UNIVERSITY of NICOSIA

Course Syllabus

Course Code	Course Title	ECTS Credits
PHAR-603	EU Regulatory Affairs System	7.5
Prerequisites	**Department**	**Semester**
None	Life and Health Sciences	1st
Type of Course	**Field**	**Language of Instruction**
Required	Pharmacy	English
Level of Course	**Lecturer(s)**	**Year of Study**
2nd Cycle	Christos Petrou George Aislaitner Maria Iacovidou	1st
Mode of Delivery	**Work Placement**	**Corequisites**
Distance Learning	NA	NA

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:

1. Explain 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
2. Discuss how the legislation helps establish an on-going benefit-risk evaluation throughout the life cycle of a medicinal product

3. Discuss and distinguish the principles of EU and National legislative provisions as applied to medicinal products
4. Analyse the role and structure of the EMA
5. Describe the role of the Management Board
6. Critically analyse the composition and the scientific role of the Committees
7. Summarise the Role and Responsibilities and structure of NCAs
8. Explain the role and impact of the European Medicines Network, CMD, Head of Agencies
9. 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
10. Appraise the requirements for the different types of scientific advice and application procedures according to the medicinal product/context in the EU/EEA
11. Critically evaluate the different referral procedures
12. 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
13. Design and critically evaluate a Paediatric Investigational Plan (PIP)
14. Evaluate applications for certification of quality and non-clinical data for ATMP
15. Discuss the European Pharmaceutical Product Liability Regimes.

Course Content:

- The EU pharmaceutical legislation and law frame
- General background about the EU and its institutions
- EMEA, ICH and Ph.Eur.
- Applications for Marketing Authorisations,
- Paediatric Investigation Plans,
- Clinical Trials and Orphan Drug Designation
- The content of a marketing authorization application
- EU registration procedures
- Scientific advice from CHMP and national authorities
- Orphan Medicinal products
- Other relevant applications

Learning Activities and Teaching Methods:

Teaching material including PowerPoint presentations with extended descriptions and explanations, asynchronous video presentations, additional readings (journal articles and e-books), access to additional videos and commercials related to the course, synchronous

meetings (WebEx), forums, chats, quizzes, case studies and other formative and summative assessments.

Assessment Methods:

Continuous Assessment (assignments), Final Exam

Required Textbooks / Readings:

Title	Author(s)	Publisher	Year	ISBN
Access to Medicine Versus Test Data Exclusivity: Safeguarding Flexibilities Under International Law, Owais H. Shaikh Pages : 256 pages Publisher : r 2016-07-26		Springe		9783662496541
Fundamentals of EU Regulatory Affairs, 7th Edition, Pamela Jones (Ed.)				
Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices,	J. Tobin, G. Walsh,	Wiley-Blackwell,	2008	
EudraBook V1 - May 2015, Compendium of EU pharmaceutical law Author(s): Directorate-General for Health and Food Safety (European Commission			2015	