COURSE OUTLINE

(1) GENERAL

SCHOOL	HEALTH AND CARE SCIENCES		
ACADEMIC UNIT	DEPARTMENTOF BIOMEDICAL SCIENCES		
LEVEL OF STUDIES	UNDERGRADUATE STUDIES		
COURSE CODE	7052	SEMESTER	7th
COURSE TITLE	Legislation of Cosmetics and Medical Devices		

INDEPENDENT TEACHING ACTIVITIES *if credits are awarded for separate components of the course, e.g. lectures, laboratory exercises, etc. If the credits are awarded for the whole of the course, give the weekly teaching hours and the total credits*	WEEKLY TEACHING HOURS	CREDITS
Teaching	3T	4
Add rows if necessary. The organisation of teaching and the teaching methods used are described in detail at (d).		

COURSE TYPE *general background, special background, specialised general knowledge, skills development*	
PREREQUISITE COURSES:	
LANGUAGE OF INSTRUCTION and EXAMINATIONS:	Greek
IS THE COURSE OFFERED TO ERASMUS STUDENTS	Yes
COURSE WEBSITE (URL)	https://eclass.teiath.gr/courses/AISTH144/

(2) LEARNING OUTCOMES

- *The aim of the course is for students to understand the basic principles of the legislative framework governing cosmetics and medical devices moving in Greece and is in line with the EU regulation. Furthermore, the course aims at understanding the rules and legislative obligations for the manufacture of cosmetic products in the industry, in accordance with the applicable requirements and regulations of the National Organization of Medicine (EOF) and the quality assurance systems, as well as medical devices, according to the National Center for Quality Evaluation & Technology in Health "EKAPTY".*
- *The aim of the course is to teach students the basic principles of the regulation of cosmetics, in accordance with the current legislation "European Regulation EC 1223/2009", regarding the notification, production, distribution, the way of market surveillance, the required pre-clinical and clinical studies and the legislative obligations of the responsible person, as well as that for Medical Devices (CE I, IIa, IIb, III) in accordance with Regulation (EU) 2017/745.*

After the end of the course students will be able to know:

- *The current legal framework (regulation) of cosmetics and medical devices*
- *The obligations of the responsible person, of distributor or representative (importer) of cosmetics & medical devices of the EU, as well as from third countries.*
- *The conditions for their legal and safe movement, in terms of labeling, ingredients, claims, clinical trials and safety of the final product, to the consumer.*
- *The basic legislative principles for the good manufacturing praxis in the industrial units (cosmetics & pharmaceutical factories)*
- *The requirements (conditions, possible penalties) of the authorities and the rules for ensuring the quality of the produced cosmetic products and medical devices.*
- *The proper observance of the necessary legal procedures and the documentation of the good manufacturing praxis(GMP) or distribution (GDP), during the market surveillance and the inspections.*
- *It will be able to understand and handle the current regulatory-legislative obligations-"Regulatory Affairs" cases in the cosmetics and medical device industry*

General Competences

Taking into consideration the general competences that the degree-holder must acquire (as these appear in the Diploma Supplement and appear below), at which of the following does the course aim?

Search for, analysis and synthesis of data and information, with the use of the necessary technology	*Project planning and management*
Adapting to new situations	*Respect for difference and multiculturalism*
Decision-making	*Respect for the natural environment*
Working independently	*Showing social, professional and ethical responsibility and sensitivity to gender issues*
Team work	*Criticism and self-criticism*
Working in an international environment	*Production of free, creative and inductive thinking*
Working in an interdisciplinary environment	*……*
Production of new research ideas	*Others…*
	…….

Autonomous work, Group work, work in an interdisciplinary environment, work in an international environment

