



Course Unit: 15736 – Quality Management and Organization

Year 3 Semester 6 ISCED Code: 711 ECTS: 3,0

Type of Course Unit: Compulsory Delivery Mode: Face-to-face Language of Instruction: Portuguese

COURSE COORDINATOR: Maria Adelaide Araújo Almeida

HOURS OF WORK

TOTAL HOURS	Contact Hours								Hours in autonomous work
	Theory	Theory and practice	Practical and laboratory work	Field work	Seminar	Internship	Tutorial guidance	Other	
75		45							35

Prerequisites (if applicable): Not applicable

LEARNING OUTCOMES (knowledge, skills and competence)

The aim of this course is to transmit knowledge related to the organization and quality management in accordance with the requirements of the standards certification (ISO 9001: 2008 and ISO 14001: 2012), of accreditation for analytical laboratories (ISO / IEC 17025, ISO / IEC 15189) and with the evaluation of its implementation (ISO 19011). Benefits of accreditation to the laboratories. The student must be able to develop a quality control manual and participate in the management and organization of the processes to improve the effectiveness and efficiency of the organization of an analytical laboratory.

CONTENTS

Introduction to quality management: Quality concepts, principles, models. Quality management system. Quality Management Standards. Portuguese System Quality. Formalizing a quality system. The Quality Standards. Laboratory Accreditation. European and international vision of accreditation. Rules and accreditation criteria in under the point of view of the Portuguese Institute of Quality (IPAC) Quality management systems: the ISO / IEC 17025 and ISO / IEC 15189 and Laboratory Accreditation. Preparation of a Quality Manual of a laboratory. Requirements of Management and Technicians for laboratory test in accordance with EN ISO / IEC 17025 Integrated systems: development of methodologies and implementation. Certification. General overview of the Portuguese Standards and the European Community. Means of access to standards and guidelines. ISO standards. Methodologies to be followed for the accreditation of laboratories. Quality assurance testing laboratory.

DEMONSTRATION OF THE CONTENTS COHERENCE WITH THE COURSE UNIT'S LEARNING OUTCOMES

The Subject of Organization and Quality Management is about topics relating to the development of methodologies, implementation and accreditation of management systems, supported by national and international standards, in the applicable and relevant legislation, making use of the most appropriate management tools, always from the perspective of integration of management systems.

TEACHING METHODOLOGIES

The teaching / learning is based on the individual student work with the concepts taught during the classes and the bibliography consultation and websites. The classes are very interactive where, after an introduction to the subject, the students will have opportunity to work the concepts based in class discussion and individual research.

DEMONSTRATION OF THE COHERENCE BETWEEN THE TEACHING METHODOLOGIES AND THE LEARNING OUTCOMES

The teaching methodology is based in expository method, supported by slides, and realization of partial tests, that allows students to acquire consistently the theoretical foundations. The study of real cases, performed in the classroom, promoting the discussion, allows students to acquire skills in accordance with the objectives of the course.

EVALUATION METHODS

Will be realized a work about a practical case, writing a report (realized in groups), with oral presentation and followed by discussion, corresponding to 40% of the final classification.

The student must have at least 8.5 on the written test. Approval with the minimum of ten values.

MAIN BIBLIOGRAPHY

Hoyle, D., ISO 9000 Quality Systems Handbook, 4th Ed., Butterworth-Heinemann, 2001.

Dempsey, C., Laboratory Accreditation and Data Certification: A System for Success, CRC Ed., 1991.

ISO 14001: 2012 – Sistema de gestão ambiental. Requisitos e linhas de orientação para a sua utilização/ Guidelines for auditing management systems of quality and / or environmental management.

ISO 9000: 2005 - Sistemas de gestão da qualidade - Fundamentos e vocabulário/ Management systems quality - Fundamentals and vocabulary

ISO 9001: 2008 – Requisitos de sistemas de gestão da qualidade/ System requirements for quality management.

ISO/IEC 15189: 2014 – Laboratórios Clínicos. Requisitos particulares da qualidade e competência/ Clinical Laboratories. Particular quality and competence requirements

ISO/IEC 17025: 2005 – Requisitos gerais de competência para laboratórios de ensaio e calibração/ ISO / IEC 17025: 2005 - Requirements for the competence of testing and calibration .

Year of implementation: 2017/2018 | Date of approval by the Technical-Scientific Board: 2016-07-27