MEDBIOT-E06:	**BIOLOGIC DRUGS**
GENERAL INFORMATION	
Course Coordinator(s)	Jasminka Milas-Ahić, MD, PhD, full prof.
Associate(s)	Suzana Mimica, MD, PhD, assist. prof. Vlatka Periša, MD, PhD Željka Kardum, MD
Study Programme	Interdisciplinary Graduate Study Programme in English: Biotechnology
Course Status	Elective
Year of Study, Semester	2nd Year /4th Semester
Credits (ECTS)	**4**
Teaching Method (number of classes)	Lectures:15; Seminars: 15; Exercises: 15
Expected Number of Students in the Course	25-30
COURSE DESCRIPTION	
Course Aims	
1. Introducing the student to the characteristics and mechanisms of action of biologic drugs (biologics) and the treatment options with different biologics in various diseases. 2. Encouraging the student to integrate and critically interpret the properties of biologic drugs, to adopt theoretical frameworks, in addition to obtain practical knowledge and skills regarding drug administration, monitoring the effect and possible side effects of biologic drugs in patients.	
Prerequisites for Enrolment and the Entry Competencies Required for the Course	
Completed and passed courses from 1st year of the study.	
Learning Outcomes at the Programme Level Contributed by the Course	
BIOTECH-2; MEDBIOT-2; MEDBIOT-4; BIOTECH-6; BIOTECH-10	
Learning Outcomes at the Course Level	
After completing the course, the student will be able to: 1. Link the general principles of action of biologics (pharmacodynamics) and the fate of the drug in the body (pharmacokinetics) 2. Critically evaluate the process of biologic medicines development and research of biologic and biosimilar drugs 3. Justify the mechanism of action of biologic drugs 4. Obtain the knowledge of biologic and biosimilar medicines development and approval process in the European Union 5. Apply acquired knowledge when planning experiments, conducting experiments, collecting and interpreting research results by learned methods. 6. Analyze biological samples qualitatively and quantitatively using appropriate research methods.	
Course Content	
Lectures. Introduction: development and types of biologic drugs in innovative medicine. The importance of clinical trials in the biologic medicine development. Characteristics and production of biologic drugs. Mechanisms of action of biologic drugs. The effectiveness of biologics. Safety of biologic drugs administration. Immunogenicity of biologic therapy. Characteristics and production of biosimilar drugs. Biologic therapy in clinical use. Biologic drugs in cancer patients. Biologics in rheumatology. Biologics in haematology. Biologics in gastroenterology. Biologics in dermatology. Biologics in neurology. **Seminars.** Types and methods of biologic drugs production. Methods of recombinant technology. Types of monoclonal antibodies. Mechanisms of action of biologic drugs. Side effects of biologic drugs. Biologic drugs in pregnancy. Administration of biologics and risk of infection. Biologic drugs and malignancies. Development and approval of biologic and biosimilar medicines in the European	

Union. Biologic drugs in the treatment of allergic diseases. Application of biologic drugs in endocrinology. Osteoporosis and growth disorders.
Exercises: Types of administration of biologic drugs. Analysis and interpretation of laboratory findings in addition to other diagnostic procedures to get patients prepared for biologic treatment.

Teaching Methods

Lectures; seminars; laboratory exercises

Students' Obligations

Attendance at all forms of classes is mandatory and the students are obligated to attend all knowledge tests. The students may be absent from 30% (full-time students) and 50% (part-time students) of each of the forms of classes, provided that the absence is justified. An exercise or a seminar which has not been completed must be made up through a midterm exam.

Monitoring the Activity of the Students *(Connecting Learning Outcomes, Teaching Methods, and Grading)*

Class-related activity	ECTS	Learning outcome	Student activity	Evaluation method	Grade points	
					Min.	Max.
Attending classes - Lectures	0.1	1-6	Attendance at classes	Keeping records	2	5
Seminars	0.4	1-4	Seminar preparation and presentation	Presentation	8	20
Exercises	1	5,6	Laboratory exercises	Report	10	25
Final exam	2.5	1-6	Studying for the final exam	Written exam	30	50
Total	4				50	100

Evaluation of the written part of the final exam:

Percentage of correct answers (%)	Grade
>95.00	50
90.00-94.99	47
85.00-89.99	45
80.00-84.99	40
75.00-79.99	38
70.00-74.99	35
65.00-69.99	33
60.00-64.99	30

Forming the final grade:
The points granted for the final exam are added to the grade points awarded during class attendance. The grading process is conducted by absolute distribution, i.e. based on total achievements, and compared to the numerical system in the following manner:
A – Excellent (5): 90-100 grade points; B – Very Good (4): 80-89.99 grade points; C – Good (3): 65-79.99 grade points; D – sufficient (2): 50-64.99 grade points

Mandatory Literature (available in the library and via other media)

Title	Number of copies in the	Availability via other media

	library	
Nagel, KM: Introduction to Biologic and Biosimilar Product Development and Analysis. Springer, 2018**.**		yes
Additional Literature		
European Medicines Agency: Biosimilars in the EU. Information guide for healthcare professionals, 2017. (available on-line)		
Quality Assurance Procedures Designed to Ensure the Acquisition of Outcomes and Competencies		
Anonymous, quantitative, standardized student survey on the course and the teacher's work implemented by the Quality improvement office of the Faculty of Medicine Osijek and/or the Faculty of Food Technology Osijek.		
Note		
E-learning is not included in the class quota, but it is used in teaching and it contains links to various sites and video and audio materials available on websites.		