

INDBIOT-E08: GOOD HYGIENE PRACTICE IN BIOPROCESS INDUSTRY	
GENERAL INFORMATION	
Course Coordinator(s)	Đurđica Ačkar, PhD, assoc. prof.
Associate(s)	Jurislav Babić, PhD, full prof. Drago Šubarić, PhD, full prof. Antun Jozinović, PhD, assist. prof.
Study Programme	Interdisciplinary Graduate Study Programme in English: Biotechnology
Course Status	Elective
Year of Study, Semester	2 nd Year /4 th Semester
Credits (ECTS)	4
Teaching Method (number of classes)	Lectures 30; Seminars 10; Exercises 15
Expected Number of Students in the Course	25-30
COURSE DESCRIPTION	
Course Aims	
This course aims to provide knowledge on basic principles of hygiene and sanitation with regard to specificities of bioprocess industry – production of food and pharmaceutical products.	
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-2; BIOTECH-5; BIOTECH-8	
Learning Outcomes at the Course Level	
After successful completion of this course students are expected to be able to:	
<ol style="list-style-type: none"> 1. Differentiate basic hygienic requirements for bioprocess facilities. 2. Describe “clean rooms” and give examples of their application in bioprocess industry 3. Categorize types of types of cleaning compounds with respect to types of soils 4. Compare systems for cleaning and disinfection 5. Explain biofilms and their formation 6. Select suitable waste treatment with respect to waste types generated during production 7. Explain basic principles of HACCP 	
Course Content	
Basic hygienic requirements for bioprocess industry, Clean rooms, Requirements for production of food and pharmaceutical products, Basic hygienic principles of manipulation with GMO microorganisms, Cleaning and disinfection (types of soil, cleaning compounds and systems), Control of hygiene (rapid testing vs. traditional methods), Biofilms, Waste treatment, Personal hygiene, Contaminants and pests, Good manufacturing practice, HACCP.	
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 (<i>Connecting Learning Outcomes, Teaching Methods, and Grading</i>)	

Class-related activity	ECTS	Learning outcome	Student activity	Evaluation method	Grade points	
					Min.	Max.
Attending classes (lectures)	0.2	1-7	Attendance at classes, and laboratory	Keeping records	2	10
Seminars	1	1-7	Seminar work – writing and presentation	Paper and oral presentation	13	28
Laboratory exercise	0.3	1,3,4	Attendance, writing report	Report	5	12
Final exam	2.5	1-7	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 library	Availability via other media
Whyte W: Cleanroom Technology: Fundamentals of Design, Testing and Operation, 2 nd Ed., Wiley, 2011.	0	-
Stanga M: Sanitation: cleaning and disinfection in the food industry, Wiley-VCH, 2010.	1	-

Additional Literature

- Okafor N, Sterility in Industrial Microbiology, In: *Modern Industrial Microbiology and Biotechnology* Poglavlja: Treatment of Wastes in Industry, 2007, pp 221-236; 505-519.
- Sandle T, Pharmaceutical Microbiology, Essentials for Quality Assurance and Quality Control, Woodhead Publishing, 2016.
- Walsh G, Biopharmaceuticals Biochemistry and Biotechnology, John Wiley and Sons, Ltd, West Sussex, England, 2003.
- Scientific and professional papers from the field (available on-line).

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 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.