UAB
Universitat Autònoma de Barcelona

Biosafety and Regulations

Code: 101021
ECTS Credits: 6

2024/2025

Degree	Type	Year
2500502 Microbiology	OB	3

Contact

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Teachers

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Teaching groups languages

You can view this information at the end of this document.

Prerequisites

Although there are no specific prerequisites it is important to have a good background in Microbiology, Molecular Biology and laboratory techniques.
On the other hand, it is highly recommended that students have a basic knowledge of English in order to be able to use the sources of information and international guidelines that are basically found in this language

Objectives and Contextualisation

This is a compulsory course of the third year of the Degree in Microbiology where students are already beginning to have an integrated vision of the microbial world and its implications in the sanitary, biotechnological and ecological fields. This knowledge will be complemented by this two-module course where the student will be introduced, on the one hand, to the analysis of biological risks and risk management systems that guarantee effective prevention and protection of human health and the environment. On the other hand, to the application and improvement of a quality management system based on a process and indicator management approach.

The main objectives of the Biosafety module are that the student can:

- To identify agents and risks factors of biological origin.
- Evaluate the existing biological risk in the different situations that may arise.
- Define the most appropriate measures to avoid or minimize the biological risk.
- Understand the concept of biocontainment and its limitations.
- Know the legal regulations, guidelines and international standards in this field and their correct application

The main objectives of the Standards module are that the student:

- Learn how to design and elaborate the documents of the Quality management system.
- Acquire basic concepts and terminology on Quality: policy, management, systems, control, evaluation, continuous improvement, standardization, audits, certification and accreditation.
- Interpret and get to know the legal regulations, Standards, Recommendations and Regulatory Bodies.
- Understand basic and comparative concepts between ISO9001 and other regularions or models related to the accreditation of technical competence, the Good Laboratory Practice Principles or the essential ones in areas related to the different professional opportunities.

Learning Outcomes

1. CM21 (Competence) Plan research in the field of microbiology with ethical responsibility, gender perspective and respect for fundamental rights and duties and animal welfare.
2. CM22 (Competence) Evaluate processes where microorganisms intervene, taking into account an adequate experimental design and the principles on biosafety and quality.
3. KM32 (Knowledge) Identify the risks of biological agents and modulating factors through the risk assessment tool.
4. KM33 (Knowledge) Define fundamental aspects of ethics applied to science and biosciences and the basic concepts and terminology related to standards or standards to ensure quality and principles of good laboratory practices.
5. SM31 (Skill) Manage computer tools, bibliography and internet resources for experimental design, as well as the search for information, regulations and guides on good practices in the field of microbiology.
6. SM32 (Skill) Apply the principles on risk assessment and control in the laboratory and regulations on biosafety regarding microorganisms and the manipulation of different biological systems.
7. SM33 (Skill) Use properly the documents of the quality management system, the registration of experimental data and biosafety protocols.

Content

MODULE I. BIOSAFETY

Unit 1. Introduction to biosafety.

Concept of biosafety, biosecurity and biocontainment. Scope of application. Historical perspective. Future challenges. Laboratory acquired infections (LAI). The biosafety professional (BSO). Legal framework and international biosafety standards.

Unit 2. Biological risk assessment.

Concept of biological agent (BA) and risk. What is a biological risk assessment? Sources of biological risk: cell cultures (microorganisms, cell lines, GMOs), vectors, biotoxins, allergens, diagnostic and environmental samples. Classification of BAs by hazard groups. The Pathogen Safety Data Sheet (PSDS). Risk factors. Bioaerosols. Biosafety levels (BSL). Classification of activities with natural or genetically modified organisms.

Unit 3. Biological risk management (Good biosafety practices).

Elements and hierarchy of risk control. Good microbiological practices. Safe use of equipment. Maintenance of equipment and facilities. Cleaning, disinfection and sterilization. Chemical and physical methods. The autoclave: principles of use. Integral pest control. Management of biological emergencies. Biological waste management. Transport and shipment of biological materials infectious and exempt.

Unit 4. Biological risk management (Primary barriers).

Biological containment systems. Viral vectors. Collective protective equipment: the biosafety cabinet (BSC). HEPA filtration. BSC limitations and qualification. Other biocontainment equipment. Personal Protective Equipment (PPE).

Unit 5. Biological risk management (Secondary barriers).

Biocontainment. Design of high biocontainment facilities. Control of flows (people, materials and waste). Constructive elements. Ventilation and air treatment systems. Waste treatment systems. Emergency systems. Virtual visit toa high biocontainment facility. Other confinedfacilities: animal facility (small and large animals), arthropod containment facility, greenhouses.

Unit 6. Biological risk management (Administrative controls)

The Institutional Biosafety Committee (IBC). The Biosafety Manual. Training/information. Signage. Risk communication. Investigation of accidents/incidents. Health surveillance. Inspections and audits. Administrative authorizations. Biosecurity.

