UNIVERSITY of NICOSIA

Course Syllabus

Course Code	Course Title	ECTS Credits
IMPH-455	Pharmacovigilance and Pharmacoepidemiology/ Φαρμακοεπαγρύπνηση και Φαρμακοεπιδημιολογία	4
Prerequisites	**Department**	**Semester**
None	Health Sciences	Fall/Spring
Type of Course	**Field**	**Language of Instruction**
Compulsory	Pharmacy	Greek/English
Level of Course	**Lecturer(s)**	**Year of Study**
1st Cycle	Dr Panayiotis Petrou	4th
Mode of Delivery	**Work Placement**	**Corequisites**
Face-to-Face	N/A	N/A

Course Objectives:

The pharmacoepidemiology course is an introduction to the evaluation of the scientific studies that supports the rational use of medication use in humans. This course provides opportunities for students to understand the concepts, methods, and applications of epidemiology and outcomes studies utilized in clinical settings as well as to provide tools to critically assess the clinical literature. In addition, the methods for the interpretational and generalization of findings from studies relevant to medical and pharmaceutical care practice will be discussed.

Drug safety monitoring and risk management are vitally important for medicinal product developers, licence holders and clinical investigators. In addition to their duty to protect public health, increasingly tight regulation and potentially massive payments to litigants provide strong incentives for pharmaceutical and biotechnology companies to ensure that they maintain efficient systems for drug safety / pharmacovigilance and that all staff are aware of the basic requirements. This course will provide them with an overview of the most important aspects of this discipline, both before and after marketing of products, especially as they apply in Europe.

Learning Outcomes:

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

1) At completion of the course the student will be able to recognize drug safety issues and apply appropriate strategies to optimize the benefit/risk ratio of the product involved and to report adverse drug reactions of high quality

2) Is expected to be able to read and understand a study protocol in a clear, and simple, manner

3) will be able to understand the main principles of Pharmacoepidemiology

Course Content:

Pharmacoepidemiology

1. Various methods to collect pharmacoepidemiologic information is a central topic.
2. Drug utilization studies, cross-section studies, observational studies, and clinical trials.
3. Spontaneous reporting of side-effects.
4. The design of studies.
5. Data collection about drug exposure and outcome, bias, and the significance of confounders.
6. The causality and the significance of pharmacoepidemiologic studies for drug assessment.

Pharmacovigilance

This course will deliver an introduction to the basics of drug safety and pharmacovigilance, including regulatory requirements, adverse event reporting, signalling and risk management. This course addresses the regulatory issues across global government agencies that improve safety but slow down the product approval process. Keeping products on the market without interruption becomes more essential with the reduced pipeline of drugs in development. Successful navigation of drug safety and pharmacovigilance are keys to product longevity, consumer confidence, and regulatory compliance. This course will provide learners with the regulatory references, processes, best practices, and analysis and investigation techniques to minimize risk, avoid product recall, and meet international standards.

Thalidomide and History of Pharmacovigilance; Limitations of Pre-approval Clinical Trials; Post-Marketed AEs; Pharmacovigilance Definitions; Assessing Adverse Events; Serious vs. Severe; Causality; Expectedness; SUSAR; Minimum Criteria for Reporting; Reporting Format; Managing Blinded Therapy Cases; Sponsor's Responsibilities; Sponsor's Responsibilities; Monitor Responsibilities; Principal Investigator Responsibilities; Adverse Reaction Types; Safety Signal Generation. Safety and reporting standards. Matrix of Safety Regulations; International Conference on Harmonisation (ICH); CIOMS; Key EU Component

Learning Activities and Teaching Methods:

Lectures, class discussion, assignments, practicals

Assessment Methods:

Final exam, Midterm exam

Required Textbooks / Readings:

Title	Author(s)	Publisher	Year	ISBN
Pharmacoepidemiology and Therapeutic Risk Management	Hartzema AG, Tilson HH and Chen A	Harvey Whitney Press, Inc. Cincinnati	2008	978-0929375304
Pharmacoepidemiology: An Introduction	Hartzema AG, Porta M, Tilson HH			
An Introduction to Pharmacovigilance	Wang D, Bahkai A.	Wiley-Blackwell	2009	
Fundamentals of Clinical Trials	Friedman, L.M., Furberg, C.D., DeMets, D., Reboussin, D.M., Granger, C.B.		2015	978-3-319-18539-2