Digital Winter School

Universidade do Porto

With the support of the Erasmus+ programme of the european union

"THE LAW, ECONOMICS & ENGINEERING OF ADVANCED MEDICAL TECHNOLOGIES"

17-28 JANUARY 2022

DEPARTMENT OF INFORMATION ENGINEERING
FACULTY OF ENGINEERING
KOSLIKER CENTER ON HEALTH TECHNOLOGY ASSESSMENT (CAHTA)

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OVERVIEW

A joint initiative of the Department of Information Engineering, the Department of Law, and the Research Center on Health Technology Assessment this winter school is part of the Jean Monnet Module European Health Law and Technology (EL&T), awarded in the framework of the Erasmus+ Programme (2018 - EAC-A02-2019-2019).

The School will provide participants with an advanced understanding of the scientific, legal, and economical framework of the development of advanced biotechnologies.

Its academic credits (in accordance with the ECTS) will be awarded upon successful completion of the Course, which requires the attendance of at least 90% of classes and a final examination. All classes will be taught in English.

Professionals, Master's degree students, PhD researchers with a background in legal or biotechnological disciplines are welcome to apply by 14 December 2021 exclusively HERE.

https://elate.pa.unipi.it/winter-school the law economics engineering of advanced medical technologies-17-28-january-2022/

Professionals, PhD researchers and master students with a background in legal, economics, and biomaginering are welcome to apply.

Academic Staff: C. De Maria, V. Caldeira, L. Pellegrini, E. Epicoco, G. Ferrannini, F. Corvi, S. Chiesa M. E. Lippi, S. Lazzini, S. Tallarico, G. Nitti.

Technological innovation in healthcare needs to conform to a complex normative matrix. In both legal and scientific education, it is essential to convey the importance of a cross-disciplinary approach to the development of technology and to provide the most relevant competencies to this field. This course - designed as an experiment in cross-fertilisation between Law, Economics, and Biomedical Engineering - offers a substantive introduction to these competences.

Participants will earn an understanding of the process of development, testing, marketing and diffusion of biomaginered medical devices, particularly within a European legal framework, with reference in particular to:

(i) rules liability risks, ensure compliance with relevant regulations, standards, and extract responsible research and innovation (RRI) requirements.

(ii) embed fundamental rights protection within the development process of biotechnological innovation from research to commercialisation.

(iii) adopt EPIs (electronic approach), identify the most appropriate business strategy and market placement.

Participants will join small cross-disciplinary teams. Each team will examine a case study, based on the problems faced by researchers and professionals in developing biotechnological applications.

All the activities will be held in line, on Microsoft Teams.

THE SCHOOL AT A GLANCE

WEEK 1
SAFETY-BY-DESIGN MEDICAL DEVICES

MORNING

DAY 1	DAY 2	DAY 3	DAY 4
INTRODUCTION CERTIFICATION OF MEDICAL DEVICES	STANDARDIZATION KEYNOTE 1: PRODUCT LIABILITY	RISK-BASED DESIGN KEYNOTE 2: GENOME EDITING	INFORMED CONSENT AND SAFETY REQUIREMENTS KEYNOTE 3: ARTIFICIAL INTELLIGENCE

AFTERNOON

DAY 1	DAY 2	DAY 3	DAY 4
TEAMBUILDING TEAMWORK	TEAMWORK	ATMP TEAMWORK	TEAMWORK INTERMEDIATE PRESENTATION 1

WEEK 2
MEDICAL DEVICE MARKET

MORNING

DAY 5	DAY 6	DAY 7	DAY 8	DAY 9
BUSINESS MODELS	STRATEGIC MARKETING KEYNOTE 5: SOCIAL IMPACT	OPERATIVE MARKETING KEYNOTE 6: SAO MARKETING - CASE STUDY 2	OWNERSHIP OF TISSUES AND DATA INTELLECTUAL PROPERTY RIGHT	THE LIABILITY FRAMEWORK KEYNOTE 7: EUROPEAN HEALTH UNION

AFTERNOON

DAY 5	DAY 6	DAY 7	DAY 8	DAY 9
KEYNOTE 4: SAO MARKETING - CASE STUDY 1 TEAMWORK	TEAMWORK	TEAMWORK INTERMEDIATE PRESENTATION 2	OPEN SOURCE MEDICAL DEVICES TEAMWORK	FINAL PRESENTATION

