

UČNI NAČRT PREDMETA / COURSE SYLLABUS

Predmet:	Biološka zdravila
Course title:	Biopharmaceuticals

Študijski program in stopnja Study programme and level	Študijska smer Study field	Letnik Academic year	Semester Semester
UŠP Kemijske znanosti, 3. stopnja	Biokemija	1.	1. in 2.
USP Chemical sciences, 3 rd Cycle	Biochemistry	1 st	1 st and 2 nd

Vrsta predmeta / Course type izbirni predmet/ selective course

Univerzitetna koda predmeta / University course code: KZ325

Predavanja Lectures	Seminar Seminar	Vaje Tutorial	Klinične vaje work	Druge oblike študija	Samost. delo Individ. work	ECTS
10	35			60	45	5

Nosilec predmeta / Lecturer: doc. dr. Gregor Gunčar/ dr. Gregor Gunčar, Assistant Professor

Jeziki / Languages: Predavanja / Lectures: slovenski / Slovenian
Vaje / Tutorial: slovenski / Slovenian

Pogoji za vključitev v delo oz. za opravljanje študijskih obveznosti:

Študent oz. kandidat mora imeti predmet opredeljen kot študijsko obveznost.

Prerequisites:

The course has to be assigned to the student.

Vsebina:

Predavanja

- Uvod v biološka zdravila
- Razvoj bioloških zdravil
- Identifikacija tarčnih proteinov in genov in bioinformatične metode za njihovo analizo. Vloga genomike, proteomike in metabolomike.
- Biotehnoške metode za proizvodnjo rekombinantnih proteinov v velikih količinah
- Terapevtske in klinične aplikacije bioloških zdravil
- Protitelesa, rastni faktorji, koagulacijski faktorji, citokini, interferoni, hormoni,

Content (Syllabus outline):

Lectures

- Introduction to biopharmaceuticals
- Development of biopharmaceuticals
- Therapeutic target protein and gene identification and bioinformatic methods for their analysis. Role of genomics, proteomics and metabolomics.
- Biotechnology methods for large scale recombinant protein production
- Therapeutic and clinical applications of biopharmaceuticals
- Antibodies, growth and coagulation factors, cytokines, interferons, hormones,

<p>encimi, DNK, RNK, vakcine in druga biološka zdravila.</p> <ul style="list-style-type: none"> • 3D strukture bioloških zdravil • Biološko podobna zdravila • Napredni načini dostave zdravil • Genska in celična terapija • Klinična evalvacija in regulacija • Prihodnost bioloških zdravil <p>Projektni seminar Moje doktorsko raziskovalno delo v kontekstu bioloških zdravil.</p>	<p>enzymes, DNA, RNA, vaccines and other biopharmaceuticals</p> <ul style="list-style-type: none"> • 3D structures of biopharmaceuticals • Biosimilars • Advance drug delivery • Gene and cell therapy • Clinical evaluation and regulation • Future of biopharmaceuticals <p>Project seminar My Ph. D. research in context of biopharmaceuticals.</p>
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Temeljni literatura in viri / Readings:

1. Ho, Rodney J.Y., and Milo Gibaldi. Biotechnology and Biopharmaceuticals: Transforming Proteins and Genes Into Drugs. 2nd ed. Edited by Rodney J. Y. Ho. Hoboken, NJ: Wiley-Blackwell, 2013.
2. Knäblein, Jörg, ed. Modern Biopharmaceuticals: Design, Development and Optimization. Chichester: Wiley-Blackwell, 2005.
3. Najnovejši pregledni in raziskovalni članki s področja /The latest review and research papers from the field.

Cilji in kompetence:

- Študenti dobijo pregled področja bioloških zdravil, njihove identifikacije, razvoja, proizvodnje, delovanja, optimizacije in uporabe.

Objectives and competences:

- Overview of the field of biopharmaceuticals, their identification, development, production, optimization, mode of action and their use.

