Identification and characteristics of the course			
Code	502703	ECTS Credits	6
Course name (English)	Quality and Regulation in Laboratories		
Course name (Spanish)	Calidad y Regulación en los Laboratorios		
Degree programs	Biotechnology		
Faculty/School	Faculty of Sciences		
Semester	8	Type of course	Elective
Module	Elective		
Matter	Quality and Regulation in Laboratories		
Lecturer/s			
Name	Office	E-mail	Web page
Eduardo C. Pinilla Gil	Departament of Analytical Chemistry	epinilla@unex.es	https://opendata.unex.es/investiga/investigadores/488f7a2b2a0e8cdefa8db68e010870c3
Subject Area	Analytical Chemistry		
Department	Analytical Chemistry		
Coordinating Lecturer (If more than one)	Eduardo C. Pinilla Gil		

Competencies /Learning Outcomes
Basic competencies
CB1: Students must have demonstrated that they possess and understand knowledge in an area of study that is based on the basis of general secondary education, and is usually at a level that, although supported by advanced textbooks, also includes some aspects that involve knowledge from the forefront of their field of study.
CB2: Students must know how to apply their knowledge to their work or vocation in a professional way and possess the competencies that are usually demonstrated through the elaboration and defense of arguments and the resolution of problems within their area of study.
CB3: Students must have the ability to gather and interpret relevant data (usually within their area of study) in order to make judgments that include reflection on relevant social, scientific or ethical issues.
CB4: Students should be able to transmit information, ideas, problems and solutions to both a specialised and non-specialised audience.
CB5: Students must have developed those learning skills necessary to undertake further studies with a high degree of autonomy.
General competencies
CG4 - Ability to apply knowledge of basic sciences and technologies to biological systems.
CG5 - Ability to identify, formulate and solve problems within broad and multidisciplinary contexts, through the integration of knowledge and participation in multidisciplinary teams.
CG7 - Ability to solve problems with initiative, decision-making, autonomy and creativity.
Transversal competencies
CT1 - Apply the knowledge acquired in the degree to their work performance in a professional and rigorous way, as well as function safely in a laboratory.

CT2 - Use and apply information and communication technology (ICT) in the training and professional field.
CT3 - Possess and understand information from advanced textbooks and access knowledge from the cutting edge of the degree's field of study.
CT4 - Develop learning, organisational and planning skills, necessary both for undertaking further studies with a high degree of autonomy, and for professional performance.
CT5 - Interpret, analyse and synthesize relevant data and information that allow the student to develop ideas, solve problems and issue critical reasoning on important social, scientific or ethical issues.
CT6 - Effectively convey results and conclusions to both specialist and non-specialist audiences.
CT7 - To express themselves correctly in written and oral form in the native language, as well as to have sufficient command of a foreign language, preferably English.
CT9 - Respect fundamental rights and equality between men and women, as well as acquire an ethical commitment to respect life and the environment.
Specific competencies
CE17 - Know how to apply experimental laboratory protocols within the area of Biosciences.
CE18 - Possess the mathematical, statistical, and computer skills to obtain, analyze, and interpret data, and to understand simple models of biological systems and processes at the cellular and molecular level.
CE20 - Acquire the ability to transmit information within the area of biosciences, including mastery of specific terminology.
CE28 - Know the current legal provisions that regulate animal experimentation and biotechnological laboratories
CE31 - Ability to develop technical and scientific skills in the context of a research laboratory or a company.
CE32 - Ability to plan, conceive, deploy and manage projects, services and systems in the field of Biotechnology, leading their implementation and continuous improvement and assessing their economic and scientific impact.
CE35 - Identify and provide solutions to technological and scientific demands in the fields of the biochemical, pharmaceutical, food and environmental industries, as well as in biomedicine, animal and plant production.
Contents
Course outline
Basic principles of quality in laboratories. Design of experiments. Process control: Statistical foundations of control charts. Analytical methodology and quality: Sampling; Traceability; Validation of procedures. Evaluation of a test laboratory: Intercomparison exercises. Quality standards.
Course syllabus
Name of lesson 1: **General aspects of quality in laboratories** Contents of lesson 1: Introduction and terminology. Concept and evolution of quality management systems. Human resources and organization. Security and facilities. Equipment: selection, installation, maintenance and calibration. Materials: reagents, solutions, purified water and consumables. Purchases and inventory. Quality of customer service.

Description of the practical activities of lesson 1: Application of these concepts in the practices of the subject.

