COURSE OUTLINE	BIOPHARMACEUTICALS

1. GENERAL

SCHOOL	HEALTH SCIENCES		
DEPARTMENT	MOLECULAR BIOLOGY AND GENETICS		
LEVEL OF STUDIES	LEVEL 7		
COURSE CODE	PHABIOTECH 3	**SEMESTER**	B
COURSE TITLE	BIOPHARMACEUTICALS		

TEACHING ACTIVITIES *If the ECTS Credits are distributed in distinct parts of the course e.g. lectures, labs etc. If the ECTS Credits are awarded to the whole course, then please indicate the teaching hours per week and the corresponding ECTS Credits. Please, add lines if necessary. Teaching methods and organization of the course are described in section 4.*	**TEACHING HOURS PER WEEK**	**ECTS CREDITS**
	3	**15**

COURSETYPE *Background, General Knowledge, Scientific Area, Skill Development*	SCIENTIFIC AREA
PREREQUISITES:	NO
TEACHING & EXAMINATION LANGUAGE:	GREEK
COURSE OFFERED TO ERASMUS STUDENTS	NO
COURSE URL	

2. LEARNING OUTCOMES

LEARNING OUTCOMES

The course learning outcomes, specific knowledge, skills and competences of an appropriate level, which the students will acquire upon successful completion of the course are described.

Refer to Appendix A

• Description of the Level of Learning Outcomes for each cycle of study in accordance with the Qualifications Framework of the European Higher Education Area

• Descriptive Indicators for Levels 6, 7 and 8 of the European Qualifications Framework for Lifelong Learning and Appendix B

• Guidelines for writing Learning Outcomes

Aim of the course

The aim of the course is to provide postgraduate students with a comprehensive understanding of the development, production, and application of biopharmaceutical products, such as monoclonal antibodies, recombinant therapeutic proteins, gene and cell therapy products, as well as biosimilars. Postgraduate students will become familiar with the technologies and processes required for the production of biologic drugs, industrial development, quality control and regulatory requirements concerning the safety and efficacy of these therapeutic approaches.

Upon successful completion of the course, the postgraduate students will:

- Understand the fundamental principles involved in the production of biopharmaceutical products, such as monoclonal antibodies, recombinant proteins and RNA-based therapies.
- Describe the production processes (upstream and downstream) of biopharmaceutical products and understand the significance of production scale and process optimization.
- Analyze the stages of clinical and preclinical development of biopharmaceutical products, focusing on immunogenicity and toxicity.

- Understand the regulatory framework governing the development, production and quality control processes of biopharmaceuticals.
- Explain the properties of biopharmaceutical products and evaluate their safety profiles and potential adverse effects.
- Understand the challenges involved in the design, development and approval processes of biosimilars and biobetters, through case studies.
- Recognize the importance of personalized pharmacotherapy and modern drug delivery technologies for biopharmaceutical products.
- Understand the regulatory requirements and quality standards (GMP, QbD, QRM) that govern the development and production of biopharmaceutical products.

GENERAL SKILLS

Considering the general competencies that the graduate should have acquired (as outlined in the Diploma Supplement and presented below), which of these skills does the course aim to achieve?

Search, analysis and synthesis of data and information, ICT Use
Adaptation to new situations
Decision making
Autonomous work
Teamwork
Working in an international environment
Working in an interdisciplinary environment
Production of new research ideas
Project design and management
Respect for diversity and multiculturalism
Respect for the natural environment
Demonstration of social, professional and moral responsibility and sensitivity to gender issues
Critical thinking and self-reflection
Promoting free, creative and inductive reasoning

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3. COURSE CONTENT

1. Biopharmaceutical antibodies - Vaccines
2. Recombinant therapeutic proteins and RNA-based therapies
3. Optimization of bioprocesses for the production of biopharmaceutical products
4. Personalized pharmacotherapy
5. Προϊόντα κυτταρικής θεραπείας- Προϊόντα γονιδιακής θεραπείαςCell therapy products - Gene therapy products
6. Pharmacotherapeutic profile
7. Development of biosimilars and biobetters
8. Principles and challenges in the design of biosimilars and biobetters
9. Case studies
10. Standardization and administration of biopharmaceutical products
11. Challenges in the Research & Development process of biopharmaceutical Products
12. Quality issues in biopharmaceutical products
13. Preclinical & Clinical trials of biopharmaceutical products
14. Regulatory framework for biopharmaceutical products

4. LEARNING & TEACHING METHODS - EVALUATION

TEACHING METHOD *Face to face, Distance learning, etc.*	The teaching includes face-to-face classes, group work, case studies and/or flipped classroom approaches, combined with lectures delivered through synchronous distance learning methods. In addition to attending lectures, postgraduate

students are expected to study the relevant literature and participate in educational activities.

