

Course Syllabus

Course: *Drug Discovery & Development: Past, Present & Future*

Department: *Life & Health Sciences*

Host Institution: *University of Nicosia, Cyprus*



UNIVERSITY
of NICOSIA | Global
Semesters

Course Summary

Course Code	Course Title	ECTS Credits
PHAR-QS1	Drug Discovery & Development: Past, Present & Future	6
Subject	Contact Hours	Prerequisites
Pharmacy	42-45	none
Department	Level of Course	Language of Instruction
Life & Health Sciences	Lower-Division	English

Course Description

The course aims to get an understanding of the developments and changes of drug discovery and development process over the years. The course will study the changes in the drug discovery process both from the scientific perspective (technology advancements) and also from the changing landscape in the pharmaceutical companies including the role of the emergence of biotechnology companies, big pharma, CRO, academic institutions etc. The pharmaceutical industry is rapidly changing its attitude in terms of data transparency, quality monitoring and development. Several issues have recently emerged that worth special attention. The course aims to understand how drugs are discovered and developed, how and where big discoveries and ideas emerge. It will identify the changes and reflect on the effectiveness of these changes to bring new medicinal products (either original or innovative generics) in the market. The role of technology such as high throughput screening, omics, bioinformatics etc will be discussed. The course is not an exclusively historic reflection of the evolvement of drug discovery and development but also a reflection on the changes as a result of technological advancements, and the effectiveness of these changes as related to the number of new drugs brought to the market.

Ultimately, the scope will be to appreciate compare and contrast the role of classical or old drug discovery processes as opposed to the modern drug discovery and development processes, and rethink or critic these processes. Questions that emerge and can be discussed are endless but can include:

- how has the changing landscape in the pharma industry affected drug discovery
- has mergers and acquisitions increased productivity?
- are omic technologies effective?
- is drug repositioning likely to play a role in the future?
- are we missing on simple observation/ serendipitous effects?
- what have we learned over the years, what is the outlook of the drug discovery process, and what is the future?
- how does profit pressure and cost reductions in the big pharma affect the discovery of novel drugs?
- are we running out of new chemical entities, targets or both?
- are we in a period where omics are about to identify the new novel blockbuster drugs?
- What is the legal and regulatory framework in EU Vs USA regarding GMP, preclinical, clinical studies and which are the requirements of obtaining Marketing Authorization of medicinal products?
- how to improve quality by designing the process in a rational and robust manner. Given that quality problems are often a result of bad design from the start of the development process?

By looking and evaluating the different stages of drug discovery we can critically evaluate the changes versus the results, and rethink drug discovery and development process. The course will be a blend of history, understanding the processes, and independent evaluate the results. It will help interested individuals appreciate the drug discovery process and generate challenging questions. It is intended for pharmacists, biologists or other scientists who would like to get a deeper understanding of the drug discovery process

Prerequisites *(if applicable)*

none

Course Outline

The process of drug discovery and development, from validation of a drug target, identification of a lead structure leading to development of a drug, encompasses various disciplines and elements. To promote the ability to understand and communicate across the different fields of the process the following topics will be covered during the course:

- Target identification, evaluation and identification of lead structures
- Medicinal Chemistry: Lead optimization and synthesis
- Pharmacology
- Non-Clinical Safety-toxicology
- Pre-formulation • Pharmaceutical Formulation
- Production
- Quality systems
- Clinical Trials
- Safety
- Regulatory affairs and Patents

Evaluation

Exercises/reports, quizzes, exams

Reading and Resources

Smith and O'Donnel, The Process of New Drug Discovery and Development

Other Academic Policies

Class attendance is compulsory. If unable to attend a class, students must inform the course lecturer in advance. A maximum of 20% excused absences is tolerated; however beyond this percentage, students will be withdrawn from the course. Moreover, any work missed due to absence must be completed on return to class.