BIOTECH-E02: **BIOETHICS, BIOSAFETY AND INTELLECTUAL PROPERTY RIGHTS IN BIOTECHNOLOGY**	
GENERAL INFORMATION	
Course Coordinator(s)	Natalija Velić, PhD, assoc. prof.
Associate(s)	Jure Mirat, MD, PhD, full prof. with tenure Domagoj Drenjančević, MD, PhD, Assoc. prof.
Study Programme	Interdisciplinary Graduate Study Programme in English: Biotechnology
Course Status	Elective
Year of Study, Semester	1st Year / 2nd Semester
Credits (ECTS)	**3**
Teaching Method (number of classes)	Lectures 20; Seminars 10; Exercises 0
Expected Number of Students in the Course	10-15
COURSE DESCRIPTION	
Course Aims	
Getting acquainted with basic concepts in the fields of bioethics, biosafety and intellectual property rights and gaining insight into their importance in the light of the rapid development of new molecular techniques.	
Prerequisites for Enrolment and the Entry Competencies Required for the Course	
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Learning Outcomes at the Programme Level Contributed by the Course	
BIOTECH-3; BIOTECH-4; BIOTECH-7; INDBIOT-1	
Learning Outcomes at the Course Level	
After successful completion of this course students are expected to be able to: 1. Critically evaluate the ethical, sociological and legal issues arising from the development of biotechnology. 2. Discuss different aspects of ethical conflicts in biotechnology (medical, research, etc.). 3. Distinguish between biosafety issues at different levels: individual, institutional, social. 4. Identify biosafety threats inside and outside the laboratory and implement security protocols to address them. 5. Review the criteria for patentability in biotechnology. 6. Outline the patent application process at national, European or international level.	
Course Content	
Lectures. *Bioethics*: basic bioethical concepts, bioethics development. Ethical, Legal and Social Issues Related to Biotechnology (ELSI). Ethical conflicts in biotechnology: medical bioethics (reproduction, euthanasia, prenatal diagnosis, transplantation, gene therapy, genetic screening, new eugenics); research bioethics (cloning, stem cells, human and animal research, bio-piracy); environmental impact; bioethics *vs.* business ethics. *Biosafety:* basic concepts. Biotechnology and the biosafety issues at different levels: individual, institutional, social, etc. Biosafety Protocol (Cartagena Protocol). Threats and challenges to biosafety inside and outside the laboratory. GRAS organisms, biosafety level of specific microorganisms, GMOs, LMOs, transgenic plants safety assessment, environmental risk assessment, food and feed safety risk assessment. Bioterrorism, biological weapons. Safety guidelines - good laboratory practice. *Intellectual property rights:* basic concept, role, significance and forms of intellectual property. Patent protection procedure, criteria for patentability in biotechnology. Routes to patents: national, European (European Patent Office - EPO), international (Patent Cooperation Treaty PCT - WIPO). **Seminars.** Bioethics, biosafety, intellectual property rights in biotechnology- case study.	
Teaching Methods	

Lectures; seminars

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.

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.
Classes, seminars,	0.3	1-6	Attendance at classes and seminars	Attendance records	5	10
Seminar work	1.2	1-6	Writing a seminar paper	Oral presentation of a seminar paper	15	40
Final exam	1.5	1-6	Studying for the final exam	Written exam	30	50
Total	**3**				**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 library	Availability via other media
Nambisan P: An Introduction to Ethical, Safety and Intellectual Property Rights Issues in Biotechnology, Academic Press, Elsevier, 2017.	-	-
Scientific papers (available online)		yes

Additional Literature

1. Talbot M: Bioethics: An Introduction, Cambridge University Press, Cambridge, 2012.

2. Sandel MJ: The Case against Perfection – Ethics in the Age of Genetic Engineering, The Belknap Press of Harvard University Press, Cambridge, Massachusetts, 2007.
3. Thomas JA, Fuchs RL: Biotechnology and Safety Assessment, 3rd Ed., Academic Press, Elsevier, 2003.
4. Singh KK: Biotechnology And Intellectual Property Rights: Legal and Social Implications, Springer, New Delhi, 2015.

Quality Assurance Procedures Designed to Ensure the Acquisition of Outcomes and Competencies

Anonymous, quantitative, standardised student survey on the course and the teacher's work implemented by the Quality improvement office of the Faculty of Food Technology Osijek and/or the Faculty of Medicine 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.