USE OF INFORMATION & COMMUNICATIONS TECHNOLOGY (ICT)

Use of ICT in Teaching, in Laboratory Education, in Communication with students

Use of ICT in Teaching and in Communication with students.
On the asynchronous e-learning platform:

- course material is made available
- supporting resources for assignments are provided
- students submit their assignments

TEACHING ORGANIZATION

The ways and methods of teaching are described in detail.
Lectures, Seminars, Laboratory Exercise, Field Exercise, Bibliographic research& analysis, Tutoring, Internship (Placement), Clinical Exercise, Art Workshop, Interactive learning, Study visits, Study / creation, project, creation, project. etc.
The supervised and unsupervised workload per activity is indicated here, so that total workload per semester complies to ECTS standards.

Avtivity	*Workload/Semester*
Courses	39
Literature Review	210
Preparation/Implementation of educational activities	120
Assessment	10
Total workload	**379**

STUDENT EVALUATION

Description of the evaluation process

Assessment Language, Assessment Methods, Formative or Concluding, Multiple Choice Test, Short Answer Questions, Essay Development Questions, Problem Solving, Written Assignment, Essay / Report, Oral Exam, Presentation in audience, Laboratory Report, Clinical examination of a patient, Artistic interpretation, Other/Others

Please indicate all relevant information about the course assessment and how students are informed

Assessment Language: Greek

Assessment Method: Formative

Individual or group written assignments (25%), in-class activities (10%), Final Examination: Written exam and/or written project (65% of the final grade).

The assessment criteria are accessible to students as they are posted on eclass. The assessment criteria for the written assignments are as follows:

ASSESSMENT CRITERIA FOR THE WRITTEN ASSIGNMENTS	max
Introduction	15
Topic development into sections and subsections (degree of alignment with the requirements of the assignment)	40
Conclusions (summary of the work)	10
Critical thinking, use and presentation of data, hypotheses and sources (depending on the topic)	15
Proper use of bibliography and citation formatting	10
Presentation, Formatting, Composition and Spelling	10
Total	**100**

ASSESSMENT CRITERIA FOR THE WRITTEN PROJECT	max
Introduction	10
Presentation of the research question/problem to be addressed/solved	10
Methodology - Suggested Approach	20
Expected Outcomes	10
Critical analysis of the selected methodology/approach	15
Conclusions (summary of the work)	15
Proper use of bibliography and citation formatting	10
Presentation, Formatting, Composition and Spelling	10
Total	**100**

5. SUGGESTED BIBLIOGRAPHY

- The materials from the instructors' presentations.
- Original research articles and review papers published in reputable academic journals.

Selected chapters from textbooks (available in the Library of the School of Health Sciences-indicative list).

- Silva A.C., Moreira J.N., Sou Lobo J.M., Almeida H. *Current applications in Pharmaceutical Biotechnology*. Springer 2019.
- Clementi F. (Editor) & Fumagalli G. (Editor) *General and Molecular Pharmacology: Principles of Drug Action.* Wiley & Sons 2015.
- Sherman D., *Advanced Textbook On Gene Transfer, Gene Therapy And Genetic Pharmacology: Principles, Delivery And Pharmacological And Biomedical Applications Of Nucleotide-Based Therapies.* WPSPC (EUROPE) 2019.
- Crommelin D.A (Editor), Sindelar R.D. (Editor), & Meibohn B. *Pharmaceutical Biotechnology: Fundamentals and Applications*. Springer 2024.
- Jugschsies G., Lindgkog L., Lacki K & Galliher P. *Biopharmaceutical Processing: Development, Design & Implementation of Manufacturing Processes*. 2018