Universitat Autònoma de Barcelona

2020/2021

Biosafety and Regulations

Code: 101021
ECTS Credits: 6

Degree	Type	Year	Semester
2500502 Microbiology	OB	3	2

The proposed teaching and assessment methodology that appear in the guide may be subject to changes as a result of the restrictions to face-to-face class attendance imposed by the health authorities.

Contact

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Use of Languages

Principal working language: catalan (cat)
Some groups entirely in English: No
Some groups entirely in Catalan: Yes
Some groups entirely in Spanish: No

Teachers

Àgueda Flores Flores

Francesc Xavier Abad Morejon de Giron

Prerequisites

Although there are no specific prerequisites it is important to have a good background in Microbiology, Molecular Biology and laboratory techniques.

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.
- To know the legal regulations 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 standards 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.

Competences

- Apply the principles of risk assessment and prevention in the laboratory, and biosafety regulations on microorganisms and manipulation of different biological systems.
- Know and apply safety and quality regulations in microbiology.
- Use bibliography or internet tools, specific to microbiology or other related disciplines, both in English and in the first language.

Learning Outcomes

1. Identify and evaluate microbiological risks in production processes.
2. Implement and manage measures to ensure the quality of the final product.
3. Know accreditation procedures.
4. Know and apply safety and quality regulations in microbiology.
5. Understand protocols for validating microbiological methods.
6. Use bibliography or internet tools, specific to microbiology or other related disciplines, both in English and in the first language.

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.

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. STANDARSD: Quality management systems.

Unit 1: Introduction to Quality and ISO Norms

Origin of quality management. Generic concepts: major global players, certification and accreditation. Institutions: ISO, AEMPS, FDA, AENOR, ENAC. Introduction of general concepts of ISO standards, glossary of commonly used acronyms and High-Level Structure (HLS).

Unit 2: ISO 9001: 2015 requirements (from chapter 0 to 4)

Introduction, object and scope, normative references and definitions of ISO 9001: 2015. Organizational context.

Unit 3: ISO 9001: 2015 requirements (from chapter 5 to 7)

Leadership, planning and support (resources, competence, awareness, communication and documented information).

Unit 4: ISO 9001: 2015 requirements (Chapter 8)

Operation: operational planning and control, product requirements, design, process and product control, production, release, control of non-conforming product.

Unit 5: ISO 9001: 2015 requirements (chapters 9 and 10). Certification process and transition periods.

Performance evaluation: monitoring, analysis and evaluation, internal audits, management review. Strategies and tools for continual improvement: DAFO, Deming(PDCA), HACCP, Ishikawa diagram, 5s. Certification process and transition periods.

Unit 6: Good Laboratory Practices

Introduction to other management systems: ISO 22716, ISO14001, ISO 22000, ISO 17052, ISO 45001 (2017) - OHSAS 18001 and GMP. 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?. Correct experimental data recording. ALCOA Principles to ensure correct data registration (Attributable, Legible, Contemporaneously recorded, Original and Accurate).

**These will be the contents unless the restrictions imposed by the health authorities force a prioritization or reduction of them.*

Methodology

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 BIOSAFETY module 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 activity will 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.

The classroom problem-solving that will be carried out in the STANDARDS module will be the following:

Seminars

This activity will be organized maintaining the working groups already created. At the beginning of the seminar, the teacher will assign a case to each group, which will allow to deepen in some concepts acquired in the classroom lecturer, and will provide information that will serve as a starting point for its development.

Work will be done in class or autonomously and will be made accessible to all students with a brief oral presentation by the students that will serve to open a time for dialogue and debate.

ADDITIONAL INFORMATION: In order to resolve doubts, clarify concepts, establish the knowledge acquired of the students personal tutorial guidance sessions will be available by e-mail appointment.

