Universitat Autònoma de Barcelona

2020/2021

Quality Analysis and Management

Code: 102501
ECTS Credits: 6

Degree	Type	Year	Semester
2502444 Chemistry	OT	4	0

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: No
Some groups entirely in Spanish: No

Prerequisites

There is no specific prerequisite. It is assumed that the student has the basic training of the first three years of the Degree in Chemistry.

Objectives and Contextualisation

The objective of the subject is to introduce the student to the concept of quality as a strategic resource for competitiveness and to provide the necessary tools to develop the laboratory's activity in the framework of a quality system based on the standards and current regulations.
As specific goals, we can emphasize:
- Define the basic principles that regulate the quality standards in laboratories, as well as the tools for their application
- Introduce to the student other tools related to quality, such as certified reference materials, document writing, good laboratory practices, etc.
- Apply concepts and statistical tools in specific cases, intercomparison exercises, methods validation, control graphics, etc.
- Know the importance of the validation of methods and their protocols
- Acquire the basic concepts of accreditation and the accreditation and certification procedures of the laboratories

Competences

- Adapt to new situations.
- Apply knowledge of chemistry to problem solving of a quantitative or qualitative nature in familiar and professional fields.
- Be ethically committed.
- Communicate orally and in writing in ones own language.
- Evaluate the health risks and environmental and socioeconomic impact associated to chemical substances and the chemistry industry.
- Handle chemical products safely.
- Have numerical calculation skills.
- Lead and coordinate work groups.

- Learn autonomously.
- Manage the organisation and planning of tasks.
- Manage, analyse and synthesise information.
- Obtain information, including by digital means.
- Propose creative ideas and solutions.
- Reason in a critical manner
- Resolve problems and make decisions.
- Show an understanding of the basic concepts, principles, theories and facts of the different areas of chemistry.
- Show initiative and an enterprising spirit.
- Show motivation for quality.
- Show sensitivity for environmental issues.
- Use IT to treat and present information.
- Use the English language properly in the field of chemistry.
- Work in a team and show concern for interpersonal relations at work.

Learning Outcomes

1. Adapt to new situations.
2. Assign the appropriate quality management system in accordance with the type of activity of the organisation in question.
3. Be ethically committed.
4. Communicate orally and in writing in ones own language.
5. Describe the necessary stages to establish an environmental certification system.
6. Design preliminary activities for auditing an organisations quality.
7. Distinguish the different quality management systems, considering their application to industry and research.
8. Draft and interpret security reports on a chemical substance.
9. Have numerical calculation skills.
10. Identify the cases of application of national and EU legislation regarding security in the use, transport and commercialisation of chemistry products.
11. Identify the different legal frameworks of chemistry activity: chemical products, safety and environmental impact.
12. Identify the relevant aspects of organic and inorganic chemistry in associated industrial sectors.
13. Lead and coordinate work groups.
14. Learn autonomously.
15. Manage the organisation and planning of tasks.
16. Manage, analyse and synthesise information.
17. Obtain information, including by digital means.
18. Propose creative ideas and solutions.
19. Reason in a critical manner
20. Resolve problems and make decisions.
21. Show initiative and an enterprising spirit.
22. Show motivation for quality.
23. Show sensitivity for environmental issues.
24. Summarise an article written in English in a reasonable time.
25. Understand current concepts of quality and work in the chemistry laboratory.
26. Use IT to treat and present information.
27. Use common English terminology for industrial chemistry, electrochemistry and corrosion, environmental chemistry, green chemistry, quality management, monitoring systems, and financial and business management.
28. Work in a team and show concern for interpersonal relations at work.

Content

SUBJECT 1. Basic aspects of quality assurance
Lesson 1. Introduction to quality: Evolution of the concept of quality. Basic components of quality.

Implementation of quality systems.
Lesson 2. Regulatory references of quality systems: Normalization and normalization bodies. Certification and accreditation. Introduction to the Standards, Institutions and related Organisms. Generic systems for quality management.
Lesson 3. Introduction to ISO 9001 and ISO / IEC 17025. General principles. Description. Types of documents used in the quality system. Risk analysis concept.
Lesson 4. Introduction to Good Laboratory Practices. Scope. General principles. Description. Documentation. Differences with ISO standards.
Lesson 5. Quality audits: Audits in a quality system. Planning and conducting audits. Documentation.
SUBJECT 2. Metrological tools.
Lesson 6. Quality in the laboratory: Metrology in chemistry. The quality in the analytical process. Traceability as a basis for analytical quality. Uncertainty in the measurement and analytical results.
Lesson 7. Statistical tools used in quality: Basic concepts and statistical tools: sample and population. Significance tests. Comparison of two sets of results. ANOVA. Calculation of the uncertainty of an analytical method. Expression of results.
Lesson 8. Quality in basic laboratory work: Materials: mass measurement and volume. Reagents: qualities. Basic andchemical patterns. Certified reference materials.
SUBJECT 3. Activities for quality.
Lesson 9. Sampling and sample management: Sample type. Sampling error and its decrease. Sampling methods. Management of samples.
Lesson 10. Validation of analytical methods: Concept and type of validation. Quality parameters. Application guides (ICH) R3.
Lesson 11. Internal quality control: Control activities. Control graphics (Shewart and accumulated sums). Practical aspects of internal quality control.
Lesson 12. Intercomparison exercises: Quality evaluation. Definition and type of intercolaboration exercises. Tests of aptitude. Collaborative and certification exercises.

Methodology

There are two types of teaching methodology in this subject, face-to-face and self-learning activities.
Face-to-face activity:
- Classes in the classroom: they will consist of the presentation of the main theoretical concepts that make up the subjects that are the object of the study.
- Exercises in the classroom: Students will have a collection of exercises and / or practical cases proposed by the teacher that will be resolved in the classroom.

