



## Course Syllabus

<b>Course Code</b>	<b>Course Title</b>	<b>ECTS Credits</b>
PHAR-615	Drug Development and Ethical Considerations in Pharma Industry	10
<b>Prerequisites</b>	<b>Department</b>	<b>Semester</b>
None	Health Sciences	Fall
<b>Type of Course</b>	<b>Field</b>	<b>Language of Instruction</b>
Compulsory	Pharmacy	English
<b>Level of Course</b>	<b>Lecturer(s)</b>	<b>Year of Study</b>
2 <sup>nd</sup> Cycle	Christos Papanephytou, Christos Petrou, Eleftheria Galatou, Konstantinos Liaras, Elena Mourelatou	1 <sup>st</sup>
<b>Mode of Delivery</b>	<b>Work Placement</b>	<b>Corequisites</b>
e-learning	--	None

### Course Objectives:

This course is designed to orient students to the basic concepts and stages of drug discovery and pharmaceutical industry ethics. It is an introductory course dealing with the overview of the development process of new drugs, including , the research approach for the discovery of new drugs, and the stages of the development of new drugs, Nonclinical Drug Safety Assessment including the concepts of Pharmacogenetics and Pharmacogenomics , toxicology and efficacy studies in animals.

In addition, ethical issues in pharma industry will be introduced as they are commonly faced. Such activities are related to the drug discovery and development processes (including the conduct of clinical trials), the assurance of quality, safety and efficacy of drugs, the management of drug-related problems, the drug promotion and advertising, as well as the development of generic formulations and the research for drugs concerning special health issues such as psychiatric disorders. Therefore, a deep overview of the ethical challenges arising in the pharmaceutical industry will be provided, so that the students will be able to identify and comprehend the ethical issues posed in the pharma industry.

**Learning Outcomes:**

After completion of the course students are expected to be able to:

- give a comprehensive overview of discovery and development of medicines including definitions of key concepts and the fundamentals of the major disciplines in the process.
- analyze the sequence and flow of the various steps and identify critical factors and bottlenecks that influence the drug development process
- Analyze the ethical aspects of drug promotion and advertising, including their influence on drug prescribing habits.
- Differentiate the ethical implications of pharmaceutical patents, generic drug development and usage, as well as of the lobbying performed by pharmaceutical companies.
- Outline the ethical issues related to drug quality, safety and efficacy, taking also into consideration the drug-related problems.

**Course Content:**

- Modern pharmaceutical research: Since the discovery and development of new drugs to medication and clinical practice
- Introduction in Drug Discovery and Development/Stages of drug discovery.
- Overview of the development process of new drugs - drug development stages
- The need for animals in biomedical research
- Pharmacogenetics and Pharmacogenomics in Drug Development and Regulatory Decision
- Nonclinical Drug Safety Assessment
- Basis of ethics and ethics of the drug discovery and development process
- Ethical aspects of clinical trials
- Ethics of the economics of drug-related morbidity and mortality and Ethical aspects of medicines promotion and advertising
- Ethics of quality, safety and efficacy of drugs and Marketing influence on doctor's medical practices
- Ethical considerations of lobbying by pharmaceutical companies
- Ethics of patents and generic drugs and pharmaceuticals in developing countries

**Learning Activities and Teaching Methods:**

Teaching material including PowerPoint presentations with extended descriptions and explanations, asynchronous video presentations, additional readings (journal articles and ebooks), access to additional videos related to the course, synchronous meetings (WebEx), forums, chats, quizzes, case studies, wikis, and major assignments.

**Assessment Methods:**

Continuous Assessment (major assignments and weekly activities), Final Exam

**Required Textbooks / Readings:**

Title	Author(s)	Publisher	Year	ISBN
Drug Delivery: Principles and Applications	Binghe Wang, Longqin Hu, Teruna J. Siahaan	Wiley	2016	9781118833360
Basic Principles of Drug Discovery and Development	Benjamin Blass,	Elsevier	2015	9780124115088
The Textbook of Pharmaceutical Medicine, 7th edition	John P. Griffin, John Posner, Geoffrey R. Barker	Wiley-Blackwell BMJ Books	2013	9780470659878
Drugs: From Discovery to Approval, 2nd edition,	Rick NG,	Wiley-Blackwell	2009	9780470195109
The Process of New Drug Discovery and Development	Charles G. Smith, James T. O'Donnell	Informa Healthcare	2008	9780849327797
The ethics of pharmaceutical industry influence in Medicine.	Haque, O. S.	Unesco Chair in Bioethics, Publications Division, Ministry of Education, Israel.	2013	978-965-444-035-6

Ethics and the Pharmaceutical Industry.	Santoro, M. A. and Gorrie, T. M	Cambridge University Press.	2007	978-0-521-85496-2
The law and Ethics of the Pharmaceutical Industry. 1st Edition.	Dukes, M. N. G.	Elsevier.	2005	9780444518682 eBook ISBN: 9780080459363
Case Studies in Biomedical Research Ethics.	Murphy, T. F.	MIT Press.	2004	9780262632867
Pharmaceutical Ethics.	Salek, S. and Edgar, A.	John Wiley & Sons.	2002	978-0-471-49057-9
Bad pharma: how drug companies mislead doctors and harm patients.	Goldacre, B	Fourth Estate Publishing.	2012	978-0-00-735074-2