Name of lesson 2: **Quality in Sampling and Sample Pretreatment**

Contents of lesson 2: Introduction. The sampling process. Nomenclature. The quality of sampling. Sources of error. The sampling plan. Quality in sample pretreatment. Normative references on sampling and sample treatment

Description of the practical activities of lesson 2: Experimental estimation of sampling and measurement errors in an analytical method

Name of lesson 3: **Internal quality control of analytical laboratories**

Contents of lesson 3: Quality in analytical laboratories. Selection of analytical methods. Validation of analytical methods. Uncertainty. Quality monitoring over time. Particular aspects of quality control in qualitative and semi-quantitative processes.

Description of the practical activities of lesson 3: Calculation of quality parameters of an analytical method against a reference method.

Name of lesson 4: **External quality control of analytical laboratories**

Contents of lesson 4: Proficiency tests. Collaborative exercises. Certification exercises.

Description of the practical activities of lesson 4: Intercomparison exercises on a method to determining ascorbic acid in soft drinks by UV/Vis spectrophotometry.

Name of lesson 5: **Standard systems for accreditation of the quality of laboratories and biotechnological processes**

Contents of lesson 5: International and National Guidelines. Concept of accreditation and certification. Regulatory support. The accreditation process. Quality manual and other documentary aspects. Manual and computerized information management. LIMS systems. Audits. Quality and process improvement. Levels of control and validation of processes. Quality in biotechnological production and marketing processes.

Description of the practical activities of lesson 5: Using UEx LIMS for Work Order Generation. Reception and statistical interpretation of results. Visit to accredited laboratories and/or production systems, or interaction with experts.

Name of lesson 6: **Most relevant quality standards in the biotechnology laboratory**

Contents of lesson 6: Standards on quality management systems. Standards on clinical laboratories and good clinical practice. Standards for testing and calibration laboratories. Principles of good laboratory practice and control of their application for testing of chemical substances. Standards on environmental management systems. Standards on the manufacture of medicinal products for human and veterinary use. Standards on R+D+i management.

Description of the practical activities of lesson 6: Use of quality standards in experimental work.

Educational activities

Student workload in hours by lesson		Lectures	Practical activities				Monitoring activity	Homework
Lesson	Total	L	HI	LAB	COM	SEM	SGT	PS
1	19	7						12
2	26	6		5			1	14
3	30	9		3				18
4	24	5		3			1	15
5	27	8		4				15
6	20	6						14
Assessment	4	4						
TOTAL	150	45		15			2	88

L: Lectures (85 students)
HI: Hospital internships (7 students)
LAB: Laboratory or field practices (15 students)
COM: Computer room or language laboratory practices (20 students)
SEM: Problem classes or seminars or case studies (40 students)
SGT: Scheduled group tutorials (educational monitoring, ECTS type tutorials)
PS: Personal study, individual or group work and reading of bibliography

Teaching Methodologies

1. Explanation and discussion of the contents.
2. Resolution, analysis and discussion of problems. Realization, exhibition and defense of works/projects.
3. Experimental activities such as laboratory practices, computer classrooms and fieldwork.
4. Individual or group follow-up activities of learning.
5. Autonomous work of the student.

Learning outcomes

This optional subject aims to transmit quality to students as a general concept, since its control is an indispensable tool in the laboratory, as well as in biotechnological industrial processes. The aim is to provide the student with basic knowledge about quality, which will allow them to adopt quality assurance procedures in the testing laboratory and their application to biotechnological industrial processes.
Define and differentiate the different internal quality control operations.
Knowledge of the requirements linked to the competence of testing and calibration laboratories.
Develop and implement management systems related to biotechnology.
Theoretical and practical training in statistical quality control
Design experiments, obtain information and interpret the results
Define and know the objectives and characteristics of the different interlaboratory studies and the systematic statistical treatment of the data.
Provide knowledge of quality standards in laboratories and environmental management.

Assessment systems

The choice of the global assessment modality corresponds to the students, who may carry it out during the first quarter of the semester (or until the last day of the enrolment extension period if it ends after that period), through a specific space created for this purpose on the Virtual Campus. In the absence of an express request by the student, the assigned modality will be continuous assessment.

Students on a continuous assessment basis. Ordinary call

-Final exam: The exam can include development or long answer questions, short answer questions, multiple-choice questions, application exercises and numerical problems. The grade obtained will account for 60% of the overall grade. This activity is recoverable in the extraordinary call.

-Evaluation of the use of practical activities: each of the practical activities is valued in terms of attendance, interest and professional attitude, ability to work safely following the indications of the script and the teaching staff, order and cleanliness in the workplace, proper waste management. The quality of each of the practice reports is also valued in terms of foundation, rigor and clarity in the description and interpretation of the experimental results according to the appropriate calculations, experimental observations and use of appropriate documentary sources. The grade obtained will account for 20% of the overall grade. This activity is non-recoverable.

