

Course Unit	Quality control in health	Field of study	Health
Master in	Applied Health Sciences - Biotechnology	School	School of Health
Academic Year	2023/2024	Year of study	1
Type	Semestral	Semester	1
Level	2-1	ECTS credits	3.5
Code	5055-669-1104-00-23		
Workload (hours)	94,5	Contact hours	T - TP - PL - TC - S - E - OT - O 42

T - Lectures; TP - Lectures and problem-solving; PL - Problem-solving, project or laboratory; TC - Fieldwork; S - Seminar; E - Placement; OT - Tutorial; O - Other

Name(s) of lecturer(s) Andrea Luisa Fernandes Afonso

### Learning outcomes and competences

At the end of the course unit the learner is expected to be able to:

1. know the importance of Quality Management Systems.
2. Promote the acquisition of knowledge necessary to understand/implement a quality management system in several health units.
3. Distinguish between certification and accreditation process of laboratories.
4. Recognize that Quality Management systems promote the validation of procedures and drive the different phases of the quality cycle for continuous quality improvement.
5. Recognize the applicability and utility of internal and external quality control methodologies within different laboratory contexts
6. Know how to interpret calibration or test certificates for thermic, of measurement and testing equipment.

### Prerequisites

Before the course unit the learner is expected to be able to:

### Course contents

I. Quality management II. Certification and standardization III. Quality Audits IV. Good Laboratory Practice V. Quality control in laboratories VI. Validation of analytical methods V. Certification and accreditation of hospital and other health facilities.

### Course contents (extended version)

1. Quality management
  - Concepts and definitions
  - The quality system
2. Certification and Accreditation
  - Legislation and standards
  - Certification and Accreditation Processes
3. Quality Audits
4. Good laboratory and pharmacy practices
  - Quality in the analytical cycle in Laboratory
  - Pre-Analytical, analytical and post-analytical variability
  - Management of Infrastructure and Equipment of community and hospital pharmacy.
  - Management of medicine and health products in community and hospital pharmacy.
5. Quality control in laboratories
  - Internal quality control
  - External quality control
6. Validation of analytical I methods
7. Metrological control
  - Certificates evaluation of calibration and/or testing of equipment.
8. Food safety management systems based on NP EN ISO 22000.
  - Good practices in hospital Nutrition and Dietetics services.
9. CHKS International Hospital Accreditation Program, Caspe Healthcare Knowledge Systems.
10. National Strategy for Quality in Health /European Union Health Programme
  - Organizational and clinical practice quality
  - Practice guidelines in clinical practice and patient safety
  - Quality and accreditation of health care providers
  - Quality and safety of pharmaceuticals

### Recommended reading

1. Norma NP EN ISO 9001: 2015. Sistemas de Gestão da Qualidade.
2. Norma ISO 19011:2018 - Linhas de orientação para auditorias a sistemas de gestão.
3. IPAC. Guia para a aplicação da NP EN ISO/IEC 17025 - Laboratórios de ensaio e calibração e NP EN ISO/IEC 15189 para laboratórios clínicos.
4. European Medicines Agency, Guideline on bioanalytical method validation, 2011, [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2011/08/WC500109686.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2011/08/WC500109686.pdf)
5. Koniczka, P. , & Namiesnik, J. (2009). Quality Assurance and Quality Control in the Analytical Chemical Laboratory: A Practical Approach (Analytical Chemistry). CRC Press.

### Teaching and learning methods

In the classes there will be a masterly exposition of the programmatic contents, and it will be proceeded to the systematization of the most relevant topics, stimulating the students to interact and discuss the topics. Practical cases will also be presented in which students will be invited to participate. Lecture in collaboration with the Polytechnic Institute of Guarda, using videoconferencing.

### Assessment methods

1. Alternative 1 - (Regular, Student Worker) (Final)
  - Intermediate Written Test - 100% (Theoretical test.)
2. Alternative 2 - (Regular, Student Worker) (Supplementary, Special)
  - Final Written Exam - 100% (Theoretical exam.)
3. Alternative 3 - (Regular, Student Worker) (Final, Supplementary, Special)
  - Final Written Exam - 100% (Theoretical exam.)

## Language of instruction

Portuguese

## Electronic validation

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08-02-2024	09-02-2024	09-02-2024	09-02-2024