Predvideni študijski rezultati:

Znanje in razumevanje:

Poznavanje bioloških zdravil. Razumevanje identifikacije tarčnih proteinov in načrtovanje bioloških zdravil. Razumevanje njihovega delovanja na osnovi primerov. Poznavanje biotehnoških metod za proizvodnjo in izboljšave bioloških zdravil. Osnove biološko podobnih zdravil, njihove analize, razvoja in regulative.

Uporaba:

Študenti bodo vedeli, kaj in kako lahko zdravimo z znanimi biološkimi zdravili. Sposobni bodo predlagati nova biološka zdravila in kako jih proizvajati.

Intended learning outcomes:

Knowledge and understanding:

Knowing what biopharmaceuticals are, how to identify new ones, design and their development. Understand their mode of action based on the studied examples.. Knowing and understanding of biotechnological methods for their production and optimization. Fundamentals of biosimilars, their analysis, development, regulation and approval.

Application

Students will know how current biopharmaceuticals are being used and will have an idea of how to find and produce new ones.

<u>Refleksija</u> Kritično vrednotenje idej študentov, izvedljivost in ekonomičnost njihove izvedbe.	<u>Analysis</u> Critical assessment of students' ideas, feasibility and economical aspects of their implementation.
<u>Prenosljive spretnosti</u> Inovativno reševanje problemov, uporaba znanstvene literature, patentov in protokolov, zasnova in razvoj nove ideje, načrt kako to idejo uresničiti v praksi in pisanje projektov.	<u>Skill-transference Ability</u> Innovative problem solving, use of scientific literature, patents and protocols, design and development of a new idea, realization planning and project writing.

Metode poučevanja in učenja:

Predavanja in projektni seminar.

Learning and teaching methods:

Lectures and project seminar.

Načini ocenjevanja:	Delež (v %) / Weight (in %)	Assessment:
Ustni izpit	70 %	Oral exam
Seminar	30 %	Seminar

Reference nosilca / Lecturer's references:

- GUNČAR, Gregor, PUNGERČIČ, Galina, KLEMENČIČ, Ivica, TURK, Vito, TURK, Dušan. Crystal structure of MHC class II-associated p41 li fragment bound to cathepsin L reveals the structural basis for differentiation between cathapsins L and S. **EMBO**, 1999, vol. 18, str. 793-803.
- WANG, Ching-I. A.*, GUNČAR, Gregor*, FORWOOD, Jade K., TEH, Trazel, CATANZARITI, Ann-Maree, LAWRENCE, Gregory J., LOUGHLIN, Fionna E., MACKAY, Joel P., SCHIRRA, Horst Joachim, ANDERSON, Peter A., ELLIS, Jeffrey G., DODDS, Peter N., KOBE, Boštjan. Crystal structures of flax rust avirulence proteins AvrL567-A and -D reveal details of the structural basis for flax disease resistance specificity. **Plant cell**, 2007, vol. 19, no. 9, str. 2898-2912.
*enakovredna prva avtorja
- FORWOOD, Jade K., THAKUR, Anil S., GUNČAR, Gregor, MARFORI, Mary, MOURADOV, Dmitri, MENG, Weining, ROBINSON, Jodie, HUBER, Thomas, KELLIE, Stuart, MARTIN, Jennifer L., HUME, David A., KOBE, Boštjan. Structural basis for recruitment of tandem hotdog domains in acyl-CoA thioesterase 7 and its role in inflammation. **PNAS**, 2007, vol. 104, no. 25, str. 10382-10387.
- KOBE, Boštjan, GUNČAR, Gregor. Crystallography and protein-protein interactions : biological interfaces and crystal contacts. **Biochem Soc Trans**, 2008, vol. 36, no. 6, str. 1438-1441.
- PAVŠIČ, Miha, GUNČAR, Gregor, DJINOVIĆ CARUGO, Kristina, LENARČIČ, Brigita. Crystal structure and its bearing towards an understanding of key biological functions of EpCAM. **Nature communications**, 2014, vol. 5, no. 8, str. 1-10.