BIOPHARMACEUTICALS

1. COURSE DESCRIPTION – GENERAL INFORMATION	
1.1. Course teacher	Associate Professor Jasmina Lovrić; Associate Professor Gordana Maravić Vlahoviček
1.2. Associate teachers	Associate Professor Lidija Bach-Rojecki; Associate Professor Sanja Dabelić; Professor Jerka Dumić; Associate Professor Ana Mornar Turk; Assistant Professor Ivana Perković
1.3. Graduate programme	Pharmacy study program
1.4. Status of the course	Elective
1.5. Year of study, Semester	4th Year, 8th Semester
1.6. Credit value (ECTS)	2,5
1.7. Type of instruction (number of hours L+E+S+e-learning)	9+0+21
1.8. Expected enrolment in the course	20
1.9. Level of use of *e*-learning (1, 2, 3 level), percentage of instruction in the course on line (20% maximum)	Level 2. Additional possibility of elearning according a personal choice (teaching materials, literature)

2. COURSE DESCRIPTION

2.1. Course objectives

To acquire knowledge on biological therapeutics - biopharmaceuticals, from discovery and development of protein- and gene-based drugs, application of biotechnology to produce these therapeutics, their pharmacology and pharmacokinetics, dosage form and route of administration to clinical evaluation and regulatory approval. To be able to appreciate the complexities of macromolecular drugs and their biological effects, one must understand the fundamental differences in drug design, dosage formulation, and time course of distribution to target tissues between biopharmaceuticals and small organic molecule drugs.

2.2. Enrolment requirements and required entry competences for the course

Passed exam in Molecular Biology with Genetic Engineering; Pharmacology, Pharmaceutical Analysis, and Drug Formulation courses completed

2.3. Learning outcomes at the level of the study programme to which the course contributes

• Applying basic knowledge of chemistry, biochemistry, and molecular biology necessary to define, analyse and propose actions related to research, development and production as well as analysis and quality control of drugs.
• Choosing the wright pharmacotherapy and providing pharmaceutical care, respecting in the same time the legislative, actual health policies and guidelines as well as the principles of pharmaceutical ethics and deontology.

2.4. Expected learning outcomes at the level of the course (4-10 learning outcomes)

After passing the exam student will be able to:
1. Describe the scientific approaches and research strategies for discovery and development of biopharmaceuticals
2. Describe the applications of recombinant DNA and hybridoma technology in discovery and development of biological drugs /biopharmaceuticals
3. Understand the challenges in administering biopharmaceuticals
4. Explain formulation and delivery strategies of biopharmaceuticals
5. Propose appropriate analytical techniques and methods to assess the structure, biological activity, purity, safety, consistency and stability of protein drugs. Describe the pharmacopoeial guidance and monograph tests to quality control of biopharmaceutical products
6. Indicate the specific procedure of approval of biopharmaceuticals (and similar biological medicinal products - biosimilars)
7. Explain the general principles of demonstrating biosimilarity to the reference biological medicinal product
8. State and explain the advantages and disadvantages of clinical application of biopharmaceutical
9. Develop skills for critical evaluation of biological drugs data, using relevant scientific literature and preparing written or oral reports.
10.Evaluate the current status and future developments in the biopharmaceutical industry.

2.5. Course content broken down in detail by weekly class schedule (syllabus)
LECTURES: • Introduction to biopharmaceuticals • The application of omics in research and development of biopharmaceuticals • Application of genetic engineering and biotechnology in discovery and early development of biopharmaceuticals • Pharmacokinetics, therapeutic dosage and response • Formulation and delivery of biopharmaceuticals SEMINARS: • Large-scale production of recombinant proteins and microbiological quality control of biopharmaceuticals • Analytical and biochemical methodology in research, development, and quality control of biopharmaceuticals • Clinical evaluation and regulatory approval of biopharmaceuticals • Clinical pharmacy and toxicology of biopharmaceuticals • Antibodies and derivatives • Hematopoietic growth and coagulation factors • Cytokines and Interferons / Hormones / Enzymes • Vaccines • Gene and cell therapy • Stem cells in regenerative medicine
2.6. Type of instruction
Lectures, independent study, multimedia and the internet, work with the mentor
2.7. Student responsibilities
Students are obliged to attend the lectures and seminars. To be eligible to acquire the ECTS and to obtain the mark, students have to prepare the project.
2.8. Screening of student's work (specify the proportion of ECTS credits for each activity so that the total number of CTS credits is equal to the credit value of the course)
Class attendance (0,5); Project (2,0)
2.9. Grading and evaluation of student work over the course of instruction and at a final exam
Students will be evaluated according to their active participation in the seminars and the quality of the project. On the final project presentation students are obliged to demonstrate the knowledge on all topics covered by the course on the level of skilful management of relevant information and synthesis of the thought matter.
2.10. Required literature (available at the library and via other media)

Title	Number of copies at the library	Availability via other media
Ho, R. J. Y. - Biotechnology and Biopharmaceuticals, 2nd ed. Wiley Blackwell, 2013	1	
Feroz Jameel, Susan Hershenson - Formulation and Process Development Strategies for Manufacturing Biopharmaceuticals, 1st Edition, Wiley, 2010	1	
Ajay K. Banga-Therapeutic Peptides and Proteins_ Formulation, Processing, and Delivery Systems, 3rd Edition-CRC Press, 2015	1	
Ahuja S., Scypinski S. Handbook of modern pharmaceutical analysis, 2nd ed. Elsevier, Amsterdam, 201	1	
Selection of original scientific literature		

2.11. Optional literature
Crommelin, Sindelar, Meibohm "Pharmaceutical Biotechnology: Fundamentals and Applications", 4th ed, 2013.
2.12. Methods of monitoring quality that ensure acquisition of exit competences
Learning outcomes will be monitored during seminars and assessed through the project presentation.
2.13. Comments
e-learning – it is not a part of teaching hours, but it is used in studying since it contains case studies, problems with explanations, links on different useful web pages