UNIVERSITY of NICOSIA

Course Syllabus

Course Code	Course Title	ECTS Credits
PHAR-623	Regulation of Medical Devices	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	Gianpiero Calabrese/ Maria Prapopoulou, Zacharia	2nd
Mode of Delivery	**Work Placement**	**Corequisites**
e-learning	--	None

Course Objectives:

To provide a comprehensive insight of the regulatory control of medical devices, particularly in the EU, in order to offer effective practical advice on the implementation of medical device legislation throughout the life cycle of a medical device.

Learning Outcomes:

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

- Describe the rational for a regulatory framework for the medical devices and explain legislation of medical devices by identifying the aspects of Multilevel Regulation applied to medical devices in Europe
- Describe the responsibilities of the stakeholders in the process of developing, marketing, selling and using a medical device and explain legislation of drug device combinations
- Define and classify medical devices
- Distinguish conformity assessment routes and identify key quality, safety and performance requirements to CE Mark a device in the EU
- Describe the application of quality management systems and quality standards and summarize how medical devices are regulated in other key markets

Course Content:

• The changing legislative environment in the EU: from a directive to a regulation

• Collaboration at European level

• Notified bodies, Competent authorities and the European Commission

• Medical Device classification

• Quality management systems, standards and essential requirements

• Clinical evaluation and investigation

• Risk management, post-market requirements and vigilance

• The content of a technical file of a medical device

• Drug-device borderline and combination products

• In-vitro diagnostics

Moderated Tutorials:

- Medical Device Case Study: Explanation of Methodological Choices

- Case Study of Regulatory Uncertainty in CE marking of medical devices in Europe

- Case Study on Borderline Medical Products in Europe

- - Case study of a Joint Actions at European level

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
European Regulation of Medical Devices and Pharmaceuticals	Chowdhury Nupur	Springer	2014	978-3-319-04594-813
Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC		EC	2017	