(3) SYLLABUS

- Definition and interpretation of the cosmetic and medical device and the current legal framework. Separation of cosmetics and medical devices from other categories (medicines, food supplements, biocides, etc.).
- The Responsibility of the Responsible person for the compliance with the provisions of the regulation. Defining the obligations of the Responsible person and the distributor. Market Surveillance by EU Member States, prior to placing on the market.
- Requirements for the Notification of the product to the National Authorities (EOF, EKAPTY). Familiarity with the environment of the European Notification "Cosmetic Products Notification Portal"
- Labeling of cosmetics and medical devices. Correct indication of claims and their limits from claims that are unacceptable and misleading to the consumer.
- Risk assessment and safety assessment of cosmetic products. Calculations "Margin of Safety" of the components, according to the "NOAEL" index (Non Observed Adverse Effect Level) and assessment of the possible risks of raw materials, packaging materials and final products based on their physico-chemical and microbiological analysis -recommendation. Existence of contaminants, "impurities", dioxins, phthalates, genetically modified ingredients, heavy metals, etc.)
- Creation of a Product information file for cosmetics, according to EOF & the EU.
- Cosmeto-Vigilance . Necessary steps for handling, recording, evaluating and informing the competent authorities.
- Rules for classification of medical devices. Specific definitions of classification rules. Date of minimum durability. Distinction of CE I, CE IIa, CE IIb, CE III compliant products. Rules of application. Non-invasive and invasive technology products.
- Preclinical & Clinical Evaluation of the safety of medical devices. Collection and analysis of the necessary bibliographic data, laboratory or "in vivo" tests for the final assessment of safety to the consumer.
- Management and risk assessment in medical devices, in accordance with ISO 14971: 2007
- Creation and Approval of the product information file and the quality assurance system, according to ISO 13485: 2012, by the competent authorities (National Center for Quality Assessment and Health Technology).
- Management of Non-Compliant Products. Recalls (handling, traceability system, cooperation with authorities). Market Surveillance. Corrective actions and sanctions by the competent authorities.
- "SOP" (Standard Operating Procedures), which must be observed, evaluated, upgraded and governed by a legally integrated quality assurance system and assessment of a potential market risk.

(4) TEACHING and LEARNING METHODS - EVALUATION

DELIVERY *Face-to-face, Distance learning, etc.*	Face-to-face
USE OF INFORMATION AND COMMUNICATIONS TECHNOLOGY *Use of ICT in teaching, laboratory education, communication with students*	Use of ICT in teaching, learning process support through e-class

TEACHING METHODS

The manner and methods of teaching are described in detail.
Lectures, seminars, laboratory practice, fieldwork, study and analysis of bibliography, tutorials, placements, clinical practice, art workshop, interactive teaching, educational visits, project, essay writing, artistic creativity, etc.

The student's study hours for each learning activity are given as well as the hours of non-directed study according to the principles of the ECTS

Activity	*Semester workload*
Lectures	90
Course total	90

STUDENT PERFORMANCE EVALUATION

Description of the evaluation procedure

Language of evaluation, methods of evaluation, summative or conclusive, multiple choice questionnaires, short-answer questions, open-ended questions, problem solving, written work, essay/report, oral examination, public presentation, laboratory work, clinical examination of patient, art interpretation, other

Specifically-defined evaluation criteria are given, and if and where they are accessible to students.

Multiple choice, development, characterization of sentences as correct or incorrect, problem solving (100%)

(5) ATTACHED BIBLIOGRAPHY

- Suggested bibliography:

1. *Σημειώσεις Νομοθεσίας Καλλυντικών και Ιατροτεχνολογικών Προϊόντων, Σ. Παπαγεωργίου και Φ. Μέλλου, Πανεπιστήμιο Δυτ. Αττικής, 2018*

- Related academic journals:

2. *http//ec.europa.eu/consumers/cosmetics/cosing/*
3. *https://www.cosmeticseurope.eu/publications-cosmetics-europe-association/recommendations.html*
4. *https://www.fda.gov/Cosmetics/GuidanceRegulation/GuidanceDocumens/default.htm*
5. *http://ec.europa.eu/consumers/sectors/medical-devices/files/meddev/2_7_1rev_3_en.pdf*
6. *http://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf*
7. *https://echa.europa.eu/regulations/biocidal-products-regulation*
8. *https://circabc.europa.eu/sd/a/51ca9945-167d-411f-9763-92e634af9e1c/Biocides-2002-01%20*
9. *Manual on Borderline and Classification in the community regulation framework for medical devices Version 1.17 (09-2015)*
10. *https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_el*
11. *Good Manufacturing Practices for Pharmaceuticals, Sixth edition, Joseph D. Nally.*
12. *Good Laboratory Practice Regulations, Fourth Edition, Anne Sandy*