MODULE II. STANDARDS: Quality management systems.

Unit 1. Introduction to Quality and ISO Norms

History and origin of quality. Generic concepts. Major global players. Organizations (Standardization, Accreditation, Certification, Inspections, Calibration and Testing). High-Level Structure (HLS).

Unit 2. ISO 9001: 2015
Organizational context, leadership, planning and documented information. Operation: operational planning and control, product requirements, design, process and product control, production, release, control of non-conforming product. Performance evaluation: monitoring, analysis and evaluation, internal audits, management Review.

Unit 3. ISO 17025: 2017
Resource requirements. Personnel, facilities and equipament. Metrological traceability. Selection and validation of methods. Ensuring the validity of results and reporting of results. Nonconforming work. Control of data and information management.

Unit 4. Experimental data registry
Raw data and its importance. Data collection, suports and archiving. Review and correction of data. Regulatory requirements for data archiving and management. Principles of ALCOA to guarantee the data integrity (Attributable, legible, contemporaraneous, original and acurate).

Unit 5. Strategies and tools for continuous improvement
Introduction to diferent quality management tools: DAFO, Deming (PDCA), Ishikawa diagram, 5s.

Unit 6. Good Laboratory Practices
Regulatory framework for active ingredients (GLP, GMP and GCP). Five key points of Good Laboratory Practices: Rules, resources, characterization, document and Quality Assurance Program.

Unit 7. Standard Operating Procedures (SOP) and experimental data record

What is an SOP? Types of SOP. How do you write an SOP? What should an SOP contain?. Writing and responsibilities associated with the SOP. SOP's management (issue, distribution, cancellation and final archiving).

Activities and Methodology

Title	Hours	ECTS	Learning Outcomes

Type: Directed			
Case study. Biosafety module	2	0.08	CM21, CM22, KM32, SM31, SM32
Lectures	28	1.12	CM21, CM22, KM32, KM33, SM31, SM32, SM33
Seminars. Biosafety module	6	0.24	CM21, CM22, KM32, KM33, SM31, SM32
Seminars. Standards module	8	0.32	CM21, CM22, KM33, SM31, SM33
Type: Supervised			
Personal tutorial guidance sessions	1	0.04	CM21, CM22, KM32, KM33, SM31, SM32, SM33
Type: Autonomous			
Literature search	20	0.8	CM21, CM22, KM32, KM33, SM31, SM32, SM33
Personal study	46	1.84	CM21, CM22, KM32, KM33, SM31, SM32, SM33
Preparation of the oral presentation	10	0.4	CM21, CM22, KM32, KM33, SM31, SM32, SM33
Reading	20	0.8	CM21, CM22, KM32, KM33, SM31, SM32, SM33

The "Biosafety and Standards" course consists of two modules, which have been programmed in an integrated way, but evaluated independently. The student will have to relate throughout the course the content and activities programmed in order to achieve the indicated skills in this guidelines.

The classroom lectures allow to introduce the basic concepts of the course. The content of the theory classes will be taught by the teacher with audiovisual support. The Moodle platform of the course will be used as an information exchange system (presentations, exercises, videos, bibliography, legal regulations, glossary, etc.) between teachers and students and to make an evaluable test at the end of each unit.

The classroom lectures are completed with the knowledge that is worked on in the case-resolution seminars and with personal and autonomous study. The group will be divided into two subgroups for these sessions, the lists of which will be made public at the beginning of the second semester, and at the same time, there will be working groups of 5-6 students that will be maintained throughout the course. It is intended to promote in the students the habit of teamwork and the development of critical spirit in different situations. The case-resolution seminars are compulsory and are based on work proposed by the teaching team, which the students will work autonomously, and which will be presented and discussed later in the classroom.

The classroom problem-solving that will take place in the modules will be as follows:

Case studies and problems

Case and problem statements will be available in the Moodle platform of the course from the beginning of the semester. The resolution of these will be done individually or in working group. During the classroom session, the students will have the opportunity to present their resolution, which will be discussed at the end collectively.

Seminars

This activitywill be organized maintaining the working groups already created. At the beginning of the semester the teacher will assign to each group a specific case study, which will allow to apply and deepen in some concepts acquired in the classroom lecturer, and will provide information as a starting point for their development. On a defined date, the written report must be presented using the Moodle platform and a brief oral presentation will be made by the students, which will serve to open up a time for debate among students.

Annotation:Within the schedule set by the centre or degree programme, 15 minutes of one class will be reserved for students to evaluate their lecturers and their courses or modules through questionnaires.

