Study Plan

School: School of Health and Human Development
Degree: *** TRANSLATE ME: Pós-Graduação ***
Course: Drug and Medical Device Life Cycles (cód. 751)

Specialization *** TRANSLATE ME: Ciclos de Vida do Medicamento e do Dispositivo Médico ***

1st Year - 1st Semester
Specialization * TRANSLATE ME: Ciclos de Vida do Medicamento e do Dispositivo Médico *****

Component code	Name	Scientific Area Field	ECTS	Duration	Hours
CMS14598O	Introduction to the Medicine and Medical Devices Life Cycles	*** TRANSLATE ME: Ciências Farmacêuticas ***	3	Semester	78
CMS14602O	Development of Medicines and Medical Devices	*** TRANSLATE ME: Ciências Farmacêuticas ***	3	Semester	78
CMS14611O	Scientific and Technical Assessment	*** TRANSLATE ME: Ciências Farmacêuticas ***	3	Semester	78
CMS14609O	Market Introduction Processes	*** TRANSLATE ME: Ciências Farmacêuticas ***	3	Semester	78
CMS14601O	Seminars in Pharmaceuticals and Medical Devices Life Cycle I	*** TRANSLATE ME: Ciências Farmacêuticas ***	3	Semester	78

1st Year - 2nd Semester
Specialization * TRANSLATE ME: Ciclos de Vida do Medicamento e do Dispositivo Médico *****

Component code	Name	Scientific Area Field	ECTS	Duration	Hours
CMS14605O	Patient Preferences in Decision Making	*** TRANSLATE ME: Ciências Farmacêuticas ***	3	Semester	78
CMS14608O	Medicines and Medical Devices Risk Management	*** TRANSLATE ME: Ciências Farmacêuticas ***	3	Semester	78
CMS14599O	Pharmacoepidemiological Methods and Techniques	*** TRANSLATE ME: Ciências Farmacêuticas ***	3	Semester	78
CMS14600O	Environment, Pharmaceuticals and Medical Devices	*** TRANSLATE ME: Ciências Farmacêuticas ***	3	Semester	78
CMS14610O	Seminars in Pharmaceuticals and Medical Devices Life Cycle II	*** TRANSLATE ME: Ciências Farmacêuticas ***	3	Semester	78

Specialization *** TRANSLATE ME: do Desenvolvimento à Introdução no Mercado ***

1st Year - 1st Semester
Specialization * TRANSLATE ME: do Desenvolvimento à Introdução no Mercado *****

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CMS14611O	Scientific and Technical Assessment	*** TRANSLATE ME: Ciências Farmacêuticas ***	3	Semester	78
CMS14609O	Market Introduction Processes	*** TRANSLATE ME: Ciências Farmacêuticas ***	3	Semester	78

Specialization *** TRANSLATE ME: Pós-Introdução no Mercado ***

1st Year - 1st Semester
Specialization * TRANSLATE ME: Pós-Introdução no Mercado *****

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CMS14598O	Introduction to the Medicine and Medical Devices Life Cycles	*** TRANSLATE ME: Ciências Farmacêuticas ***	3	Semester	78

1st Year - 2nd Semester
Specialization * TRANSLATE ME: Pós-Introdução no Mercado *****

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CMS14600O	Environment, Pharmaceuticals and Medical Devices	*** TRANSLATE ME: Ciências Farmacêuticas ***	3	Semester	78

Conditions for obtaining the Degree:

*** TRANSLATE ME: Para a conclusão do curso de Pós-Graduação em Ciclos de Vida do Medicamento e do Dispositivo Médico e obtenção do respetivo Diploma, o estudante tem de obter aproveitamento às uc's do 1º e 2º semestre

1º Ano

1º semestre

5 Uc's obrigatorias - 15 ECTS

2º semestre

5 Uc's obrigatorias - 15 ECTS

Os estudantes que obtiverem aproveitamento às 4 primeiras uc's do 1º semestre (excluindo a uc Seminários em Ciclos de Vida do Medicamentos e do Dispositivo Médico I) num total de 12 ECTS, obterão um certificado de Curso de curta duração em Ciclos de Vida do Medicamento e do Dispositivo Médico: do Desenvolvimento à Introdução no Mercado

