UNIVERSITY of NICOSIA

Course Syllabus

Course Code	Course Title	ECTS Credits
IMPH-465	Good Practices (GxPs)/ Κανόνες Ορθής Πρακτικής (GxPs)	4
Prerequisites	**Department**	**Semester**
-	Health Sciences	Fall/Spring
Type of Course	**Field**	**Language of Instruction**
Elective	Pharmacy	English
Level of Course	**Lecturer(s)**	**Year of Study**
1st Cycle	Dr Mourelatou Elena	4th
Mode of Delivery	**Work Placement**	**Corequisites**
Face-to-Face	N/A	N/A

Course Objectives:

Good Practices (GxPs) are a set of regulations and guidelines established and implemented to ensure the quality, safety and effectiveness of pharmaceuticals and biopharmaceuticals.
The application of these rules is a legislative requirement for the pharmaceutical industry, as well as the medical device and cosmetic industry worldwide.
GxPs denotes several different regulations that concern different fields, for example the production of medicines (Good Manufacturing Practices, GMPs), the conduct of clinical trials (Good Clinical Practices, GCP), the non-clinical laboratory studies (Good Laboratory Practices, GLP), the distribution of drugs (Good Distribution Practices, GDP), extemporaneous preparations (Good Compounding Practices, GCP), pharmacy practice (Good Pharmacy Practices, GPP) and more.
The main objectives of the course are students to:

- Understand the importance of applying Good Practices (GxPs) to the various stages of the research and development process of a pharmaceutical, medical device or cosmetic product;
- Obtain the necessary knowledge regarding established regulations and guidelines related to the research, production, storage and distribution of safe and effective medicines, that will allow to implement them.

Learning Outcomes:

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

1. Recognize the importance of implementing Good Practices (GxPs) for the protection of public health.
2. Describe the basic principles of Good Practices (GxPs).
3. Understand the design of quality systems.
4. Understand the processes of quality assurance and quality control.
5. Recognize the importance and the manner in which qualifications and validations are carried out.
6. Identify the requirements of written documentation.
7. Explain the need for Standard Operating Procedures (SOPs) and how to write them.
8. Determine the requirements of inspections (internal and external).
9. Identify important documentation and links to regulations governing the research, production, storage and distribution of medicinal products.

Course Content:

GxPs: Definitions, Basic Requirements, Historical Background and Purpose.
Design of quality systems, Basic principles of quality management and tools used.
Good Manufacturing Practices (GMPs): Basic Requirements for Personnel, Facilities and Equipment, Basic Documentation Principles, (Site Master File, SOPs, Protocols, etc.), Quality Control Processes and Requirements, Internal and External Audits, Complaint and Recall Management, Qualification and Validation procedures.
Basic Principles of Good Clinical Practices (GCP)
Basic Principles of Good Laboratory Practices (GLP)
Basic principles of Good Distribution Practices (GDP),
Basic principles of Good Compounding Practices (GCP),
Basic Principles of Good Pharmacy Practices (GPP)

Learning Activities and Teaching Methods:

Lectures, Assignments in writing SOPs and / or other protocols.

Assessment Methods:

Final exam, Assignments, Midterm exam

Required Textbooks / Readings:

Title	Author(s)	Publisher	Year	ISBN
EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines	European Commission	-	-	-
EudraLex - Volume 10 - Clinical trials guidelines	European Commission	-	-	-
Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP)	European Commission	-	-	-
Guidelines on GDP of medicinal products for human use	European Commission	-	-	-
Good Compounding Practices	US Pharmacopoeia (USP29)	-	-	-
Good Pharmacy Practice, Joint FIP/WHO Guidelines on GPP: Standards for quality of pharmacy services	WHO Technical Report Series, No. 961, Annex 8	-	2011	-

Recommended Textbooks / Readings:

Title	Author(s)	Publisher	Year	ISBN
WHO good manufacturing practices for pharmaceutical products: main principles	Annex 2, WHO Technical Report Series 986	WHO headquarters	2014	
WHO good distribution practices for pharmaceutical products	Annex 2, WHO Technical Report Series 957	WHO headquarters	2010	
HANDBOOK FOR GOOD CLINICAL RESEARCH PRACTICE (GCP)	WHO	WHO headquarters	2002	
Handbook: good laboratory practice (GLP): quality practices for regulated non-clinical research and development - 2nd ed.	WHO	WHO	2001	978 92 4 154755 0