

Course guide

370035 - DIRTEC - Optical Shop Managing

Last modified: 04/07/2025

Unit in charge: Terrassa School of Optics and Optometry
Teaching unit: 731 - OO - Department of Optics and Optometry.

Degree: BACHELOR'S DEGREE IN OPTICS AND OPTOMETRY (Syllabus 2020). (Compulsory subject).

Academic year: 2025 **ECTS Credits:** 3.0 **Languages:** Catalan

LECTURER

Coordinating lecturer: Solà Parés, Ramon (Professor Associat <https://futur.upc.edu/RamonSolaPares>)

Others:

DEGREE COMPETENCES TO WHICH THE SUBJECT CONTRIBUTES

Specific:

CE14. (ENG) Comprendre els aspectes psicològics en la relació entre l'òptic-optometrista i el pacient. Conèixer el sistema sanitari espanyol i els aspectes bàsics relacionats amb la gestió dels serveis de salut, fonamentalment els que estiguin relacionats amb l'atenció i rehabilitació de la salut. Conèixer i aplicar les tècniques d'educació sanitària i els principals problemes genèrics de salut ocular. Conèixer els principis de salut i malaltia. Capacitat per actuar com agent d'atenció primària visual. Conèixer els fonaments i tècniques d'educació sanitària i els principals programes genèrics de salut als que l'opotmetrista ha de contribuir des del seu àmbit d'actuació.

CE25. (ENG) Conèixer els aspectes legals i psicosocials de la professió

Generical:

CG10. Communicate treatment indications of visual health and their conclusions to the patient, relatives and other professionals involved in the patient's care, adapting to the sociocultural characteristics of each person.

CG18. (ENG) Adquirir la capacitat per a realitzar una gestió clínica centrada en el pacient, el l'economia de la salut i en l'ús eficient dels recursos sanitaris, així com la gestió eficaç de la documentació clínica amb especial atenció a la confidencialitat.

Transversal:

CT1. (ENG) Emprenedoria i innovació. Conèixer i entendre la organització d'una empresa i les ciències que regeixen la seva activitat; tenir capacitat per entendre les normes laborals i les relacions entre la planificació, les estratègies industrials i comercials, la qualitat i el benefici.

CT5. Efficient use of information resources. To manage data and technical and scientific information acquisition, organization, analysis and visualization and to provide a critical appraisal of the results of this management

TEACHING METHODOLOGY

MD1 - Participatory expository class of theoretical and practical contents

MD3 - Practical resolution class, with the participation of students, of practical cases and/or exercises related to the contents of the subject

MD5 - Reading teaching material, texts and articles related to the contents of the subject (mandatory attendance on the days indicated at the beginning of the course)

LEARNING OBJECTIVES OF THE SUBJECT

- Determine whether the medical devices involved in the field of an optician's establishment comply with the UNE regulations on ophthalmic optics and eye protection.
- To understand the role of the Optician-Optometrist as a primary eye health care professional, and specifically in regulatory aspects
- Knowledge of the obligations of the technical director of an optical health establishment and be competent in the exercise of the same.
- Knowledge and competence in the application of the professional code of ethics, as it relates to regulatory aspects.
- Knowledge of the health regulations that apply to health products for use, prescription, dispensing/sale in an optical health establishment

STUDY LOAD

Type	Hours	Percentage
Hours medium group	30,0	40.00
Self study	45,0	60.00

Total learning time: 75 h

CONTENTS

Regional, national and European regulations of medical devices

Description:

Introduce future visual and eye health professionals to aspects related to the regulatory responsibility of the technical directors of an optical health establishment
Ethical-professional fundamentals in regulatory concepts and the role of technical managers

Specific objectives:

- Know the regulations and the regulatory framework that is applicable to medical devices in the field of visual and ocular health
- Regulations of application in optical health establishments
- Rights and duties of the technical director of an optical establishment

Related activities:

- Identification of current knowledge of the health regulations that affect the technical directors of the optical establishments
- Field work with the UNE standards that are applicable in the visual and ocular health sector (CTN45)

Full-or-part-time: 75h

Theory classes: 30h

Guided activities: 15h

Self study : 30h

ACTIVITIES

WORK WITH APPLICATION STANDARDS IN THE VISUAL HEALTH SECTOR. REGULATIONS FOR THE IMPORT AND DISTRIBUTION OF VISUAL HEALTH PRODUCTS.

Description:

Classification and knowledge of the basic aspects of the ISO standards applicable in the visual and ocular health sector.
Know the AEMPS guidelines regarding the import and distribution of eye care products.

