UNIVERSITY of NICOSIA

Course Syllabus

Course Code	Course Title	ECTS Credits
PHAR-617	Regulatory Strategy and Marketing Applications for New Medical Products	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	Drs Prapopoulou, Calabrese, Liaras, Koulourou, Zacharia	1st
Mode of Delivery	**Work Placement**	**Corequisites**
e-learning	--	None

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:

- Evaluate the role of regulatory professionals in project teams
- Select and apply appropriate regulatory clinical development / study requirements

according to the proposed use of the medicinal product

- Analyze and consider strengths and weaknesses of a product in order to develop regulatory strategies and target product profile.
- Evaluate opportunities for alternative approaches, compared with conventional approaches, to medicines developments
- Recognise regulatory and business considerations which may drive the decision-making process during medicines development and assess their impact.
- Assess strategic considerations for specific product types/ patient populations
- 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
- Intro to 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 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
Regulatory Strategy 101'	Brown-Tuttle M.	Regulatory Affairs Focus	2012	
Foundation review: Nonclinical development of biopharmaceutical	Baumann A		2009	Drug Discovery Today, Volume 14, Numbers 23/24 Dec
Non-clinical studies in the process of new drug development – Parts I and II	Calixto et al.		2016	Brazilian Journal of Medical and Biological Research (2016).
How to create, submit and withdraw a CTA. CTIS Training Programme – Module 10 – Version 1.1.		EMA (European Medicines Agency),	2021	
Handbook for good clinical research practice (GCP) : guidance for implementation.		WHO (World Health Organization	2005	92 4 159392 X

EU Pricing & Reimbursement Pricing & reimbursement schemes in major European countries.		Hogan Lovess.	2014	
Health policy studies Pharmaceutical Pricing Policies in Global Market. Chapters 3 and 5		OECD	2008	9789264044159
Drugs from discovery to Approval, 3rd Edition, Chapters 7 to 9,	Rick NG	Wiley-Blackwell	2015	9780470195109
Regulatory Intelligence and Policy: Shaping the Global Landscape. Regulatory Intelligence and Policy, Vol. 2, No. 4,		RAPS	2019	
Guideline on good pharmacovigilance practices (GVP) Module XVI – Risk minimisation measures: selection of tools and effectiveness indicators	EMA	EMA	2017	
Eudralex Volume 4 EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use. Part 1 Chapter 8: Complaints, Quality Defects and Product Recalls		EU		

International Standards for Clinical Trial Registries – Version 3.0		WHO (World Health Organization)	2018	