UNIVERSITY of NICOSIA

Course Syllabus

Course Code	Course Title	ECTS Credits
PHAR-605	Regulatory Strategy and Marketing Applications for new Drugs	7.5
Prerequisites	**Department**	**Semester**
None	Life and Health Sciences	2nd
Type of Course	**Field**	**Language of Instruction**
Required	Pharmacy	English
Level of Course	**Lecturer(s)**	**Year of Study**
2nd Cycle	Maria Prapopoulou	1st
Mode of Delivery	**Work Placement**	**Co-requisites**
Distance Learning	NA	NA

Course Objectives:

Regulatory strategy encompasses a wide range of activities and disciplines. However, how strategy is defined and implemented by each regulatory professional varies across the profession. Regulatory strategy could be seen as the adaptations a company makes to move its product from development to marketing approval. A strategy document would therefore be an organized meld of all the facets of drug development from pre-IND through NDA and into commercialization that have been agreed upon by multiple stakeholders.

The aim of the course is to provide a comprehensive overview of regulatory strategic considerations and an understanding of the role of Regulatory Affairs Professionals in drug development in identifying key factors in the development of regulatory strategies, consultations with authorities, intellectual property rights and compilation of the application dossier.

By the end of this course, students will be able to make strategic considerations regarding regulatory plans and decisions within pharmaceutical drug development and to understand the components of a marketing application dossier.

Learning Outcomes:

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

1. Evaluate the role of regulatory professionals in project teams
2. Revise the elements of strategic regulatory considerations

3. Select and apply appropriate regulatory clinical development / study requirements according to the proposed use of the medicinal product
4. Analyze and consider strengths and weaknesses of a product in order to develop regulatory strategies and target product profile.
5. Evaluate opportunities for alternative approaches, compared with conventional approaches, to medicines developments
6. Identify regulatory and business considerations which may drive the decision-making process during medicines development and assess their impact.
7. Manage strategic considerations for specific product types/ patient populations
8. Compile the marketing application dossier

Course Content:

- Managing the Contribution of Regulatory Affairs to Product Development, Maintenance and Commercialisation
- Strategic Planning in Regulatory Affairs
- Regulatory Strategy for a New Active Substance: Nonclinical Development
- Regulatory Strategy for a New Active Substance: Global Clinical
- Regulatory Strategic Planning and Life Cycle Management after Initial Marketing Authorization
- Regulatory Strategy: The Market Place
- Regulatory Intelligence
- Development of the Drug Development Plan (GAP analysis)
- Regulatory Submission Step
- Intellectual Property Rights
- Pricing and Reimbursement negotiation in EU
- Preparation of the application dossier
- Module1: Administrative information and prescribing information
- Module 2: Common technical document summaries
- Module 3: Quality
- Module 4: Non – clinical study reports
- Module 5: Clinical study reports

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
The Importance of Developing a Global Regulatory Strategy Towards the Goal of Registration, available at site: https://www.slideshare.net/MarcusEvansPharma/the-importance-of-developing-a-global-regulatory-strategy-towards-the-goal-of-registration-carlos-langezaal-eisai-inc (accessed: 07/12/17)	Langeza C		2011	
Management of regulatory influences on corporate strategy and structure'	Frankenberger S	Deutscher Universität sverlag	2006	978-3-8350-9350-8