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Assessment

Continous Assessment Activities

Title	Weighting	Hours	ECTS	Learning Outcomes
Biosafety module: Final exam	25%	1.5	0.06	CM22, KM32, SM32
Biosafety module: Resolution of cases studies and problems	10%	1	0.04	CM22, KM32, SM32
Biosafety module: Seminar evaluation	10%	1	0.04	CM21, CM22, KM32, SM32
Biosafety module: Test multiple choice	5%	1	0.04	CM22, KM32, SM32
Standards module: Cas-resolution seminars assessment	10%	1	0.04	CM22, KM33, SM33
Standards module: Final exam	25%	1.5	0.06	CM21, CM22, KM33, SM33
Standrads Module: Evaluation of written work seminars	10%	1	0.04	CM22, KM33, SM33
Standrads Module: Resolution of questionnaires	5%	1	0.04	CM21, CM22, KM33, SM31, SM33

The evaluation will be individual and continuous through a monitoring of the teaching and learning process to assess the achievement of competencies. Work and continuous effort will be encouraged, which is the only way to integrate and relate knowledge and achieve objectives.

The modules of Biosafety and Standards have the same weight in the overall mark of the course (50% the Biosafety Module and 50% the Standards Module). In order to pass the course, a minimum overall score of 5 must be achieved for each module and is evaluated as follows:

Biosafety

- Assessment of the theory lectures module (50% of the module grade). The assessment of the theoretical contents will be carried out by means of a multiple choice test related to the topics dealt with in class.
- Assessment of case studies and problems (20% of the module grade). The assessment will consist of a written test with the resolution of a couple of practical cases and two short answer questions.

In order to be able to weight in the score of the module, the sum of the marks obtained in the two previous tests must reach a minimum value of 4 points out of 10, otherwise both will have to be re-evaluated on the scheduled for the final exam.

- Assessment of the seminars (20% of the module grade). The assessment is made from the written report of the issue raised and the oral presentation and public defence.
- The individual resolution of the test at the end of each unit will also be considered (10% of the module grade).

Standards

- Global written exam (50% of the module grade). The evaluation of the theoretical contents will be carried out by carrying out a mandatory written test where the development questions will be combined with multiple choice questions related tothe topics covered in class. So that you can weigh in the module note, the minimum value to achieve will be 4.
- The resolution of the questionnaires of each topic (10% of the module grade)
- Assessment of the seminars (40% of the module grade):
  Assessment of the works presented (20%): The evaluation is carried out based on the resolution of the cases raised and the contents of the works delivered.
  Assessment of presentations in public (20%): The evaluation is carried out based on the communication skills in the oral presentation of each case and the support used.

In the case of not passing the written exam (less than 4) or not having taken the exam, there will be the possibility of making a re-assessment of the theorymodule, which will include all the units dealt with, on the dates indicated in the general programming of the course. The final exam will independently evaluate the contents of each of the modules. If one of the modules is suspended in the final exam, the course is suspended, but the mark of the module passed for the following year will be kept.

In both modules, classroom seminars are compulsory. Students who have not submitted the required written report will receive the grade of "Non-evaluable" in the corresponding module. The course is suspended but the module of the grade approved for the following year will be kept.

In orderto participatein the re-assessment, the student must have been previously evaluated in a set of activities, the weight of which is equivalent to a minimum of two thirds of the total grade of the course or module. Therefore, the student will be graded as "Non- evaluable"if the weighing of all conducted evaluation activities is less than 67% of the final score.

Students wishing to improve their final grade of the course will waive the qualification previously obtained for the course and must communicate this in writing to the teacher responsible for the course at least 72 hours before the day scheduled for the re-assessment. The grade improvement exam will be a global exam (Biosafety and Standards) that will include questions of all the activities of the course and will be carried out on the same day and time as the final exam.

The repeating students will not have to carry out the activities corresponding to the cas-resolution seminars modules and will only have to evaluate of the theory modul.

Single assessment option

For those students who choose the single assessment system, this will consist of a unique written test in which the contents of the entire program of the subject will be assessed. The test may consist of multiple choice questions, short questions and problems to develop. The grade obtained in this synthesis test will account for 80% of the final grade for the subject. The single assessment test will coincide with the date of the last assessment test. As regards the seminar evaluation (20% of the final mark), the students will work with a team as in the continuous evaluation system, and the delivery of the work will be within the period indicated at the beginning of the subject. For the single assessment option, the same system for retake and review of the final grade and the same criteria to pass as for the continuous assessment system will be applied.

Bibliography

Recull de Guies de Referencia en matèria de Bioseguretat (Comitè de Bioseguretat de la UAB) (https://www.uab.cat/web/legislacio-i-normatives/guies-de-referencia-1345749541678.html)

Guia tècnica per a l'avaluació i prevenció dels riscos relacionats amb l'exposició a Agents Biològics (INSST) 2014. (https://www.uab.cat/doc/Guia_664)

Laboratory Biosafety Manual (WHO), fourth edition (2020) (https://www.uab.cat/doc/Manual_bioseguridad_OMS_2005)

Manual de Bioseguretat de la UAB (2021) (https://intranet-nova.uab.es/doc/manual_bio_uab)

CDC/NIH Biosafety in Microbiological and Biomedical Laboratories, 5th Edition, U.S. Govt. Printing Office, Washington, 2009. (https://www.uab.cat/doc/Manual_CDC_2009).

Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), Department of Health and Human Services, National Institutes of Health, 2016. (https://www.uab.cat/doc/GuidelinesNIH_2016).

Canadian Biosafety Standards and Guidelines. 2nd edition. 2015 (https://www.uab.cat/doc/Guia_Canada_2015).

Canadian Biosafety Handbook. 2nd Edition. 2016 (https://www.uab.cat/doc/Handbook_Canada_2016).

Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories (CDC) 2012 (https://www.uab.cat/doc/GuidelinesSafe_Work_Practices_Human_Animal_Medical_Diagnostic_Laboratories201

Greenhouse Research with Transgenic Plants and Microbes, a Guide to Containment. 2nd edition 2008 (https://www.uab.cat/doc/guiesref_plantcontainment_2008)

Laboratory biosecurity guidance (OMS) 2006 (https://www.uab.cat/doc/Guia_biosecurity_OMS_2006).

Guidelinefor Disinfection and Sterilization in Healthcare Facilities 2008 (https://www.uab.cat/doc/Guideline_Disinfection_2008).

Guidelines for Biosafety in Teaching Lab (ASM) 2012 (https://www.uab.cat/doc/teaching_lab_ASM).

Wooley, D.P., and Byers, K.B., Biological Safety: Principles and Practices, 5thEdition, ASM Press, Washington, D.C. 2017. (https://onlinelibrary.wiley.com/doi/book/10.1128/9781555819637)

UNE 171400-1:2019 Diseño de instalaciones de nivel 3 de contención biológica (NCB3).
UNE-EN ISO 9000:2015 Sistemas de gestión de la calidad. Fundamentos y vocabulario.
UNE-EN ISO9001:2015 Sistemas de gestión de la calidad. Requisitos.
UNE-EN ISO 9004:2018 Gestión para el éxito sostenido de una organización. Enfoque de gestión de la calidad.
UNE-EN ISO 19011:2012 Directrices para la auditoría de los sistemas de gestión.
UNE-EN ISO/IEC 17025:2017 Requisitos generales para la competencia de los laboratorios de ensayo y de calibración.
UNE-EN ISO 22000:2018 Sistemas de gestión de la inocuidad de los alimentos. Requisitos para cualquier organización en la cadena alimentaria.
NCF: Directiva 2003/94/CE principios y directrices de las prácticas correctas de fabricación de los medicamentos de uso humano y de los medicamentos en investigación de uso humano.
UNE-EN ISO 22716:2008 Productos cosméticos. Buenas prácticas de fabricación (BPF).Guía de buenas prácticas de fabricación.
UNE-EN ISO 14001:2015 Sistemas de gestión ambiental. Requisitos con orientación para su uso.
ISO/DIS 45001 Sistema de gestión de la seguridad y salud en el trabajo. Requisitos con orientación para su uso.
UNE-ISO 26000:2021 Guía deresponsabilidad social.
UNE-ISO 31000:2018 Gestión del riesgo. Principios y directrices.

Webs d'interès

Comitè de Bioseguretat de la Universitat Autònoma de Barcelona (https://www.uab.cat/bioseguretat/)

Centers for Disease Control and Prevention,USA: https://www.cdc.gov/labs/index.html

Organització Mundial de la Salut: https://www.who.int/es/

Organización Mundial de Sanidad Animal (OIE): http://www.oie.int/es

European Biosafety Association (EBSA): https://ebsaweb.eu/

American Biological Safety Association (ABSA): https://absa.org/

Asociación Española de Bioseguridad (AEBioS): https://aebios.org/

Notes tècniques de prevenció (NTPs) (https://www.uab.cat/web/legislacio-i-normatives/guies-de-referencia-1345749541678.html)

ISO: https://www.iso.org/

AENOR: https://www.aenor.com

ENAC: https://www.enac.es

AEMPS: https://www.aemps.gob.es/
PIC/S: https://www.picscheme.org/
FDA: https://www.fda.gov/

Altres textos recomanats així com enllaços d'interès es trobaran disponibles a l'aula Moodle de l'assignatura. (https://www.uab.cat/web/enlaces-de-interes-1345767065202.html)

Software

NA

Language list

Name	Group	Language	Semester	Turn
(SEM) Seminars	731	Catalan	second semester	morning-mixed
(SEM) Seminars	732	Catalan	second semester	morning-mixed
(TE) Theory	73	Catalan	second semester	morning-mixed