral communication to effectively transmit ideas and conclusions to a scientific audience.

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 a 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 need to spend 12 hrs of study and preparation weekly. At the beginning of the lectures, students should be on time and should not leave before the end of the lecture without an accepted excuse. **If the student missed a class, it is him/her responsibility to find out about any announcements or assignments they have missed.** For any clarification, students should communicate with their instructor at her posted office hours or by appointment. Students should listen well to the lecture, if anyone has a question, he/she should ask the instructor. Students can find the course material at the course Microsoft 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

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 disconduct, 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 in 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 The 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

Course Calendar and Assessment

Students will be graded through the following means of assessment and their final grade will be calculated from the forms of assessment 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%	~ 6th week	A	B	C	D
Second Exam	25%	~ 10th week	A	B	C	D

Quizzes/ Homework/ Assignments /Projects	10%	During the semester			C	D
Final Exam	40%	~ 15th /16th week	A	B	C	D

Description of Exams
Test questions will predominately come from the material presented in the lectures. Semester exams will be conducted during the regularly scheduled lecture period. The exam will consist of a combination of multiple-choice, short answer, match, true and false, calculation problems, and/or descriptive questions.

Homework: Will be given for the selected chapters, while the chapter in progress you are supposed to work on continuously and submit at the announced date.
You are also expected to work on in-chapter examples, self-tests and a representative number of ends of chapter problems. The answers of self-tests and end of chapter exercises are given at the end of the book.

Quizzes: Announced quizzes will be given during or/and at the end of each chapter based upon the previous lectures.

No make-up exams, homework or quizzes will be given. Only documented absences will be considered as per HU guidelines.

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

Letter Grade	Description	Grade Points
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

Note: For Physical Pharmacy 2 sections with 2 lecture periods per week (S/T or M/W), one lecture period covers 1.5 lecture hours (80 minutes). The course content specifies the sections in chapters of the reference textbooks that will be included in quizzes, homework and exams.

75% of the lectures are delivered by face-to-face learning, while 25% are recorded and given via Microsoft teams.

		Course Content				
Week Numbe	**No. of Hours**	**CILOs**	**Chapters in the main reference**	**Subject**	**Delivery Methods**	**Assessment Methods**
1-4	**24**	A1,2	**Ref 3**	**1. Biological drugs:** - Introduction to biological drugs - Principles of Recombinant DNA Technology - Production Methods: - Cloning and Recombinant DNA Technology. - Molecular Cloning and Subsequent Protein Production by Fermentation Tank or Biopharming. - Polymerase Chain Reaction (PCR) - Chemical Modification of Products - Purification Technology - Characterization Methods - Therapeutic application	PowerPoint Lectures Active Classroom-Based Discussions	Exams

5-6	**6**	A1,2	**Ref 1 & 3**	**Therapeutic Proteins** - Delivery Challenges - Potential Methods of Delivery	PowerPoint Lectures Active Classroom-Based Discussions	Exams
7-9	**12**	A, B, C, D	**Ref 1 & 3**	**Analysis and Regulation of Biologics, Including Biosimilars** - Innovator Biologic Approval - Biosimilar Pathway - Totality of the Evidence - Interchangeability - Product Switching - Product Naming - Marketplace Uptak - Pricing and Market Opportunities - Potential Gains from Biosimilars - Biosimilar Risks and Return on Investment - The future of biosimilars	PowerPoint Lectures Active Classroom-Based Discussions	Exams
10-11	**12**	A, B, C, D	**Ref 1& 4**	**Biopharmaceutical Development and Manufacturing of Biosimilars (Chemistry and Manufacturing Controls (CMC), Quality by Design (QbD), Quality Target Product Profile (QTPP)):** - Understanding the Reference Drug	PowerPoint Lectures Active Classroom-Based Discussions	Exams Quizzes Homework

				- Expression Systems and Clonal Selection - Effect of Raw Materials on Product Quality - Effect of Manufacturing Conditions on Product Quality and Control Strategy for Biosimilars - Implementing a Successful CMC and Analytical Strategy for the Development of Biosimilars		
12-13	**12**	A, B, C, D	**Ref 1& 4**	**Biological Activity Assays for Antibody Therapeutics** - Definition of Bioassay and Potency Assays. - Types of Biological Activity Assays for Antibody Therapeutics. - Biological Assay Selection Based on Their Therapeutic Mechanism of Actions (MoA). - Biological Assays in Biosimilar Product Life-Cycle Management - Special Considerations of Biological Assays Comparing Innovative Biologics and Biosimilar	PowerPoint Lectures Active Classroom-Based Discussions	Exams

14	**3**	A, B, C, D	**Ref 2**	**Innovation, Patents and Biologics: The Road to Biosimilar Competition: Factors Influencing Investment, Business Decisions and Marketing of Biosimilars** - Introduction - Biologics R&D Costs - Biosimilar Barriers to Entry - Economic Justification for Patents and Exclusivity - Data and Market Exclusivity - Patents as Barriers to Entry - Litigation Concerning the Patent Dance	PowerPoint Lectures Active Classroom-Based Discussions	Exams
15	**3**	A, B, C, D	**Ref1**	**Regulation of Biologi Including Biosimilars JFDA** - **Biologics:** registrat of biological produ in Jordan **Biosimilars:** Biosimil under the JFDA registrat guidelines; Scope a application; Quality standa	Active Classroom-Based Discussions	Exams
16	**-**			**University Final Exams**		