Course Unit	New product development and regulation			Field of study	Health		
Master in	Applied Health Sciences - Biotechnology			School	School of Health		
Academic Year	2023/2024	Year of study	1	Level	2-1	ECTS credits	4.0
Type	Semestral	Semester	1	Code	5055-669-1105-00-23		

Workload (hours)	108	Contact hours	T	TP	PL	TC	S	E	OT	O
			-	-	-	-	-	-	-	38

T - Lectures; TP - Lectures and problem-solving; PL - Problem-solving, project or laboratory; TC - Fieldwork; S - Seminar; E - Placement; OT - Tutorial; O - Other

Name(s) of lecturer(s): Isabel Cristina Jornalo Freire Pinto

Learning outcomes and competences

At the end of the course unit the learner is expected to be able to:
1. Know the regulatory framework of medicines and health products at national anda european level
2. Know and realise the importance of the different stages of research and development of new medicines and health products, and ethical issues
3. Identify the different types of Marketing Authorization (MA) procedures of medicinal products in Europe
4. Develop skills of organization and evaluation of information and documents necessary for registration of new medicines and new health products
5. Acquire capacity of planning for surveillance and risk management of health products
6. Develop de capacity of self-learning, research and choice of appropriate information
7. Demonstrate adequate synthesis and communication skills

Prerequisites

Not applicable

Course contents

1-Regulatory authorities of medicines and health products in Portugal and Europe 2-Investigation and industrial property 3-Investigation and development of new medicines 4-Investigation and development of new health products

Course contents (extended version)

1. Regulatory authorities of medicines and health products in Portugal and Europe
2. Investigation and industrial property
3. Investigation and development of new medicines
   - Chemical and pharmaceutical development
   - Preclinical studies
   - Clinical trials
   - Marketing Authorization Procedures
   - Common Technical Document
   - Regulatory and ethical aspects at different stages of research and development
4. Investigation and development of new health products
   - Innovation and research of new health products
   - Classification of different health products and main regulatory aspects
   - Procedure for registration and placing on the market of new health products
   - Surveillance and risk management plans

Recommended reading

1. EudraLex - Pharmaceutical Legislation Notice to applicants and regulatory guidelines medicinal products for human use
2. L46/2004 (L21/2014); DL102/2007-Dir2005/28/CE; L67/98 (L103/2015)-Dir95/46/CE; Port1005/92, Rec2007/526/CE; RegC 1/2005; DL265/2007; DL176/2006 (L51/2014); Port214/2015; DL307/2007 (DL75/2016).
3. Legislação farmacêutica e de produtos de saúde disponível em: www. infarmed. pt; http: //www.ema.europa.eu/ema/; http: //www. ich. org/home. html; www. dgav. min-agricultura. pt; http: //www. ceic. pt
4. CIOMS, WHO (2002). International Ethical Guidelines for Biomedical Research Involving Human Subjects. Geneva. ISBN 92 9036 075 5
5. Documentos da EMA, Infarmed, UE, CEIC e de outros organismos internacionais

Teaching and learning methods

The teaching methodologies include typologies: T, TP, TC, OT. The theoretical themes will be approached in a theoretical-practical context in which practical exercises will be proposed with consultation of the regulatory entities websites. Official documents will be analyzed. In TC and OT classes students will organize DTC or FIP modules. Teaching in collaboration with IPG, using videoconferencing

Assessment methods

- Unique alternative - (Regular, Student Worker) (Final, Supplementary, Special)
  - Work Discussion - 30% (Individual written work (minimum grade of 8. 0, according to Pedagogical Regulation))
  - Final Written Exam - 70% ((minimum grade of 8. 0, according to Pedagogical Regulation))

Language of instruction

Portuguese

Electronic validation

Isabel Cristina Jornalo Freire Pinto	Ana Maria Geraldes Rodrigues Pereira	Luis Migue Fernandes Nascimento	Adília Maria Pires da Silva Fernandes
21-11-2023	22-12-2023	22-12-2023	03-01-2024