Os estudantes que obtiverem aproveitamento à primeira uc's do 1º semestre (Introdução aos Ciclos de Vida do Medicamento e do Dispositivo Médico) e às 4 primeiras uc's do 2º semestre (excluindo a uc Seminários em Ciclos de Vida do Medicamentos e do Dispositivo Médico II) num total de 15 ECTS, obterão um certificado de Curso de curta duração em Ciclos de Vida do Medicamento e do Dispositivo Médico: Pós-Introdução no Mercado

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Program Contents

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Introduction to the Medicine and Medical Devices Life Cycles (CMS14598O)

1. General approach to medicines and medical device life cycles: the steps, regulation and regulators;
2. Medicines:
a. Concept of drug and medicine;
b. How they are classified;
c. Who participates in the life cycle of the medicine;
d. Market data;
e. Regulatory sources;
f. International, European and national authorities;
3. Medical device:
a. What is a medical device;
b. How they are classified;
c. Who participates in the life cycle of the medical device;
d. Market data;
e. Regulatory sources;
f. International, European and national authorities.
4. Workshop: Differences and similarities between medicines and medical devices throughout their life cycles

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Development of Medicines and Medical Devices (CMS14602O)

1. Development of medicines:
a. Discovery of new drugs;
b. Design;
c. Development of new molecules with therapeutic potential;
d. Development of biopharmaceuticals
e. Patents;
2. Development of medical devices:
a. Design and value engineering;
b. Manufacturing, assembly, packaging and testing of combination products;
c. Good manufacturing practices for medical devices (ISO 13485).
3. Workshop: common ground/differentiation.

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Scientific and Technical Assessment (CMS14611O)

1. Preclinical and clinical trials:
a. Historical aspects.
b. Ethical aspects.
c. Classification.
d. Operationalization.
e. National and European regulations (incl. ICH).
f. Stakeholders (researcher, sponsor, trial sites, CRO's, competent authorities, CEIC).
2. Scientific and technical assessment of medicines:
g. Pre-clinical evaluation: pre-clinical trials.
h. Clinical evaluation: clinical trials.
i. Bioavailability/bioequivalence assessment.
j. Pharmaceutical evaluation: quality tests of the active substance, formulation and packaging.
3. Clinical assessment of medical devices:
k. Pre-clinical evaluation: pre-clinical trials.
l. Clinical assessment based on clinical data.
m. Functional assessment: in vitro diagnostic medical devices.
4. Common points/differentiation.

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Market Introduction Processes (CMS14609O)

1. PT and EU regulatory framework: medicines and medical devices.
2. National and European authorities.
3. Medicines for human use:

a. Marketing Authorization Procedures (MA) – EU and PT.
b. MA file (common technical document).
c. Modification and revocation of the MA file.
d. Adaptive pathways.
e. Priority medicines (PRIority MEDIcines, PRIME programme).
f. Generic and biosimilar medicines.

4. Medical devices:

a. Definition, classification, and demarcation of borders.
b. Competent authority notified body and associations.
c. CE marking.
d. Essential requirements and harmonized standards.
e. Supporting technical documentation.
f. Compliance assessment.
g. Conformity declaration.
h. Registration, encoding, traceability and unique identification.

5. Common points/different

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Seminars in Pharmaceuticals and Medical Devices Life Cycle I (CMS14601O)

This curricular unit has an open program, being taught in line with the research areas of the professors invited to participate. The seminars will address topics that will highlight recent advances in the area and its interdisciplinarity, the problems raised by development, manufacturing and end of life of Ps and MDs, the challenges faced by health professionals in their application and the methodologies developed to deal with these challenges. This rationale will continue in the Curricular Unit Seminars II. The seminars are:

- MDs in veterinary medicine.
- Medicines for veterinary use.
- Environment, resistance to antimicrobials and "one health".
- Fundamentals of ethics in clinical research.
- Frontier products.
- Sterilization of medical devices.
- MDs in the treatment/diagnosis of chronic diseases.
- Industrial and intellectual property.
- Pharmacogenomics: effectiveness and safety.
- Digital solutions and artificial intelligence.

