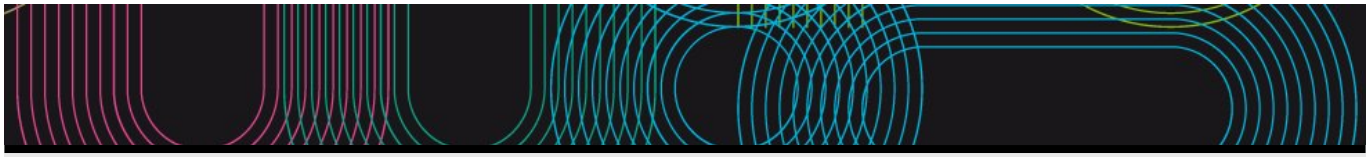

IDENTIFYING DATA				
(*)Certificación de productos sanitarios e innovación en tecnoloxía médica				
Subject	(*)Certificación de productos sanitarios e innovación en tecnoloxía médica			
Code	V04M192V01302			
Study programme	Máster Universitario en Ingeniería Biomédica			
Descriptors	ECTS Credits	Choose	Year	Quadmester
	6	Mandatory	2nd	1st
Teaching language	Spanish Galician			
Department				
Coordinator	Comesaña Campos, Alberto			
Lecturers	Comesaña Campos, Alberto			
E-mail	acomesana@uvigo.es			
Web	http://moovi.uvigo.gal/			
General description	This subject, which is part of the core module of the Master in Biomedical Engineering, focuses its objectives on the training related to the fulfilment of the necessary requirements for the professional use of a medical device. For this purpose, two main blocks of content are developed to cover the regulatory framework in which the medical device may be developed after its design. In the first block, the certification process of sanitary products will be studied, describing their classification, analysis and implementation. All the regulations involved in this process will be considered, from the implementation of a quality management system to compliance with the precise regulations. Then, in the second block, a generalized study of the industrial and intellectual protection process will be addressed, analyzing their respective characteristics and functions, reviewing the concepts, regulations and legislation in this regard, and also analyzing both the precise requirements for applying for a patent or utility model, as well as the procedure to be followed. Finally, and because of the processes described above, the process of innovation and entrepreneurship in biomedical engineering will be defined, contextualized and discussed. At the end of the course, the student should have sufficient skills and competences to understand the processes involved in the innovation of medical devices, to develop the procedure for the intellectual and industrial protection of these products and, in addition, to certify them appropriately and normatively for their end use.			

Training and Learning Results	
Code	
A1	Knowledge and understanding that provide a basis or opportunity for originality in developing and / or applying ideas, often in a research context.
A2	That the students can 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.
A3	That students are able to integrate knowledge and handle complexity and formulate judgments based on information that was incomplete or limited, include reflecting on social and ethical responsibilities linked to the application of their knowledge and judgments.
A4	Students can communicate their conclusions, and the knowledge and rationale underpinning these, to specialist and non-specialist audiences clearly and unambiguously.
A5	Students must possess the learning skills that enable them to continue studying in a way that will be largely self-directed or autonomous.
B4	Ability to solve problems with initiative, decision making, creativity, critical reasoning and to communicate and transmit knowledge, abilities and skills in the field of biomedical engineering.
B7	Ability to analyze and assess the social and environmental impact of the technical solutions.
B8	Ability to apply the principles and methods of quality.
B10	Knowledge, understanding and ability to apply legislation related to the field of Biomedical Engineering.

B12	To operate effectively in a multidisciplinary team whose members, together, exercise leadership, create a collaborative and inclusive environment, set goals, plan tasks and meet goals.
C12	Ability to manage and audit development, production and quality of medical devices and creative ability to develop ideas and new and original methods in the biomedical area.
D1	Ability to understand the meaning and application of the gender perspective in the different fields of knowledge and in professional practice with the aim of achieving a more just and equal society.
D3	Sustainability and environmental commitment. Equitable, responsible and efficient use of resources.

Expected results from this subject	
Expected results from this subject	Training and Learning Results
Knowledge about the certification of health and biomedical products.	A1 A3 B13 B13 B7 B8 B10 C15 C15 C15 D1 D4 D3
Know the regulations and the procedures on protection of the copyright and intellectual property.	A1 A4 A5 B13 B13 B13 B13 B10 C15 C15 C15 C12 D4 D4 D4
Apply knowledges about the certification, innovation and protection of the copyright, in the field of biomedical engineering.	A2 A3 A5 B4 B13 C15 D1 D3 D4
Develop and execute projects of innovation in medical technology.	A2 A4 B4 B13 B13 B12 C15 C15 C15 C15 D4 D4 D4