Specific objectives:

- Know how to look for ISO standards
- Identify the parts of the rules
- Relate ISO standards
- Know the requirements for marketing medical devices in Spain

Material:

Data base AENOR in UPC Bibliotecnia

<https://www.aemps.gob.es/productosSanitarios/docs/2025/guia-comercializacion-ps-2025.pdf>

Delivery:

Individual or groupal work

Full-or-part-time: 15h

Guided activities: 15h

IDENTIFICATION CURRENT STATUS TECHNICAL DIRECTORS OF OPTIC HEALTH ESTABLISHMENTS IN CATALONIA

Full-or-part-time: 5h

Guided activities: 5h

EUROPEAN DIPLOMA IN OPTOMETRY COMPETENCES

Description:

This module contributes to the European Diploma in Optometry competencies indicated in the following link:

https://drive.google.com/drive/folders/1bwmHBsvkrGnY63DfXAnWZB_i0I2pXa-I?usp=drive_link

GRADING SYSTEM

TEST TYPE EXAM (40%)

INDIVIDUAL/GROUP WORK (50%)

PARTICIPATION FORUM ATENEA (10%)

RE-EVALUATION: IN THE CASE OF OBTAINING A GRADE, IN THE PROPOSED GRADING SYSTEM, HIGHER THAN 3.5 BUT LESS THAN 5, THERE WILL BE THE OPTION TO TAKE A TEST (WITH INDIVIDUAL OR GRUPAL WORK PRESENTED).

EVALUATION OF TRANSVERSAL COMPETENCES:

CT1 AND CT5: INCLUDED IN INDIVIDUAL/GROUP WORK

EXAMINATION RULES.

MANDATORY PRESENTATION OF INDIVIDUAL/GROUP WORK

PARTICIPATION IN THE ATENEA FORUM OF THE SUBJECT

MANDATORY PRESENTATION OF THE DOCUMENT ON TRANSVERSAL COMPETENCES

IMPORTANT:

In the case of partial or total copying in any of the subject evaluations, what is provided for in the Academic Regulations for undergraduate and master's studies at the UPC will be applied: "Irregular actions that may lead to a significant variation in the grade of one or more students constitute a fraudulent performance of an evaluation act. This action entails a descriptive grade of failure and a numerical rating of 0 in the evaluation and subject report, without prejudice to the disciplinary process that may arise as a consequence of the acts carried out. If the student considers the decision incorrect, he or she may file a complaint with the director or dean of the teaching center and, if the response is not satisfactory, he or she may file an appeal with the rector. The total or partial reproduction of academic or research works, or their use for any other purpose, must have the explicit authorization of the authors. It is the responsibility of the director or dean of the teaching center to resolve allegations regarding aspects not included in the regulations.

BIBLIOGRAPHY

Basic:

- Casado, María. Materiales de bioética y derecho. Barcelona: Cedecs, 1996. ISBN 8489171483.
- Codi deontològic de l'òptic optometrista [on line]. Madrid: Grupo ICM Comunicación, 2019 [Consultation: 31/07/2024]. Available on: <https://www.cnoo.es/codigo-deontologico>. ISBN 9788412060843.
- Sánchez de León Pérez, Enrique [et al.]. Diccionario técnico jurídico del medicamento y productos sanitarios. Cizur Menor, Navarra: Aranzadi, 2012. ISBN 97888490142622.
- Gili Saldaña, Marian. El producto sanitario defectuoso en derecho español. Barcelona: Atelier, 2008. ISBN 9788496758360.
- Melvin, Tom; Torre, Marina. "New medical device regulations: the regulator's view". EFORT open reviews [on line]. 2019, vol. 4, núm. 6, p. 351-356 [Consultation: 15/02/2023]. Available on: <https://doi.org/10.1302/2058-5241.4.180061>.
- Aronson, J. K.; Heneghan, C.; Ferner, R. E. "Medical devices: definition, classification and regulatory implications". Drug safety [on line]. 2020, núm. 43, p. 83-93 [Consultation: 15/02/2023]. Available on: <https://link-springer-com.recursos.biblioteca.upc.edu/article/10.1007/s40264-019-00878-3>.

RESOURCES

Audiovisual material:

- Nom recurs. Resource
- Nom recurs. Resource

Other resources:

- MDR Regulation 745/2017 (<https://eur-lex.europa.eu/legal-content/ES/TXT/PDF/?uri=CELEX:32017R0745&from=DA>). /> - Code of ethics for optometrists.
- AENOR DB UPC Library.
- RD 1591/2009 (<https://www.boe.es/buscar/doc.php?id=BOE-A-2009-17606>). /> - RD 192/2023 (<https://www.boe.es/buscar/doc.php?id=BOE-A-2023-7416>). /> - Clinical History Law 21/2000 (<https://portaljuridic.gencat.cat/ca/document-del-pjur/?documentId=246194>). - Various AEMPS documents.
- White Paper on Health Professions in Catalonia (<http://hdl.handle.net/11351/1461>). /> - https://ec.europa.eu/health/medical-devices-sector_en. />