UNIVERSITY OF PATRAS
SCHOOL OF HEALTH SCIENCES
DEPARTMENT OF PHARMACY
UNDERGRADUATE STUDIES' COURSES

COURSE DESCRIPTION: **PHARMACEUTICAL BIOTECHNOLOGY**
COURSE CODE: **PHA-C12-NEW**

PHARMACEUTICAL BIOTECHNOLOGY
COURSE DESCRIPTION

1. GENERAL

SCHOOL	HEALTH SCIENCES		
SEPARTMENT	PHARMACY		
LEVEL OF COURSE	UNDERGRADUATE		
COURSE CODE	**PHA-C12-NEW**	**SEMESTER OF STUDIES**	**5th**
COURSE TITLE	PHARMACEUTICAL BIOTECHNOLOGY		

INDEPENDENT TEACHING ACTIVITIES	**TEACHING HOURS PER WEEK**	**ECTS CREDITS**
Lectures	4	6
Laboratory practice	3	

COURSE TYPE	Scientific Field course
PREREQUISITE COURSES:	-
TEACHING AND ASSESSMENT LANGUAGE:	Greek
THE COURSE IS OFFERED TO ERASMUS STUDENTS	Yes [Instructed/Guided self study in english for Erasmus+ Students]
COURSE WEBPAGE (URL)	http://www.pharmacy.upatras.gr/images/DS/PHA-C12-EN.pdf

2. LEARNING OUTCOMES

Learning Outcomes
• To understand basic concepts. • To understand basic and advanced technical tools and methodologies in applied Molecular and Pharmaceutical Biotechnology. • To acquire basic skills in the laboratory. • To learn the most important applications, i.e. new biotechnology products and services such as in molecular diagnosis. • Emphasis is placed mainly and extensively on approved biological drugs. • New technologies are exploited in teaching. • High e-class visitation daily throughout the semester.
General Abilities
• Searching, retrieval, analysis, and synthesis of data and information by use of mainstream technologies and laboratory-experimental tools.

- Critical thinking.
- Conceptual thinking and novel ideas.
- Develop out of the box, creative and inductive thinking.
- Independent work.
- Team work.
- Interdisciplinary work.
- Work design and management.
- Decision making.
- Social, professional, ethical responsibility and sensitivity.

3. **COURSE CONTENT**

Lectures
Introduction into Molecular Biotechnology-Historical discoveries.
Basic and advanced tools of recombinant DNA technology: PCR and applications, methodologies for quantification of gene expression, cDNA and genomic libraries, DNA sequencing technologies, gene cloning, gene transfer in bacteria and eukaryotic cells, site-directed mutagenesis, production of recombinant proteins, protein engineering, transponsons, genetic engineering of plants, transgenic technologies, gene targeting, gene silencing, RNAi, gene editing.
"Omics" technologies. Genome sequencing and annotation. Genetic footprinting and applications.
Microbial synthesis of organic molecules (biotransformations-bioconversions).
Antisense technologies. Oligonucleotide drugs.
Biophysical and biochemical analysis of recombinant proteins.
Production, scale up, processing of biotechnology products. Immunogenicity of pharmaceutical proteins.
Pharmaceutical proteins: [1] insulins, [2] growth hormones, [3] haematopoietic factors, [4] interferons and interleukins, [5] coagulants and thrombolytic factors.
Production and engineering of monoclonal antibodies (humanized, chimeric, hybrid, human).
Catalytic antibodies (abzymes). Immunotoxins.
Monoclonal antibodies as drugs (anticancer, anti-inflammatory).
Vaccines produced by recombinant DNA technology. Biosimilars.
Cell therapies (iPCs, new technologies).
Regulatory issues and approval of biotech products.
Bioethics. Intellectual property.