-Preparation of work and its presentation: the preparation, oral presentation and discussion of proposed works on different aspects of the subject is valued. The grade obtained will account for 20% of the overall grade. This activity is non-recoverable.

Students on a continuous assessment basis. Extraordinary call

-Exam: The exam can include development or long answer questions, short answer questions, multiple-choice questions, application exercises and numerical problems. The grade obtained will account for 60% of the overall grade.

-Evaluation of the use of practical activities: A grade obtained in the ordinary call is applied, which will account for 20% of the overall grade.

-Preparation of works and their presentation: A grade obtained in the ordinary call is applied, which will account for 20% of the overall grade.

Students in a global assessment regime. Ordinary call

-Final exam: The exam can include development or long answer questions, short answer questions, multiple-choice questions, application exercises and numerical problems. The grade obtained will account for 60% of the overall grade. This activity is recoverable in the extraordinary call.

-Evaluation of the use of practical activities: theoretical-practical examination on safety in field and laboratory work, characteristics and handling of materials and equipment, substantiation of experiments, description and interpretation of experimental results according to appropriate calculations, experimental observations and use of appropriate documentary sources, and waste management. The grade obtained will account for 20% of the overall grade. This activity is recoverable in the extraordinary call.

-Preparation of work and its presentation: theoretical-practical exam on the contents of the work proposed during the teaching of the subject. The grade obtained will account for 20% of the overall grade. This activity is recoverable in the extraordinary call.

Students in a global assessment regime. Extraordinary call

-Final exam: The exam can include development or long answer questions, short answer questions, multiple-choice questions, application exercises and numerical problems. The grade obtained will account for 60% of the overall grade.

-Evaluation of the use of practical activities: theoretical-practical examination on safety in field and laboratory work, characteristics and handling of materials and equipment, substantiation of experiments, description and interpretation of experimental results according to appropriate calculations, experimental observations and use of appropriate documentary sources, and waste management. The grade obtained will account for 20% of the overall grade.

-Preparation of work and its presentation: theoretical-practical exam on the contents of the work proposed during the teaching of the subject. The grade obtained will account for 20% of the overall grade.

Bibliography (basic and complementary)

-Books:
1) World Health Organization. Laboratory Quality Management System (LQMS). Edited by WHO, 2016. Available on the Internet: http://www.who.int/ihr/publications/lqms/es/
2) R. Compañó Beltrán and A. Ríos Castro. Quality assurance in analytical laboratories". Ed. Síntesis, S.A., 2002
3) J.N. Miller; J.C. Miller. Statistics and Chemometrics for Analytical Chemistry, 4th Ed. Prentice Hall, 2002
4) S. Sagrado Vives, E. Bonet Domingo, M. J. Medina Hernández, Y. Martín Biosca and L. Escuder Gilabert. Practical manual on quality in laboratories. ISO 17025 approach. Ed. AENOR Internacional, S.A.U., 2017

-Quality standards:
1) UNE-EN ISO 9001 Standard. Quality management systems. Requirements.
2) UNE-EN ISO 15189 standard. Clinical laboratories. Particular requirements for quality and competence.
3) UNE-EN ISO/IEC 17025 standard. Conformity assessment. General requirements for the competence of testing and calibration laboratories.

4) UNE-EN ISO 14001 Standard. Environmental management systems. Requirements with guidance for their use.

Other resources and complementary educational materials

The slides used for the explanation of content in class are provided, accompanied by the teacher's notes on some topics.
Collections of problems solved are provided.
Practice scripts are provided.
During the course, links are provided to multiple resources on the Internet, such as instrument tutorials, application videos, instrumentation supplier websites, collections of official methods and application notes, etc.
All the information about the subject is centralised in the virtual classroom (UEx virtual campus). The virtual classroom is also used as a means of completing questionnaires, as a means of delivering assignments, and as a basic means of communication (messaging and forums).

1) US-FDA (Food and Drug Administration) Laboratory Quality Standards Manual: https://www.fda.gov/ScienceResearch/FieldScience/LaboratoryManual/default.htm
2) Portal of Good Laboratory Practices of the Spanish Agency for Medicines and Health Products: https://www.aemps.gob.es/industria/inspeccionBPL/home.htm
3) OECD Portal on Good Laboratory Practice: http://www.oecd-ilibrary.org/environment/oecd-series-on-principles-of-good-laboratory-practice-and-compliance-monitoring_2077785x#
4) ENAC (National Accreditation Entity) web portal https://www.enac.es/web/enac
5) Sampling manual for EU customs and taxation authorities: https://ec.europa.eu/taxation_customs/dds2/SAMANCTA/EN/index_EN.htm