**The proposed teaching methodology may experience some modifications depending on the restrictions to face-to-face activities enforced by health authorities.*

Activities

Title	Hours	ECTS	Learning Outcomes
Type: Directed			
Case study. Biosafety module	6	0.24	4, 1, 2, 6
Lectures	28	1.12	5, 3, 4, 1, 2
Seminars. Biosafety module	2	0.08	4, 1, 2, 6
Seminars. Standards module	8	0.32	5, 3, 4, 1, 2, 6

Type: Supervised			
Personal tutorial guidance sessions	1	0.04	5, 3, 4, 1, 2, 6
Type: Autonomous			
Literature search	20	0.8	5, 3, 1, 6
Personal study	48	1.92	5, 3, 4, 1, 6
Preparation of the oral presentation	10	0.4	5, 3, 4, 1, 2, 6
Reading	20	0.8	5, 3, 4, 1, 6

Assessment

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 (49% 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 (21% of the module grade). The assessment will consist of a written test with the resolution of a practical case of biological risk assessment 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 defense.
- Attendance, participation and individual attitude during the whole learning process will also be considered (5% of the module grade).
- The individual resolution of the test at the end of each unit will also be considered (5% of the module grade).

STANDARDS REGULATION

- Global written exam (50% of the module grade). The assessment of the theoretical contents will be carried out by means of a compulsory written test in which the developmental questions will be combined with multiple choice questions related to the topics dealt with in class. In order to be able to weight in the grade of the module, the minimum value to reach will be 4.
- Assessment of the seminars (40% of the module grade):

  Assessment of the papers presented (20%): The assessment is made from the resolution of the cases raised and the contents of the written report submitted.
  Assessment of oral presentations (20%): The assessment is based on the communicative skills in the oral presentation of each case and the support used.

- Attendance, participation and individual attitude in classroom activities throughout the learning process will also be considered (10% of the module grade).

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 theory module, 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 order to 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.

**Student's assessment may experience some modifications depending on the restrictions to face-to-face activities enforced by health authorities.*

Assessment Activities

Title	Weighting	Hours	ECTS	Learning Outcomes
Biosafety module: Final exam	24,5%	1.5	0.06	5, 3, 1
Biosafety module: Participation and individual attitude	2,5%	0	0	5, 3, 4, 1, 2, 6
Biosafety module: Resolution of cases studies and problems	10,5%	1	0.04	5, 4, 1, 2, 6
Biosafety module: Seminar evaluation	10%	1	0.04	4, 6
Biosafety module: Test multiple choice	2,5%	1	0.04	5, 3, 1
Standards module: Cas-resolution seminars assessment	20%	1	0.04	4, 6
Standards module: Final exam	25%	1.5	0.06	5, 3, 1, 2
Standards module: Participation and individual attitude	5	0	0	5, 3, 4, 1, 2, 6

Bibliography

Guia técnica para la evaluación y prevención de los riesgos relacionados con la exposición a agentes biológicos (INSST) 2014.

Manual de bioseguridad en el laboratorio (OMS). 3a edición 2005.

CDC/NIH Biosafety in Microbiological and Biomedical Laboratories, 5th Edition, U.S. Govt. Printing Office, Washington, 2009.

Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), Department of Health and Human Services, National Institutes of Health, 2016.

Canadian Biosafety Standards and Guidelines. 2nd edition 2015.

Canadian Biosafety Handbook. 2nd Edition 2016.

Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories (CDC) 2012.

Greenhouse Research with Transgenic Plants and Microbes, a Guide to Containment. 2nd edition 2008.

Laboratory biosecurity guidance (OMS) 2006.

Guideline for Disinfection and Sterilization in Healthcare Facilities 2008.

Guidelines for Biosafety in Teaching Lab (ASM 2012).

Wooley, D.P., and Byers, K.B.,Biological Safety: Principles and Practices, 5thEdition, ASM Press, Washington, D.C. 2017.

UNE-EN ISO 9000:2015 Sistemas de gestión de la calidad. Fundamentos y vocabulario.
UNE-EN ISO 9001:2015 Sistemas de gestión de la calidad. Requisitos.
UNE-EN ISO 9004:2009 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. (ISO 19011:2011).
UNE-EN ISO/IEC 17025:2005 Requisitos generales para la competencia de los laboratorios de ensayo y de calibración.
UNE-EN ISO 22000:2005 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. (ISO 22716:2007).
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 26000:2012 Guía de responsabilidad social.
UNE-ISO 31000:2010 Gestión del riesgo. Principios y directrices.

Webs of interes

Institutional Biosafety Committe of UAB

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

Organització Mundial de la Salud: 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/

NTP: Notas técnicas de prevención

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/