UNIVERSITY of NICOSIA

Course Syllabus

Course Code	Course Title	ECTS Credits
PHAR-627	International Regulatory Harmonization	10
Prerequisites	**Department**	**Semester**
None	Health Sciences	Fall
Type of Course	**Field**	**Language of Instruction**
Elective	Pharmacy	English
Level of Course	**Lecturer(s)**	**Year of Study**
2nd Cycle	Drs, Mourelatou, Zampatis, Galatou, Prapopoulou, Savsek	2nd
Mode of Delivery	**Work Placement**	**Corequisites**
e-learning	--	none

Course Objectives:

The expansion of global markets has resulted in increasing regulatory demands for the pharmaceutical industry. More and more pharmaceutical companies are expanding their activities and are trying to establish their presence in many regions and countries. As a result they are facing the challenge of having to cope with diverse regulatory requirements and operating standards.
The aim of the course is to provide an overview of the different regulatory agencies and regulations applied in major international markets for pharmaceutical products and medical devices, such as the United States of America, Canada, Japan and BRIC countries. The differences between these countries and the European Union in terms of pharmaceutical legislation will be discussed. Moreover, international harmonization efforts and global collaboration are going to be explored and the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines are going to be examined.
By the end of this course, students will be able to apply knowledge of international regulations in order to plan a global regulatory strategy for product development for international markets.

Learning Outcomes:

After completion of this course, students will be able to:

- Interpret the role of both national agencies and international bodies in the regulation of pharmaceutical products and medical devices.

- Comprehend the role of International Conference on Harmonisation (ICH) in medicines regulation.
- Compare and contrast the pharmaceutical product and medical device regulations implemented to international markets.
- Distinguish the principles applied in the European Union compared to provisions implemented in other countries.
- Assess the documentation required for application and approval as well as labeling requirements in international markets.
- Critically reflect upon global medicines legislation and guidelines.

Course Content:

- Historical overview of the development of pharmaceutical laws and regulations worldwide (EU, US and Japan).
- International Conference of Harmonization (ICH): role, structure procedures, and Common Technical Document (CTD) requirements.
- Role of World Health Organization (WHO) in the international harmonization process.
- Regulatory framework in the US, Canada, Japan and BRIC countries.
- Overview of pre-market and dossier documentation requirements in international markets.
- FDA Drug Approval, Regulation and Compliance procedures.
- Overview of GxPs in the US.
- Regulation of Advertising, Promotion and Labeling in the US.
- Differences between US and EU requirements for the manufacture and control of pharmaceutical products and medical devices.
- Annual reporting requirements, changes to approved marketing applications, post-marketing adverse reaction reporting, GMP inspections, product recalls, and risk management.

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
International Cooperation, Convergence and Harmonization of Pharmaceutical Regulations, A Global Perspective.	Lezotre, P. L.	Elsevier.	2013	9780128005699
International Pharmaceutical Product Registration.	Cartwright, A. C., Matthews, B, R	CRC Press.	2016	9781420081831
Historical Overview of Pharmaceutical Industry and Drug Regulatory Affairs	Hasumati Rahalkar	Pharmaceut Reg Affairs S11-002	2012	
Medical Devices Regulations, Standards and Practices..	Seeram Ramakrishna Lingling Tian, Charlene Wang Susan Liao and Wee Eong Teo	Elservier	2015	978-0-08-100289-6/ 9780081002919
E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry.		FDA	2018	
OECD SERIES ON PRINCIPLES OF GOOD LABORATORY PRACTICE AND COMPLIANCE MONITORING		OECD	2015	ISSN: 2077785X https://doi.org/10.1787/2077785x

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FDA Regulatory Affairs. Third Edition..	David Mantus Douglas J. Pisano	CRC Press	2014	9781841849201