

| Course Unit      | nit Hygiene, Safety and Quality Laboratory |               |          | Field of study | Biomedical Laboratory Sciences                  |                                                                                 |
|------------------|--------------------------------------------|---------------|----------|----------------|-------------------------------------------------|---------------------------------------------------------------------------------|
| Bachelor in      | in Biomedical Laboratory Sciences          |               |          | School         | School of Health                                |                                                                                 |
| Academic Year    | 2023/2024                                  | Year of study | 1        | Level          | 1-1                                             | ECTS credits 5.0                                                                |
| Туре             | Semestral                                  | Semester      | 2        | Code           | 9995-804-1205-00-23                             |                                                                                 |
| Workload (hours) | 135                                        | Contact hours | T - TP - | 40 PL 15 Tu    | C - S -                                         | E - OT 5 O -<br>Fieldwork: S - Seminar: E - Placement: OT - Tutorial: O - Other |
|                  |                                            |               |          | 3.             | <b>3</b> ,1,1,1,1,1,1,1,1,1,1,1,1,1,1,1,1,1,1,1 |                                                                                 |

Name(s) of lecturer(s) Andrea Luisa Fernandes Afonso, Bruno Henrique Andrade Galvão

Learning outcomes and competences

- At the end of the course unit the learner is expected to be able to:
  1. Know the international and national laws on hygiene and safety at work, biosafety, biosecurity and chemical safety.
  2. Identify the main safety risks and procedures and practices for their prevention and control.
  3. Acquire basic knowledge of microbiology and immunology.
  4. Understand the concept of quality. Know the legislation and normative references for good laboratory practices.
  5. Understand the objectives and methodologies of the certification and accreditation processes.
  6. Use the main statistical tools for quality control.
  7. Recognize the need to analyze and evaluate new diagnostic methodologies prior to routine use (validation).
  8. Evaluate and interpret calibration reports of measuring laboratory equipment.

### Prerequisites

Not applicable

#### Course contents

Hygiene and safety at work - national and european legislation. Safety in clinical, public health and pathological anatomy laboratories. Biossecurity and biosafety. Good laboratorial practice. Implementation of a quality management system. Accreditation of laboratories. Laboratory quality control. Methods validation. Calibration and evaluation of laboratory equipment. Basic concepts of microbiology and immunity.

#### Course contents (extended version)

- 1. Safety and occupational health. National and european legislation Occupational health and safety. Ergonomics.
- Occupational health and safety. Ergonomics.
  Individual protection equipment.
  Signage and eccefficiency.
  Manual of good laboratory practice: clinical analysis and pathological anatomy.
  ACSP e APTC laboratories licensing.
  Biosafety and biosecurity in ACSP and APCT laboratories
  Biosafety program: classification of biological agents.
  Good laboratory practice in level 2 areas.
  Biological risks and their determination.
  Biological risk management.
  Containment levels: BSL1, 2, 3 and 4.
  Sterilization and disinfection

- Containment levels: BSL1, 2, 3 and 4.
  Sterilization and disinfection.
  Chemical safety in ACSP and APCT laboratories
  Classification, packaging and labeling.
  Acquisition and storage of chemicals.
  Chemical handling care (good practice).
  Risk estimation of exposure to chemicals.
  Specific legislation and exposure values.
  Other types of laboratory risk
  Risk of fire, electric hazards and radiation.
  Accidents at work
  Eacting contributing to accidents, risk managen
- - Factors contributing to accidents, risk management, prevention and treatment. Accidents involving infectious substances, chemicals and cuttings. Fire and natural disasters.
- First aid.

- First aid.
  6. Laboratory waste
   Hospital waste management Legislation.
   Laboratory waste as a public health problem, and its processing and control.
  7. Concepts of microbiology and immunology
   Global description (morphology and structure) of microorganisms.
   Microorganisms classification: bacteria, virus, fungi, parasites, prions.
   Immune response to infection

  - Immune response to infection. Cells involved in the innate and acquired immune response.
- . Transport of dangerous substances. . Certification and Acreditation process.

- Implementation of a quality management system (NP EN ISO 9001).
   Accreditation of laboratories by standards NP EN ISO/IEC 17025 e NP EN ISO 15189.
   Methods validation and laboratory quality control
   Methods validation.

- Internal quality control vs. external quality control.
   Incernal quality control vs. external quality control.
   Process quality control- quality control charts.
   Determination of uncertainties.
   Practical exercises.

- Practical exercises.
  11. Metrological control.
  Evaluation of calibration reports of measuring laboratory equipment.
  12. Practical laboratory classes hygiene and safety
  Observe the antibacterial effect of antiseptics on the microbiota of the hands.
  Know and apply ways of sterilizing material and disinfecting surfaces.
  Interpret labels and safety data sheets for chemical products.
  Describe the composition of culture media, types and sowing techniques.
  Observe the ability of different dyes to color typical bacteria.
  13. Practical laboratory classes quality control
  Preparation of a calibration curve.
  Determination of concentration of samples and control standards (MRI and MRC).

#### Course contents (extended version)

- Apply internal control methodologies (relative error of control standards, sample duplicates).
  Prepare a control chart and know how to interpret results obtained from control standards.
  Understand and apply external control methodologies Interlaboratory Tests (EIL).

### Recommended reading

- CDC (2020). "Biosafety in Microbiological and Biomedical Laboratories", 6ª Edição, Centers for Disease Control and Prevention, National Institutes of Health 2. WHO (2020). "Laboratory Biosafety Manual", 4ª Edição, World Health Organization
   WHO (2011). "Laboratory quality management system: handbook", World Health Organization
   Guias para Certificação e Acreditação de laboratórios, determinação de incertezas e validação de métodos do Instituto Português de Acreditação (IPAC)
   Abbas, A. K., Lichtman, A. H., Pillai, S. Cellular and Molecular Immunology. 10th Edition, Elsevier (Capítulos 2, 3, 4 and 16)

#### Teaching and learning methods

Lectures using powerpoint presentations, resolution of practical exercises in statistics applied to internal and external quality control, validation of methods and determination of uncertainties. Physical knowledge of the laboratory, to carry out disinfection and sterilization methodologies; understanding of chemical labeling and waste management.

## Assessment methods

- Alternative 1 (Regular, Student Worker) (Final)

   Final Written Exam 50% (Written exam)
   Laboratory Work 50% (- Presentation of a work and discussion 25%)
   Laboratory work reports 25%)

   Alternative 2 (Regular, Student Worker) (Supplementary, Special)

   Final Written Exam 100% (Written exam)

# Language of instruction

## Portuguese

| Electronic validation                                           |                      |                                 |                                       |  |  |  |  |  |
|-----------------------------------------------------------------|----------------------|---------------------------------|---------------------------------------|--|--|--|--|--|
| Andrea Luisa Fernandes Afonso, Bruno<br>Henrique Andrade Galvão | Josiana Adelaide Vaz | Luis Migue Fernandes Nascimento | Adília Maria Pires da Silva Fernandes |  |  |  |  |  |
| 21-05-2024                                                      | 22-05-2024           | 22-05-2024                      | 22-05-2024                            |  |  |  |  |  |