

## **Quality Analysis and Management**

Code: 102501 ECTS Credits: 6

Degree	Туре	Year	Semester
2502444 Chemistry	OT	4	1

## Contact

Name: Manel Alcala Bernardez

Email: manel.alcala@uab.cat

#### **Teaching groups languages**

You can check it through this <u>link</u>. To consult the language you will need to enter the CODE of the subject. Please note that this information is provisional until 30 November 2023.

## 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 one's own language.

2023/2024

- 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 one's own language.
- 5. Describe the necessary stages to establish an environmental certification system.
- 6. Design preliminary activities for auditing an organisation's 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.

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.

#### 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

#### CONTINUED AVALUATION

The evaluation of the subject will be carried out through a continuous evaluation that will consist of: 1) Presentation of written work to be done in previously defined groups of students. Sending files via Moodle. They must be approved (minimum average grade of 5.0 out of 10) so that they weigh in the final grade, otherwise the subject will be suspended. The average grade of the written assignments will be 20% of the final grade.

2) Presentation of an oral summary of each conference or seminar given. This summary will be presented individually by sending a video file via Moodle. They must be approved (minimum average grade of 5.0 out of 10) so that they weigh in the final grade, otherwise the subject will be suspended. The average grade of the oral summaries will be 5% of the final grade. Attendance at seminars or conferences is mandatory. If for any reason they could not be carried out, their weighting in the evaluation would be distributed equally to the other items.

3a) Two partial written exams that will evaluate theory and problems, and that will be carried out individually. The two partials will assess approximately two halves of the syllabus. It is necessary to pass both partials (each with a minimum grade of 5.0 out of 10) so that they weigh in the final grade, otherwise each suspended partial will be replaced by a make-up exam. The grade for each partial exam will be 37.5% of the final grade. 3b) A written recovery exam that will evaluate theory and problems of the part of the syllabus corresponding to the failed partial. This recovery replaces the suspended partial and is not intended to increase the grade when the partial has been approved. Making up the recovery will result in the invalidation of the grade of the suspended partial. A minimum grade of 5.0 out of 10 must be obtained in the recovery for it to count in the final grade, otherwise the subject will be suspended. The grade for the make-up exam will be 37.5% of each failed partial. You can only recover the grade of the failed exams. The marks and weightings of the written or oral assignments suspended are not recovered.

To pass the subject you must obtain a minimum final grade of 5.0 points out of 10 in the weighted sum of each of the parts (written assignments 20%, oral summaries 5%, partial exams 2 x 37.5%).

If the written works or the oral summaries of the conferences and seminars are not submitted, the student will

be classified as "not evaluable", regardless of the grade of the partial exams.

To participate in the recovery, students must have previously been assessed in a set of activities whose weight is equivalent to a minimum of two-thirds of the subject's total grade.

#### UNIQUE ASSESSMENT

Students taking the single assessment must do the following:

1) The presentation of written work does not require attendance and its weight in the final grade is 20%. The files will be sent via Moodle on the day of the single exam that coincides with the date of the second partial exam. They must be approved (minimum average grade of 5.0 out of 10) so that they weigh in the final grade, otherwise the subject will be suspended.

2) Presentation of an oral summary of each conference or seminar given, they do not require attendance and their weight in the final grade is 5%. The video files will be sent via Moodle on the day of the single exam that coincides with the date of the second partial exam. They must be approved (minimum average grade of 5.0 out of 10) so that they weigh in the final grade, otherwise the subject will be suspended. If for any reason the conferences or seminars could not take place, their weighting in the evaluation would be distributed equally to the other items.

3a) A single written exam that will evaluate theory and problems of the entire syllabus, and that will be carried out individually. The day of the single exam coincides with the date of the second partial exam. It is necessary to pass the single exam (minimum grade of 5.0 out of 10) so that it counts in the final grade, otherwise it will be replaced by a recovery exam. The grade of the single exam will be 75% of the final grade.

3b) A written recovery exam that will assess theory and problems from the entire syllabus. This retake replaces the failed single exam and is not intended to raise a grade when the single exam is passed. Completing the recovery will result in the invalidation of the grade of the single failed exam. The day of the make-up exam is the same date as the make-up exam of the continuous assessment. A minimum grade of 5.0 out of 10 must be obtained in the recovery for it to count in the final grade, otherwise the subject will be suspended. The grade of the make-up exam will be 75% of the final grade. You can only recover the grade of the failed exam. The marks and weightings of the written or oral assignments suspended are not recovered.

To pass the subject you must obtain a minimum final grade of 5.0 points out of 10 in the weighted sum of each of the parts (written assignments 20%, oral summaries 5%, single exam 75%).

To participate in recovery, students must have been e.g re-evaluated in a set of activities whose weight is equivalent to a minimum of two-thirds of the subject's total grade.

Title	Weighting	Hours	ECTS	Learning Outcomes
Cooperative activities	20	19	0.76	1, 14, 21, 22, 15, 16, 13, 3, 23, 17, 18, 19, 25, 20, 24, 9, 28, 26, 27
Midterm exam I	37,5	3	0.12	1, 2, 4, 22, 5, 6, 7, 16, 3, 18, 19, 25, 20, 9, 27
Midterm exam II	37,5	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	5	3	0.12	1, 14, 21, 15, 16, 13, 3, 17, 18, 19, 20, 24, 28, 26, 27

## Assessment Activities

## 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 ebook 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).

#### Software

Microsoft Excel will be used