PERSONA CIÈNCIA EMPRESA
Universitat Ramon Llull

COURSE: QUALITY AND INFORMATION MANAGEMENT

SUBJECT: MANAGEMENT
MODULE: Management
PROGRAM: University Master's Degree in Analytical Chemistry

GENERAL FEATURES *

Type: ☐ Basic Training ☑ Compulsory ☐ Elective
☐ Master's thesis work, ☐ Practicum

Duration: Semester **Semester / s:** 2
Number of ECTS credits: 5
Language / s: Spanish, Catalan

DESCRIPTION

BRIEF DESCRIPTION AND JUSTIFICATION (The meaning of the course in relation to the program. Between 100 and 200 words.)

Introducing new tools for Quality Management and its application to laboratories and chemical companies. Quality Systems with a wider implementation in the various sectors of industry and chemical laboratories are presented: 9001, 17025, GLP and GMP including numerous applications and case studies or problems on equipment calibration, validation procedures, internal audits, defining processes and indicators, methodology for improvement, etc.

COMPETENCES (Of course you put in relation to the skills pre-assigned in the field.)

Basic competences
CB6 - Have and understand knowledge which provides the ground or opportunity to be innovative in the development and/or application of ideas, often in a research context
CB7 - Apply their knowledge and their ability to solve problems in new or unfamiliar environments within broader (or multidisciplinary) contexts related to their field of study
CB8 - Integrate knowledge and deal with the complexity of formulating judgments based on information which, being incomplete or limited, includes reflections on social and ethical responsibilities related to the application of their knowledge and judgments
CB9 - Communicate conclusions, and the reasons that sustain them, to specialized and non-specialized audiences in a clear and unambiguous way.

General competences
CG1 - Ability to lead, direct and manage projects in academic or business environments adapting to the structures, needs and ways of operation of each institution

Specific competences
E11 - Demonstrate knowledge of Quality Management concepts and tools for its application to analysis laboratories and industry in general
E12 - Ability to lead, direct and manage projects in chemistry according to the requirements of a quality system

* These features should not be modified without the approval of the bodies responsible for academic higher-level structures (field, module and / or system).

Transversal competences
T3 - Ability to assess the impact of the use of chemistry in sustainable development of society

PREREQUISITES * (Modules, materials, disciplines or expertise needed to track the subject. Contain subjects that must have been completed can be made.)
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CONTENTS (Sections that make up the syllabus, to a second level of detail.)

1. Introduction: Evolution of quality concept and definitions
2. Quality Systems:
   - UNE-EN-ISO 9001
   - UNE-EN-ISO 17025
   - GLP (Good Laboratory Practice)
   - GMP (Good Manufacturing Practice)
3. Resource management:
   - Equipment (calibration)
   - Reagents (REACH)
4. Validation of Analytic Procedures
5. Personnel management
6. Procurement and subcontracting
7. Documentation System / Documented information
8. Evaluation Activities
9. Management by Processes and Indicators
10. Strategic quality planning

METHODOLOGY

TRAINING ACTIVITIES * (Complete the table relating activities, workload in ECTS credits, and skills.)

Training Activities	ECTS	Competences
Sessions of exposition of concepts	1.1	E17, E18, T3, CB6, CB7, CG1
Sessions solving exercises, problems and cases	0.2	E17, E18, T3, CB6, CB7, CG1
Seminars	0.1	E17, E18, T3, CB8, CB9, CG1
Presentations	0.2	E17, E18, T3, CB8, CB9, CG1
Activities of personal study by students	3.3	E17, E18, T3, CB6, CB7, CB8, CG1
Evaluation activities (exams, monitoring controls ...)	0.1	E17, E18, T3, CB6, CB7, CB8, CB9, CG1
TOTAL	**5**	

TEACHING METHODOLOGY (Justifying the teaching methods used in relation to the competences and contents of the course. Between 100 and 200 words.)

In this course 40 hours of classes are taught by the teacher in the classroom.
At sessions dedicated to the presentation of concepts, the highlights of each topic are introduced taking care of relationships with the knowledge that the student already has of other subjects, those integrating concepts of chemistry and management.
Resolution and discussion of problems and case studies gives a highly applied approach to the subject.
In the seminars the difficulties students have encountered are discussed, especially during the resolution of problems or preparation of projects.
Classes are developed in a participatory manner, maintaining a constant dialogue with students.
Blackboard platform is used for students to have the basic and supplementary material of this subject.

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EVALUATION

ASSESSMENT SYSTEM * (Complete the table relating evaluation methods, competences and weight in the course grade.)

Evaluation Methods	%	Competences
Final Exam	40%	E17, E18, T3, CB7, CG1
Monitoring activities	25%	E17, E18, T3, CB6, CB7, CG1
Projects and presentations	30%	E17, E18, T3, CB8, CB9, CG1
Participation	5%	T3

LEARNING OUTCOMES (Explanation of the embodiments that allow the student skills assessment, relating them to the skills and methods of assessment.)

- The student must demonstrate understanding and knowledge of the concepts and tools for quality management in laboratories and pharmaceutical chemical industry.
- The student must demonstrate that properly uses the terminology of quality management.
- The student must show ability to interpret the statement of problems, to solve them and interpret the results.
- The student must demonstrate an understanding of the importance of quality and ethical behavior in relation to the exercise of their profession.
- The student must demonstrate the ability to communicate orally and in writing to convey their knowledge, findings and opinions related to quality management.
- The student must demonstrate the ability to lead, direct and manage projects in chemistry contemplating the requirements of a quality system.
- The student must demonstrate the ability to lead and manage teams

QUALIFICATION (Explanation of the computer system of the course grade.)

The grade of this course is obtained:

Final exam	40%
Monitoring activities	25%
Projects and presentations	30%
Participation	5%

- The **final exam** includes theoretical and practical aspects.
- **Monitoring activities** include works (exercises, problems and cases) that perform and deliver the students during the course.
- Students do group **Projects** of 2-3 people. Some of these works include presenting it to other peers.

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- The **participation** includes attendance, initiative and the attitude shown by the student in relation to the teacher and their peers.

Final exam grades, monitoring activities and projects and presentations must be greater than or equal to 4 points to pass the course.

ASSESSMENT OF THE COMPETENCES (Define calculation expressions for each competence and the relevant evaluation methods.)

Evaluation methods	Competences
Final exam	E17, E18, CB7, CG1
Monitoring activities	E17, E18, CB6, CB7, CG1
Projects and presentations	E17, E18, T3, CB8, CB9, CG1

BIBLIOGRAPHY (Recommended and accessible to students.)

Norma UNE-EN-ISO 9001:2015 Sistemas de gestión de la calidad. Requisitos.
UNE-EN-ISO 17025:2005 "Requisitos generales para la competencia de los laboratorios de ensayo y calibración"
BPL: Real Decreto 1369/2000 "Buenas Prácticas de Laboratorio"
GMP: http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol4_en.htm.

DOCUMENT HISTORY

PREVIOUS CHANGES (You set the date and author / s, the most recent first)
- September 2013 (Dr. Mª J. Blanco.)
- July 2012 (Dr. Mª J. Blanco.)
- January 2015 (Dr. Mª J. Blanco.)

LAST REVISION (Indicate date and author / s.)
January 2016 (Dr. Mª J. Blanco)