WEEK 1
SAFETY-BY-DESIGN MEDICAL DEVICES

Day 1 – Monday Jan 17 2022

TIME	TOPIC	SPEAKERS
9:30 – 10:00	Introduction	V. Caldeira, L. Pellegrini, C. De Maria, G. Nitti, M. Mancini
10:00 – 11:00	Fundamentals on EU legislation on healthcare	V. Caldeira
11:00 – 13:00	Medical Device Regulation 2017/745	C. De Maria
14:30 – 15:30	Project Based Learning and team Building	C. De Maria
15:30 – 18:30	Teamwork: selection and classification of a medical device	C. De Maria

Day 2 – Tuesday Jan 18 2022

TIME	TOPIC	SPEAKERS
10:00 – 11:00	Standardization: scope and rationale	E. Epicoco
11:00 – 13:00	Relevant standards for Medical Technologies	S. Chiesa, F. Corvi
12:00 – 13:00	Keynote 1: Product liability in the medical device sector EU regulation 2017/1128, Solvitur specific equals	S. Sofianelli (Studio Legale Sofianelli) G. Ferrannini (Sofianelli)
14:30 – 18:30	Teamwork: Identification of relevant standards	C. De Maria

Day 3 – Wednesday 19 Jan 2022

TIME	TOPIC	SPEAKERS
10:00 – 12:00	Risk-based design	L. Di Paolo (IMEDI)
12:00 – 13:00	Keynote 2: The Era of Precise Genome Editing	Y. Kadir (University of Pisa)
14:30 – 16:30	Advanced Therapy Medicinal Products	I. Chiesa, G. M. Fortunato
16:30 – 18:30	Teamwork: risk analysis	C. De Maria

Day 4 – Thursday 20 Jan 2022

TIME	TOPIC	SPEAKERS
10:00 – 12:00	Informed Consent and Safety Requirements	V. Caldeira
12:00 – 13:00	Keynote 3: Trustworthy AI	S. Kerda (University of Bologna), M. Bertolini (Scuola Sant'Anna)
14:30 – 16:30	Teamwork	C. De Maria
16:30 – 18:30	Intermediate presentation 1	C. De Maria

WEEK 2
MEDICAL DEVICE MARKET

Day 5 – Monday 24 Jan 2022

TIME	TOPIC	SPEAKERS
10:00 – 13:00	Business Models	L. Pellegrini, S. Lazzini
14:30 – 15:30	Keynote 4: Strategic & Operative Marketing in AAA Dental	D. Coppenol (AAA Dental)
16:30 – 18:30	Teamwork	L. Pellegrini, S. Lazzini, S. Tallarico

Day 6 – Tuesday 25 Jan 2022

TIME	TOPIC	SPEAKERS
10:00 – 12:00	Strategic Marketing	L. Pellegrini, S. Lazzini
12:00 – 13:00	Keynote 5: Social Impact of Medical Technologies	G. Ionori (Medtronic) "Pay What Matters"
14:30 – 18:30	Teamwork	L. Pellegrini, S. Lazzini, S. Tallarico

Day 7 – Wednesday 26 Jan 2022

TIME	TOPIC	SPEAKERS
10:00 – 12:00	Operative Marketing	L. Pellegrini, S. Lazzini
12:00 – 13:00	Keynote 6: Strategic Marketing in Brazil: Hedging	F. Corelli (Bonsai)
14:30 – 18:00	Teamwork	
18:00 – 18:30	Intermediate presentation 2	L. Pellegrini

Day 8 – Thursday 27 Jan 2022

TIME	TOPIC	SPEAKERS
10:00 – 11:30	Tissues and Data Ownership	V. Caldeira, M.E. Lippi
11:30 – 13:00	Intellectual property rights	M.E. Lippi
14:30 – 16:30	Open Source Medical Devices	M.E. Lippi, C. De Maria
16:30 – 18:30	Teamwork	

Day 9 – Friday 28 Jan 2022

TIME	TOPIC	SPEAKERS
10:00 – 12:00	The liability framework	E. Epicoco
12:00 – 13:00	Keynote 7: Towards a European Health Union: strengthening EU competences in a post-COVID scenario	M. Krichel (European Parliament, Research Service)
14:30 – 16:30	Teamwork	V. Caldeira
16:30 – 18:30	Final Presentations and closing remarks	V. Caldeira, L. Pellegrini, C. De Maria, G. Nitti, M. Mancini