UNIVERSITY OF PATRAS

SCHOOL OF HEALTH SCIENCES

DEPARTMENT OF PHARMACY

POSTGRADUATE PROGRAM: DRUG DESIGN AND DEVELOPMENT

COURSE TITLE: **PRECLINICAL AND CLINICAL DRUG EVALUATION**

CODE: DPHA_4

PRECLINICAL AND CLINICAL DRUG EVALUATION
COURSE OUTLINE

1. GENERAL

SCHOOL	HEALTH SCIENCES
ACADEMIC UNIT	DEPARTMENT OF PHARMACY
PARTICIPATING INSTITUTIONS	-
TITLE of POSTGRADUATE PROGRAM	DRUG DESIGN AND DEVELOPMENT
LEVEL	POSTGRADUATE

COURSE CODE	DPHA-4	**SEMESTER**	A'

COURSE TITLE	PRECLINICAL AND CLINICAL DRUG EVALUATION

INDEPENDENT TEACHING ACTIVITIES	**WEEKLY TEACHING HOURS**	**CREDITS**
Courses	5	8

COURSE TYPE	General Knowledge: Revision and analysis of basic concepts, in order to obtain a background "harmonization" of students with varying undergraduate degrees. Scientific field: In-depth understanding of the Approaches and Methods in Preclinical and Clinical Drug Development. Development of Skills in critical evaluation and synthesis of experimental (and other) data.
PREREQUISITE COURSES	Not required. However, the successful enrolment in the course supposes important pre-existing knowledge and background in (among others) Biochemistry, (Patho)Physiology and Cell/Molecular Biology.
LANGUAGE of INSTRUCTION and EXAMINATIONS	Greek. However, a large part of lecture material, scientific articles and final exam questions are in english.
COURSE OFFERED to ERASMUS STUDENTS	Yes
COUSRSE (URL)	http://www.pharmacy.upatras.gr/images/DS/DPHA_4_EN.pdf

2. LEARNING OUTCOMES

Learning Outcomes
Understanding of a variety of basic concepts, methodologies and approaches (and of their combination) used in the Preclinical and Clinical Evaluation of bioactive compounds. Development of ability for Critical Thinking in the evaluation of literature, methodology, approaches, results and conclusions.

Independent analysis and synthesis of experimental and other data (e.g. from publications), enabling the extraction of conclusions.

Development of the skills required for oral and written presentation and argumentation, based on experimental and/or clinical data.

Acquisition of the ability to plan the appropriate experimental methodology and approach in order to evaluate and develop bioactive compounds for the treatment of a specific disease (problem solving).

General Competences

- Search for, analysis and synthesis of data and information, with the use of the necessary technology
- Adapting to new situations
- Decision-making
- Working independently
- Team work
- Working in an international environment
- Working in an interdisciplinary environment
- Criticism and self-criticism
- Production of free, creative and inductive thinking

3. SYLLABUS

LECTURES

Basic pharmacological and biochemical terms and definitions characterizing compound bioactivity (EC_{50}, IC_{50}, Km, etc).

Biochemical, immunological and immunochemical methods used to evaluate the activity of compounds in vitro.

In vitro cell-based and organoid-based models for the identification and evaluation of bioactive compounds.

Use of organs-on-a-chip in the preclinical evaluation of bioactive compounds.

In vivo experimental models used in the preclinical evaluation of bioactive compounds.

Regulatory framework of preclinical research in animals.

Preclinical data (ADMET) requirements for entering into clinical studies.

Regulatory framework of clinical drug development.

Regulatory processes and mechanisms of drug approval.

Regulatory framework for the approval of drugs with pharmacogenomic biomarker labeling (Companion Diagnostics).

Monitoring of drug safety – Pharmacovigilence.

4. TEACHING and LEARNING METHODS - EVALUATION

DELIVERY	Face to face
USE of INFORMATION and COMMUNICATIONS TECHNOLOGY	Extensive use of E-class to share archives and lectures, to communicate with students and to organize the lecture schedule.
TEACHING METHODS	*Activity* *Semester Workload* Lectures from Faculty and presentations by students based on processing assigned material and on analysis of scientific literature 200 **Course Total** **(25 hours of work-load per ECTS credit)** **200**
STUDENT PERFORMANCE EVALUATION	Written exam comprising questions requiring short or extensive explanations, multiple questions and problem solving. - The exam and answers are given in greek, but the initial material of the problems may be in English (e.g. data from a scientific publication). - The exam takes place with "open books" ("material"), i.e. all students have access to all the class' scientific content (lectures, articles etc), which they have received or downloaded throughout the semester. - During the exam, the students have no access to the internet.

5. RECOMMENDED BIBLIOGRAPHY

Related Academic Journals:
Access / use of scientific journals, preferably wide-circulation ones including (non-exhaustive list):
- Nature and all Nature journals
- Science and all Science journals
- Cell and all Cell journals
- Annual Reviews series
- Journal of Clinical Investigation
- PNAS