UNIVERSITY of NICOSIA

ECTS Syllabus

Course title	**Current Topics in Drug Design and Development**				
Course code	PHPHD-701				
Course type	Required				
Level	PhD				
Year / Semester	1st Year/1st Semester				
Teacher's name	Dr Yiannis Sarigiannis				
ECTS	10	**Lectures / week**		**Laboratories / week**	
Course purpose and objectives	The primary aim of this course is to provide an understanding of the scientific principles underlying pharmaceutical drug discovery, development, preclinical research, good laboratory practices, and clinical trials. It covers the skills, knowledge, and methodologies essential for successful drug discovery and preclinical and clinical development. The course places significant emphasis on the processes involved in drug design and development, encompassing both preclinical and clinical research stages. Additionally, it highlights quality control and regulatory science aspects pertinent to drug development, specifically focusing on CTD modules 4 and 5. This course seeks to impart a comprehensive understanding of drug chemistry and functional groups, the discovery and selection of drug candidates, the stages of drug development, fundamental pharmacology concepts, the processes of preclinical and clinical trials, and biological factors in drug design. It also addresses drug metabolism and the regulatory aspects of drug discovery and development. Moreover, students will explore topics such as drug formulation and quality, pharmacokinetic characterization, drug stability, bioequivalence, bioanalytical methods, and adherence to clinical Good Laboratory Practices (GLPs).				

Learning outcomes	After completion of the course students are expected to be able to: 1. critically evaluate the process of discovery and development of drugs (the milestones from the drug discovery to approval) 2. critically evaluate the early-stage drug discovery and AI 3. develop an in-depth knowledge of how drugs candidates are discovered, developed, put through clinical trial, and regulated 4. recognize the differences between generic and innovator drugs 5. develop in-depth knowledge of pharmacokinetics, biopharmaceutics and an understanding of scientific methods and research skills. 6. explain and apply the theory of bioequivalence, narrow therapeutic drugs and the regulatory requirements of pharmaceutical development. 7. plan a development and discovery drug process and identify the critical factors which effect the process of drug development. 8. critically evaluate and apply preclinical research techniques to assess the safety and efficacy of potential drug candidates, including in vitro and in vivo testing methodologies. 9. Interpret and analyze data derived from preclinical studies to guide decision-making in drug development and predict clinical outcomes.		
Prerequisites	None	**Required**	
Course content	- The role of bioinformatics, pharmacogenetics, and pharmacogenomics in drug development and discovery - AI in Drug Discovery: Finding the Lead Compound - Metabolism and pharmacokinetics-pharmacodynamics optimization strategies in new drug development and discovery - Pharmacology in drug discovery - Biological Drug Development - Preclinical Research Techniques and Methodologies*: In vitro and in vivo* testing strategies to evaluate drug efficacy and safety - Assessing drug safety (non-clinical drug safety assessment) - Test of preclinical genotoxicity and immunogenicity - Interpretation and analysis of preclinical data - Clinical development development (Clinical Trial Design/Conduct) - Assessing drug safety (non-clinical drug safety assessment)		

	- Combinatorial Chemistry in the Modern Drug Discovery Setting - Fundamentals of Regulatory Affairs for drug development and discovery (Requirements in the European Union overview)
Teaching methodology	Teaching material including PowerPoint presentations with extended descriptions and explanations, additional readings (journal articles and e-books), access to additional videos and commercials related to the course), quizzes, case studies and other formative and summative assessments.
Bibliography	1. "Drug Discovery and Development", Ramarao Poduri, Springer Singapore, 2021, ISBN: 978-981-15-5534-3 2. "*Drug Delivery: Principles and Applications*", Binghe Wang, Longqin Hu, Teruna J. Siahaan, Wiley, 2016, ISBN: 9781118833360 3. "*Basic Principles of Drug Discovery and Development*", Benjamin Blass, Academic Press, 2015, ISBN: 978-0124115088. 4. "Preclinical Drug Development: A Practical Guide" by Mark Rogge and David R. Taft, CRC Press, 2019, ISBN: 978-0367394046. 5. European Medicines Agency. "Guideline on the Non-clinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals." EMEA/CPMP/ICH/286/95. 6. EMA Guidelines on Clinical Research: 7. European Medicines Agency. "Guideline for Good Clinical Practice." E6(R2)
Assessment	Continuous Assessment (assignments), Final Exam
Language	English