UNIVERSITY of NICOSIA

Course Syllabus

Course Code	Course Title	ECTS Credits
PHAR-602	The DRA Professional	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	Maria Prapopoulou Sylvana Papaioannou	1st
Mode of Delivery	**Work Placement**	**Corequisites**
Distance Learning	NA	NA

Course Objectives:

The Drug Regulatory Affairs (DRA) professionals play critical roles in the pharmaceutical industry because they are concerned about the healthcare product's lifecycle, they provide strategic, tactical and operational direction and support. They provide these expertise within regulations to expedite the development and delivery of safe and effective healthcare products to individuals around the world. The role of a DRA professional is

- to develop and execute a regulatory strategy to ensure that the collective efforts of the drug development team results in a product that is approvable by global regulators but is also differentiated from the competition in some way
- to ensure that the company's activities, from non-clinical research through to advertising and promotion, are conducted in accordance with the regulations and guidelines established by regulatory authorities

The aim of the course is to provide a comprehensive overview of roles and responsibilities of the DRA professional within a pharmaceutical organisation, as these begin right from development of a product to making, marketing and post marketing strategies.

By the end of this course, students will be able to make plans for and discuss roles and responsibilities of a DRA Professional

Learning Outcomes:

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

1. Understand and discuss the history, evolution and future of DRA professionals
2. Explain and discuss the role and responsibilities of DRA professionals in all aspects of a drug development process and product life cycle management
3. Explain and discuss how quality build into daily activities may improve performance and may result in faster submissions and approvals of drugs, biologics and medical devices
4. Explain and discuss the role of DRA professionals in regulatory control of Clinical Operations
5. Explain and discuss how quality aspects influence on regulatory affairs, the basic issues of Good Regulatory Practice (GRP), including polices processes standards and expectations to DRA professionals as specialists, coordinators, and trouble-shooters, are also included
6. Discuss communication and cooperation skills of DRA professionals

Course Content:

- History, Evolution and Future of the Regulatory profession
- Role and Responsibilities of a DRA professional in Drug Development and PLC management
- Compliance with EU/national regulations
- Regulatory Strategic Planning Prior to Initial Marketing Authorization
- Regulatory Submissions: Drugs and Biologics
- Regulatory Submissions: Medical Devices
- Quality Management and Inspections
- Basic issues of Good Regulatory Practice (GRP) in polices, processes and standards
- Expectations to Regulatory Affairs Professionals as Specialists, Coordinators and Trouble shooters

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
Pharmaceutical Competitive Intelligence for the Regulatory Affairs Professional ' Springer Briefs in Pharmaceutical Science & Drug Development,	Huml, R.A.'	Springer-Verlag	2016	9781461436812
'6 Essential Skills of a Regulatory Affairs professional', , available at site:	William Wei Lim Chin	Catalena Pharma Solutions	2014	https://www.linkedin.com/pulse/20140730184407-22974881-6-essential-skills-of-a-regulatory-affairs-professional (Accessed: 07Dec2017)
'FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics', Third Edition,	Pisano D.J., Mantus D.	Informa Healthcare,	2014	9781841849195