- Seminars: Practical aspects derived from the introduction of a system of quality assurance in laboratories by experts in the subject that work in an industry will be discussed in the classroom. Specific cases to be resolved by means of spreadsheets (so that the student has contact with the management and data control systems) will be also considered.
The material presented to the theory classes and the exercises will be available to the students in Moodle in advance enough before each subject.
Self-learning activity:
- Preparation and delivery of specific numerical cases and practical cases, both individually and in groups, proposed by the teacher. This activity will be considered in the student's evaluation.
- If the number of students allows it, preparation and defense of a specific case on quality assurance / validation. Evaluable section.
Class transparencies are in English (mostly) and Spanish. The exams and works can be done in English, Catalan or Spanish.

Activities

Title	Hours	ECTS	Learning Outcomes
Type: Directed			

Practical classes in the classroom	10	0.4	4, 21, 22, 15, 17, 19, 20, 24, 9, 27
Theory	34	1.36	2, 22, 5, 6, 7, 10, 11, 3, 23, 8, 25, 24, 27
Type: Supervised			
Seminars	7	0.28	1, 4, 21, 3, 23, 18, 19, 20, 9, 27
Type: Autonomous			
Autonomous study	60	2.4	1, 14, 2, 4, 21, 22, 5, 6, 7, 15, 16, 10, 11, 3, 23, 17, 18, 19, 8, 25, 20, 24, 9, 26, 27
Type of activity: Self-learning	11	0.44	1, 14, 4, 21, 22, 15, 16, 13, 3, 23, 17, 18, 19, 20, 24, 9, 28, 26, 27

Assessment

The evaluation process follows the principle of continuous evaluation. For the evaluation of the subject, they will be carried out:

(1) Two midterm exams on the dates indicated by the faculty, each one corresponding, approximately, to half of the syllabus of the subject. Midterm exams are individual. Each midterm exam will have two parts, the first one will consist of several questions related to the theory part of the subject (it may be type test and may also include some short questions). In the second part, the student will have to solve some problems. The theory part will be worth between 40 and 60% of the partial mark, and the part of problems between 40-60%. To be able to make an average for the final mark, the qualification of the midterm exam must be equal to or greater than 4.0. The final mark of these two tests will have a weighting of 70% in the final grade.

(2) Presentation of works. These works will be carried out in groups and the maximum number of participants will be set prior to each work. The overall mark of this work will have a weighting of 20% in the final grade.

(3) Presentation of a summary of each conference or seminar given. This summary will be written individually. The global mark of these abstracts will have a 10% weighting in the final grade.

The final grade is the sum of the weighted notes of the three previous items. To pass the subject, students must obtain an average of 5.0 or more.

Attendance at seminars or conferences is mandatory.

If the proposed works or the summaries of the conferences are not presented, the student will be described as "not evaluable", regardless of the mark of the midterm exams.

The student who does not pass the normal evaluation will have an extraordinary evaluation, in the dates determined by the faculty.

To be able to take the recovery exam, students must have participated in evaluation activities throughout the course that are equivalent to 2/3 of the final grade.

Only the mark referred to in paragraph (1) can be recovered. The marks and weightings of sections (2) and (3) will be the same as before. The student will have to retake each of the midterm exams with a mark less than 4.0. In the event that the final grade is less

than 5.0, and the partial ones have a mark greater than 4.0, the student may decide to take the extraordinary evaluation of both midterm exams or only the extraordinary evaluation of that exam with the lowest mark.

The mark of the retaken exam will replace the previous one in the calculation of the global grade. To be able to make an average for the final grade, the qualification of the partial examination must be equal to or greater than 4.0.

Assessment Activities

Title	Weighting	Hours	ECTS	Learning Outcomes
Cooperative activities	20	15	0.6	1, 14, 21, 22, 15, 16, 13, 3, 23, 17, 18, 19, 25, 20, 24, 9, 28, 26, 27
Midterm exam I	35	3	0.12	1, 2, 4, 22, 5, 6, 7, 16, 3, 18, 19, 25, 20, 9, 27
Midterm exam II	35	3	0.12	1, 4, 22, 16, 10, 11, 3, 23, 18, 12, 19, 8, 25, 20, 9, 27
Seminars or lectures in the classroom	10	7	0.28	1, 14, 21, 15, 16, 13, 3, 17, 18, 19, 20, 24, 28, 26, 27

Bibliography

Although it does not follow the order of the program and the regulations referred to are not the current ones, it can be considered a textbook with the basic content of the subject: R. Compañó Beltrán, A. Ríos Castro; Garantía de la calidad en los Laboratorios analíticos ". Editorial Síntesis. Madrid (2002).

Review and update of a classic textbook on the subject. The UAB has the electronic version of the book that is free to access: E. Prichard, V. Barwick; *Quality assurance in analytical chemistry*. Wiley (2007).

General statistics text; It is simple, convenient and practical:James Miller, Jane C Miller and Robert D. Miller; Statistics and Chemometrics for Analytical Chemistry, 7th Ed, Pearson Higher Education (2018).
A book about statistical tools applied to quality. (There is an e-book of 2012): P. Konieczka, J. Namieśnik; *Quality assurance and quality control in the analytical chemical laboratory: A practical approach*. CRC Press, Boca Ratón (2009). Un libro sobre las herramientas estadísticas aplicadas a la calidad. (Existe una edición e-book del 2012).

Tools for the use in statistical tests, linear regression, validation of methods, control charts, interlaboratory exercises, etc. There is an electronic version available at the UAB: M. Reichenbächer, J.W. Einax; *Challenges in Analytical Quality Assurance*. Springer (2011).