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Patient Preferences in Decision Making (CMS14605O)

1. The patient preference concept;
2. Decision-making models;
3. The role of patient organizations;
4. Patient Preference Studies (PPS):

a. Methods;
b. Design;
ç. Application;

5. The use of patient preference:

a. Value generation;
b. Inclusion of patient preferences in decision-making in:

i. Industry;
ii. Regulatory entity;
iii. Health technologies assessment (HTA).

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Medicines and Medical Devices Risk Management (CMS14608O)

1. Concepts of risk management, assessment, and communication.
2. Quality management systems.
3. Pharmacovigilance:

a. The National Pharmacovigilance System.
b. National and international entities.
c. Regulatory aspects.
d. Passive (routine) and active (systematic).
e. Medicines safety assessment, periodic reporting, and arbitration procedures.
f. Risk management plans and measures.
g. Post-marketing studies (PASS and PAES).
h. Information sources.
i. Disclosure and communication.

4. Materiovigilance:

a. The. National Medical Device Surveillance System.
b. National and international entities.
c. Regulatory aspects.
d. Incident notification.
e. Medical devices safety assessment, periodic reporting, and arbitration procedures.
f. Post-marketing clinical follow-up requirements.
g. Post-marketing studies.
h. Information sources.
i. Disclosure and communication.

5. Patient safety: medication in the transition of care; in polymedication; and in risky situations.

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Pharmacoepidemiological Methods and Techniques (CMS14599O)

- Background – Epidemiology and pharmacoepidemiology: definition, problems, and methodologies.
- The pharmacoepidemiology in the medicine life cycle.
- Legal and ethical aspects of pharmacoepidemiologic research.
- Types of pharmacoepidemiologic studies: conceptual, methodological, and operational design. Limitations.
- Pharmacoepidemiology in assessing the safety and efficacy/effectiveness of drugs.

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Environment, Pharmaceuticals and Medical Devices (CMS14600O)

Drugs in the environment: Pharmaceutical active compounds (PhACs) and personal care products (PCPs) as contaminants; Exposure routes and effects of pharmaceutical products; Agrochemicals; Epigenetic effects; The "boomerang effect"; "Effluent Epidemiology" in the Screening of illicit drugs and pharmaceuticals; Drugs, emerging vectors and climate change; Ecopharmacovigilance; Drug elimination and environmental regulation in the European Union and North America; Methods for the control of drugs in the environment.

Medical devices in the environment: Design, production, use and end of life of medical devices; Medical Devices and Sustainability; Lifecycle assessment and ecodesign; Single-use devices and environmental impacts; Recycling, reuse and reprocessing of single-use devices; Reusable devices and environmental impacts; Polymeric materials and environmental impacts; Biopolymers and environmental impacts; Medical devices and climate change.

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Seminars in Pharmaceuticals and Medical Devices Life Cycle II (CMS14610O)

This curricular unit has an open program, being taught in line with the research areas of the invited experts and the teaching and non-teaching staff of the University. The addressed topics will highlight methods of evaluation, application, marketing, distribution, access and administration of Pharmaceuticals and Medical Devices, their framing within the NHS and with the patient. This rationale represents a sequence of the Curricular Unit "Seminars in Pharmaceuticals and Medical Devices Life Cycle I". The seminars planned are:

Technologies applied to health and sport;
Big Data Generation;
Economic evaluation of drugs;
Health technology assessment;
Certification of medicines and medical devices quality;
Access to therapeutic innovation;
Drug Marketing and Advertising;
Drug distribution;
The Portuguese National Health System;
Individual care plan.