



UNIVERSITY OF
PATRAS
ΠΑΝΕΠΙΣΤΗΜΙΟ ΠΑΤΡΩΝ

DEPARTMENT OF PHARMACY

SCHOOL OF HEALTH SCIENCES

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



COURSE DESCRIPTION: **BIOETHICS - ELEMENTS OF DRUG REGULATION**
COURSE CODE: **PHA-B21-NEW**

**BIOETHICS - ELEMENTS OF DRUG REGULATION
COURSE DESCRIPTION**

1. GENERAL

SCHOOL	HEALTH SCIENCES		
SEPARTMENT	PHARMACY		
LEVEL OF COURSE	UNDERGRADUATE		
COURSE CODE	PHA-B21-NEW	SEMESTER OF STUDIES	4th
COURSE TITLE	BIOETHICS - ELEMENTS OF DRUG REGULATION		
INDEPENDENT TEACHING ACTIVITIES	TEACHING HOURS PER WEEK	ECTS CREDITS	
Lectures	3	6	
COURSE TYPE	Scientific Field course		
PREREQUISITE COURSES:	-		
TEACHING AND ASSESSMENT LANGUAGE:	Greek		
THE COURSE IS OFFERED TO ERASMUS STUDENTS	Not offered		
COURSE WEBPAGE (URL)	http://www.pharmacy.upatras.gr/images/DS/PHA-B21-EN.pdf		

2. LEARNING OUTCOMES

Learning outcomes
<p>Students learn and understand the issues and importance of Bioethics as well as the Basic Principles of Legislation, adapted to the science of Pharmacy.</p> <p>Students acquire the necessary knowledge to understand the legal, ethical and ethical framework governing the research, development and marketing of health products, as well as the regulatory framework for the profession of pharmacist.</p> <p>At the end of the course, students are able to use the knowledge and understanding they have gained so that they can in future (in their professional rehabilitation) better approach the role (profession) of both the Pharmacist and other professional directions such as preclinical & clinical research, vigilance (safety), marketing approvals.</p> <p>Students are also able to recognize the great importance of collaborating pharmacists, clinicians, laboratory and nursing staff and lawyers with the aim of describing, monitoring and continuously renewing the rules on the optimal way of developing and marketing health products, understanding the complex scientific, legal and ethical challenges.</p>
General Abilities
<p>Data and information searching, analysis and combination, using the necessary technologies</p> <p>Independent work</p> <p>Team-work</p> <p>Work in an international environment</p>

Work in an interdisciplinary environment
 Generation of new research ideas

3. COURSE CONTENT

Drug discovery and development

- Research and Ethics in Research
- Animal experiment rules and guidelines
- Human Research: Rules of Good Clinical Practice

Nuremberg Code
 Declaration of Geneva
 Declaration of Helsinki (Original text, revisions, modern wording)
 Genetic and prognostic genomics
 Genetics and society
 Regulatory Framework for Marketing Authorizations for Medicines and Health Products

- Drugs
- Medicinal products of natural origin
- Medical equipment
- Cosmetics

Pharmacovigilance and Medical Devices Vigilance
 Death and moral issues about death
 Pharmaceutical Law (Pharmacy Operation)

4. TEACHING AND LEARNING METHODS - ASSESSMENT

TEACHING METHOD	Lectures Face to face								
USE OF INFORMATION AND COMMUNICATION TECHNOLOGIES	<ul style="list-style-type: none"> • The teaching and learning process is supported by the Upatras e-class platform. The teaching material (lectures, tutorials, laboratory experimental protocols) is uploaded and stored on the e-class and it is freely accessible to all students. • Teaching process is supported by Information and Communication Technologies (ICTs). 								
TEACHING ORGANIZATION	<table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;"><i>Teaching Method</i></th> <th style="text-align: right;"><i>Semester Workload</i></th> </tr> </thead> <tbody> <tr> <td>Lectures</td> <td style="text-align: right;">39</td> </tr> <tr> <td>Private, unsupervised study</td> <td style="text-align: right;">111</td> </tr> <tr> <td>Total number of hours for the Course (25 hours of work-load per ECTS credit)</td> <td style="text-align: right;">150</td> </tr> </tbody> </table>	<i>Teaching Method</i>	<i>Semester Workload</i>	Lectures	39	Private, unsupervised study	111	Total number of hours for the Course (25 hours of work-load per ECTS credit)	150
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STUDENT ASSESSMENT	Written examination at the end of the courses, including topic development and answers to multiple choice questions								

5. RECOMMENDED LITERATURE

Suggested Books:
 Alachiotis S. "Bioethics" in Greek language only, Livanis Publications, 2011