Laboratory-Experiments
1. Introduction into recombinant DNA technology (VCR)
2. Isolation and quantification of genomic DNA. Analysis of VNTR polymorphisms in mtDNA.
3. Genetic Engineering I: bacterial cultures, preparation of competent bacterial cells, transformation, determination of yield of transformation. [Hands On]
4. Genetic Engineering II: Isolation, purification and quantification of plasmid DNA. Digestion with restriction enzymes, agarose electrophoresis, determination of restriction fragment sizes. [Hands On]
5. Genetic Engineering III: Site-directed mutagenesis-Single amino acid substitution in a protein by two-step PCR reaction. [Hands On]
6. Genetic Engineering IV: Electrophoresis, isolation/purification and confirmation of PCR products obtained in GE II, restriction digest, ligation for production of a recombinant DNA molecule (expression construct). [Hands On]

7. Bioinformatics (*in silico*):
   - ✓ Biotechnology databases (NCBI: OMIM, PubChem BioAssay/Compound/ Substance, Genbank/ EMBL, PDB)
   - ✓ Pharmaceutical databases (PharmLinks, FDA, EMA, κλπ).
   - ✓ BLAST searches, retrieval of nucleotide and protein sequences, and analysis (restriction maps, translation, secretion signal, functional motifs, multiple sequence alignment, phylogenetic tree, hydrophobicity/hydrophilicity and antigenicity plots, prediction of posttranslational modification sites, promoter sequences and transcription factor consensus sequences).
8. Production of monoclonal antibodies by hybridoma technology (VCR).
9. Development and production of 1st, 2nd and 3rd generation pharmaceutical proteins by bioengineering (VCR).

4. TEACHING AND LEARNING METHODS - ASSESSMENT

Teaching method	Interactive teaching within a classroom
Use of information and communication technologies	1. E-class 2. Biotechnology databases. 3. Software for data retrieval and analysis. 4. Educational videos, e.g. http://www.pharmacy.upatras.gr/index.php/el/research/labs/357--a-
Teaching organization	***Teaching Method*** — ***Semester Workload*** Lectures — 52 Laboratory training — 39 Preparation/Reports for Lab. training — 39 Supervised study — 20 ***Total number of hours for the Course*** **(25 hours of work-load per ECTS credit) — 150**
STUDENT ASSESSMENT	I. Final Examination-Written (70% or 60% for those involved in seminar presentations) Escalating difficulty, descriptive and critical questions and problems, as well as multiple choice. Knowledge, critical thinking and problem solving capacity is tested. Representative template tests are presented and discussed during lectures and are to be found on e-class II. Laboratory (30%) 1. Final Examination-Written 2. Written Test/Quiz at the end of each Laboratory Experiment or VCR presentation 3. Oral Questions during Laboratory training 4. Written Report-Presentation and analysis of anticipated and obtained experimental results, Description of conclusions III. Group and individual oral presentations on specific topics-Supervised study (10%, voluntary) Exam in Greek In English for ERASMUS students

5. RECOMMENDED LITERATURE

Suggested Books:

1. 1st Greek Edition of "Pharmaceutical Biotechnology. Fundamentals and Applications" by Daan J.A. Crommelin, Robert D. Sindelar, Bernd Meibohm, 3rd Edition, Informa Healthcare (2008). Published by Parisianou Scientific Editions (2011).
2. 1st Greek Edition of "Recombinant DNA. Genes and Genomes-A Short Course" by James Watson, Amy Caudy, Richard Myers, Jan Witkowski, W. H. Freeman and Company, Cold Spring Harbour Laboratory Press, 3rd Edition (2007).
   Published by Basdra Academic Editions (2007)
3. Laboratory Excercises by G Sotiropoulou, I Zarkadis (2007)
   Available on E-class

Suggested Literature:

1. Handbook of Pharmaceutical Biotechnology. Edited by Shayne Cox Cad, Wiley-Interscience, A John Wiley & Sons, Inc., Publication, 2007
2. Crommelin DJ, Storm G, Verrijk R, de Leede L, Jiskoot W, Hennink WE. (2003) Shifting paradigms: biopharmaceuticals versus low molecular weight drugs. Int J Pharm 266: 3-16.
3. Mitragotri S, Burke PA, Langer R. (2014) Overcoming the challenges in administering biopharmaceuticals: formulation and delivery strategies. Nat Rev Drug Discov 13: 655-672.
4. Kimbrel EA, Lanza R. (2015) Current status of pluripotent stem cells: moving the first therapies to the clinic. Nat Rev Drug Discov 14: 681-692.

Suggested Scientific Journals

- Nature Biotechnology, Nature Reviews Drug Discovery, Nature, Science, Cell, PNAS USA
- BMC Systems Biology, Systems and Synthetic Biology.
- Pharmaceutical Journals.

Web Sources: