UNIVERSITY of NICOSIA

Course Syllabus

Course Code	Course Title	ECTS Credits
PHAR-616	The EU Regulatory Affairs System	10
Prerequisites	**Department**	**Semester**
None	Health Sciences	Fall
Type of Course	**Field**	**Language of Instruction**
Compulsory	Pharmacy	English
Level of Course	**Lecturer(s)**	**Year of Study**
2nd Cycle	Sideri A. Kitromilidou C., Aislaitner G, Zampatis D.	1st
Mode of Delivery	**Work Placement**	**Corequisites**
e-learning	--	None

Course Objectives:

The course will give an overview of the European regulatory system for human medicines, including the legislative processes and European Networks, the different routes for obtaining a license for the European market, the centralized, the decentralized and the mutual recognition procedures, and the national procedures. In addition, the specific European procedures for orphan drugs, pediatrics, advanced therapies and combination products will be discussed. This will cover the different steps and timelines in the different procedures, the clock-stops, the compiling of questions etc. An introduction regarding the drug's lifecycle will be given with respect to pharmacovigilance, variations and renewals.
The course will cover the current registration systems available for approval of medicinal products.

Learning Outcomes:

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

- Differantiate the principles of the EU legislative framework underpinning each step of the drug development process (pre-approval, approval and post-approval phase), and the roles and responsibilities of the key players in the EU regulatory process
- Analyse the role and structure of the EMA and the role of the Management Board, and of NCAs
- Compare and Categorise the different types of MAH applications (Full application,

Generic application, Hybrid application, Similar biological application, Well-established use application, Fixed combination application, Informed consent application)

- Categorise, asses and apply the different referral procedures related to Safety issues, quality, manufacturing or efficacy issues, Paediatric medicine issues, Harmonisation, mutual-recognition procedure and decentralised procedure issues
- Design and critically evaluate a Paediatric Investigational Plan (PIP)
- Evaluate applications for certification of quality and non-clinical data for ATMP

Course Content:

- The European System for Medicinal Products - General Background to EU and Institutions
- The European System for Medicinal Products – EMA
- The European System for Medicinal Products – National Competent Authorities (NCAs)
- Marketing Authorisation System for Pharmaceuticals in the EU
- Referrals
- Legal framework of variations in EU/ Variations to nationally authorised products
- Regulatory Data Protection in the EU.
- Regulation on Medicinal Products for Paediatric use
- Advanced Therapies Medicinal Products – ATMP
- Liability – Labelling
- Orphan Medicinal Products
- Regulation of medical devices

Learning Activities and Teaching Methods:

Teaching material including PowerPoint presentations with extended descriptions and explanations, asynchronous video presentations, additional readings (journal articles and ebooks), access to additional videos related to the course, synchronous meetings (WebEx), forums, chats, quizzes, case studies, wikis, and major assignments.

Assessment Methods:

Continuous Assessment (major assignments and weekly activities), Final Exam

Required Textbooks / Readings:

Title	Author(s)	Publisher	Year	ISBN
EudraBook V1 - May 2015, Compendium of EU pharmaceutical law	Directorate-General for Health and Food Safety	European Commission	2015	978-92-79-44434-0
Volume 2A Procedures for marketing authorization. Chapter 1. Marketing authorization		European Commission	2019	------
Setting the Scene: Introduction to the EU Regulatory Network. The EU and the EU regulatory system for medicines 2nd International Awareness Session -	Riccardo Luigetti	The EU medicines regulatory system and the European Medicines Agency	2018	-----