UNIVERSITY of NICOSIA

Course Syllabus

Course Code	Course Title	ECTS Credits
IMPH-475	Quality Control/ Έλεγχος Ποιότητας	4
Prerequisites	**Department**	**Semester**
None	Health Sciences	Fall/Spring
Type of Course	**Field**	**Language of Instruction**
Elective	Pharmacy	Greek/English
Level of Course	**Lecturer(s)**	**Year of Study**
1st Cycle	Dr Evroula Hapeshi	4th
Mode of Delivery	**Work Placement**	**Corequisites**
Face-to-Face	N/A	N/A

Course Objectives:

The main objectives of the course are to:

- Acquire knowledge on Quality Control of pharmaceuticals.
- Understand the responsibilities and the individual functions of the Quality Control Unit in a pharmaceutical industry.
- Understand the way that the quality control affects the various activities of pharmaceutical industry to ensure that the quality of the product compliances with the regulations of pharmaceutical industry
- Design a detailed procedure which is applied in a pharmaceutical industry for the identification, quantification and purity of pharmaceuticals

This course provides the basic principles and practices of quality control and assurance of pharmaceuticals and the use of various quality systems in the pharmaceutical industry. As it is known, the Quality Control is a useful knowledge subject which is required by employees in various fields of the pharmaceutical industry such as in the research and development of drugs, the development of analytical methods and the quality control and assurance of pharmaceuticals.

Learning Outcomes:

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

- Understand the importance of quality assurance (QA), quality control (QC) and regulatory affairs, which are vital in a pharmaceutical industry.

- Obtain knowledge and skills for use an approach to apply appropriate strategies related to quality control (identity, quantification and purity of pharmaceuticals)
- Select and apply physicochemical quality control methods
- Explain / describe the terms of pharmacotechnical and biological / microbiological control methods
- Understand the Rules of Good Laboratory Practices
- Demonstrate the ability to follow the analytical approach to solve the problem in chemical analysis and adhere to good laboratory practice
- Present and interpret the scientific data

Course Content:

1. Introduction to Quality Control (definitions, Legislation, production of pharmaceuticals, assurance of good functioning rules (properly trained personnel).
2. Quality Assurance, Rules of Good Practice (Good Laboratory Practices)
3. Study of Pharmacopoeia (information from pharmacopoeia, editions, monographs and its use).
4. Physicochemical methods (criteria for selection of analytical methods for drug quality control, spectroscopic methods, chromatographic methods and others) - Quality control and analytical methods
5. Study of the identification and the purity of pharmaceuticals
6. Control of the content of raw materials and final products
7. Pharmacotechnical control methods (control of packaging materials / excipients, control of the content uniformity, etc.)
8. Biological / Microbiological control methods
9. Drug stability (chemical, physical, photochemical, microbial degradation, study of the reaction rate, study of the effect of various parameters such as temperature)

Learning Activities and Teaching Methods:

Lectures, class discussion, tutorials

Assessment Methods:

Final exam, Midterm exam

Required Textbooks / Readings:

Title	Author(s)	Publisher	Year	ISBN
Μέθοδοι Ελέγχου Φαρμάκων	Μανόλης Γεωργαράκης	Εκδόσεις Πήγασος	2009	960-317-004-6
Quality Assurance of Pharmaceuticals [OP]: A Compendium of Guidelines and Related Materials	World Health Organization	World Health Organization	2007	978-9241547086
Quality Control of Pharmaceuticals: Compendial Standards and Specifications	Md. Sahab Uddin	Published by SPS	2017	978-3330650503
Pharmaceutical Quality Control Handbook	Bryant, Rhys	Aster Pub Corp; Revised edition	1989	978-0943330174