UNIVERSITY of NICOSIA

Course Syllabus

Course Code	Course Title	ECTS Credits
PHAR-601	Drug Discovery and Development	7.5
Prerequisites	**Department**	**Semester**
None	Life and Health Sciences	1st
Type of Course	**Field**	**Language of Instruction**
Required	Pharmacy	English
Level of Course	**Lecturer(s)**	**Year of Study**
Graduate	Michael Plioukas Christos Papaneophytou	1st
Mode of Delivery	**Work Placement**	**Corequisites**
Distance Learning	NA	NA

Course Objectives:

The purpose of the course is to provide regulatory, industry, and university professionals with a comprehensive understanding of the regulatory rules and requirements as applied to medicines development and lifecycle management.

This course is designed to orient students to the basic concepts in drug chemistry and functional groups, medicinal chemistry approaches to optimizing drug action, principles of pharmacology, biological and target considerations in drug design, and how drugs are metabolized and eliminated from the body. Furthermore, this course will examine key aspects of drug development, including drug formulation and quality, stability testing, pharmacokinetic characterization, bioequivalence, preclinical toxicology, methods of bioanalysis, and non-clinical and clinical Good Laboratory Practices (GLPs).

Learning Outcomes:

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

1. 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.
2. list major steps, elements, and milestones of the drug discovery and development process from discovery to approval

3. plan a development process within the regulatory and identify the important transition points that require involvement of authorities
4. analyze the sequence and flow of the various steps and identify critical factors and bottlenecks that influence the drug development process

Course Content:

- Bioinformatics, Data Management and Statistics
- Pharmacogenetics and Pharmacogenomics in Drug Development and Regulatory Decision-Making
- High-Throughput Screening and the Identification of lead structures
- Combinatorial Chemistry in the Modern Drug Discovery Setting - Lead optimization and synthesis
- Non-clinical Drug Safety Assessment
- Preclinical Genotoxicity Testing
- Animal biology and pharmacology
- Pre-formulation Activities
- Pharmacokinetics – Pharmacodynamics in New Drug Development
- Pharmaceutical formulation and Delivery Systems
- Objectives and design of clinical trials
- Regulatory Procedures and Requirements in the European Union (overview)
- Quality Management and Inspections
- Medical Marketing - Economics of Health Care

Learning Activities and Teaching Methods:

Teaching material including PowerPoint presentations with extended descriptions and explanations, asynchronous video presentations, additional readings (journal articles and e-books), access to additional videos and commercials related to the course, synchronous meetings (WebEx), forums, chats, quizzes, case studies and other formative and summative assessments.

Assessment Methods:

Continuous Assessment (assignments), 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,		2015	9780124115088
"The Textbook of Pharmaceutical Medicine", 7th edition,	John P. Griffin, John Posner, Geoffrey R. Barker,	Wiley-Blackwell BMJ Books,	2013,	9780470659878
"Drug Discovery and Development. Technology in Transition",	Humphrey P. Rang, Raymond Hill, Churchill Livingstone		2012	9780702042997
"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