Contents
Topic

1. Certification of medical products. Legislative framework and national and international regulations.	1.1. Current regulations at the national and international level. 1.2. Main definitions according to current regulations. 1.2. Essential requirements. Sanitary guarantees of the products. 1.3. Precise facilities and licenses for the development of sanitary products. 1.4. Classification and risk analysis of medical devices. 1.5. Labeling of medical devices and CE marking. 1.5.1. CE declaration. 1.5.2. CE exam. 1.5.3. CE verification.
2. Request and maintenance of the certification of sanitary products.	2.1. Application to a notified body. 2.2. Marketing and commissioning. 23. Process and regulations related to clinical investigations. 2.4. Surveillance and inspection system. 2.5. Quality system. 2.5.1. Application regulations. 2.5.2. Implementation. 2.5.3. Audits.
3. Industrial and intellectual property: concepts, regulations and legislation.	3.1. Current regulations at the national and international level. 3.2. Legislation relating to the protection of industrial and intellectual property. 3.3. Concepts and definitions according to current regulations. 3.3. The Spanish Patent and Trademark Office (SPTO) 3.3. Intellectual property. 3.4. Industrial property. 3.5. National and international patent databases.
4. Characteristics and requirements of invention patents, utility models and industrial designs.	4.1. Patentability. 4.2. The invention patent. 4.3. The European invention patent. 4.3. The utility model. 4.4. Industrial design. 4.5. The distinctive signs. 4.6. Requirements to apply for a patent. 4.6.1. Novelty. 4.6.2. inventive activity 4.6.3. industrial application. 4.6.4. Executable 4.7. Patent right.
5. Application procedure for patents and utility models.	5.1. Invention patent application procedure. 5.1.1. Application requirements. 5.1.2. Presentation of the application. 5.1.3. Designation of the inventor. 5.1.4. unit of invention 5.1.5. Description of the invention. 5.1.6. Claims. 5.2. Invention patent grant procedure. 5.2.1. Reception at the SPTO 5.2.2. Trade exam. 5.2.3. Issuance of the report on the state of the art. 5.2.3. Publication of the application and the report. 5.2.4. Substantive exam. 5.2.5. Processing, resolution and announcement of concession. 5.3. Application procedure and granting of utility models. 5.4. European invention patent application and grant procedure.
6. Innovation in biomedical technology.	6.1. Innovation and entrepreneurship in medical technologies. 6.2. Innovation tools: innovation management methods. 6.3. Technology transfer environments in biomedicine.
Practices. Certification and industrial protection of a biomedical product. R&D&i management in the health sector. In these practical exercises, the students will have to document the process that allows, on the one hand, the complete and correct certification of a medical device and, on the other hand, its intellectual and industrial protection in the field of biomedical engineering. There will also be an exercise on the integral management of healthcare R&D&i.	1. Choice of product. 2. Analysis of preliminary steps and previous conditions. 3. Documentation and review of the health certification process. 4. Comprehensive management of healthcare R&D&i. 5. Documentation and review of the intellectual and industrial protection process. 6. Submission and presentation of the process.

Planning

	Class hours	Hours outside the classroom	Total hours
Lecturing	20	18	38
Problem solving	8	0	8
Laboratory practical	12	5	17
Practices through ICT	6	2	8
Objective questions exam	1	10	11
Essay questions exam	1	15	16
Problem and/or exercise solving	0	7	7
Laboratory practice	0	20	20
Report of practices, practicum and external practices	0	25	25

*The information in the planning table is for guidance only and does not take into account the heterogeneity of the students.

Methodologies

	Description
Lecturing	The theoretical content will be presented by the lecturer during the classes, complemented by discussion and interpretation of the same. They will be coordinated with the planned practical activities.
Problem solving	In a complementary way to the presentation of the theoretical contents, different application exercises will be proposed and developed, which the students will have to solve in a comprehensive and reasoned way.
Laboratory practical	From a practical point of view, the course covers two large blocks of action, which are procedurally different but related by their application example and their objectives. On the one hand, the process of sanitary certification of the product and, on the other hand, its industrial protection. In addition, there is the study and practice of the integral management of healthcare R&D&i. Thus, once a biomedical product has been selected, the practices will cover these blocks as follows. Product certification: Working in groups and under the guidance and supervision of the lecturer, the students must define and develop the documentary process necessary for the certification of a medical device. The implementation of the quality system must be specified and all the steps necessary to achieve the correct and complete certification of the product must be detailed. It will also be possible to review the process of integral management of research, development and innovation in the health sector. Intellectual and industrial protection of the product: Using the same groups and the same product as in the previous block and in the same circumstances, the students will have to document the intellectual and industrial protection procedure, as the case may be, describing and writing the protection process followed and analyzing each of its stages in detail. Although the sanitary product that will be used as a vehicle example should preferably be the same, if necessary and after acceptance and supervision of the lecturer, the two blocks of exercises could use different products.
Practices through ICT	In the development of the practices of the subject, the students must actively use different information and communication technologies, even implementing some of them.

Personalized assistance

Methodologies	Description
Laboratory practical	Proposition and review of the outcomes of the course activities, aiming to support individually the learning process in small groups of students. An appropriate follow-up will be performed on student's work to verify that the best practices shown in theory classes are applied, and that the procedimental recommendations provided by the lecturer are followed. The tutorial sessions can be carried out using IT tools (email, video-call, Moovi forums, etc.) according to the modality of prior concertation of the virtual place, date and time.

Assessment

	Description	Qualification	Training and Learning Results
Objective questions exam	During the course, a series of objective and short-answer evaluation questionnaires will be carried out on the theoretical topics, either considering all the topics as a whole or individualizing each of them.	20	A1 B10 C12 A2 A3
Essay questions exam	At the end of the course there is an examination which includes development questions relating to the theoretical and practical content of the course.	25	A1 B4 C12 A2 B10 A3

Problem and/or exercise solving	The problems solved in class, after being checked and corrected, can be collected and supplemented with new ones. All of them will have to be commented on and justified before they are finally handed in. Their understanding, explanation and detailed justification will be assessed.	5	A1 B4 C12 A2 B10 A3	
Laboratory practice	The practices of the subject will be carried out in consideration of two coherent and and complementary blocks: First block - Certification: Students must define and develop the documentary and regulatory process that will allow the certification of a health product previously defined in the classes. Each step of the process must be detailed, defining the implementation of the precise quality system and compliance with current regulations. It will also be possible to review the process of integral management of research, development and innovation (R&D&i) in the health sector. Second Block - Intellectual and Industrial Protection: In this block, the students will have to define the process of intellectual and industrial protection, as the case may be, describing and finally writing the protection process related to a medical device, which could be the one used in the first block, preferably, or another one. The objective will be to explain in detail each of the steps of the said protection process, describing and analyzing the different stages followed. In both blocks, the precision and adequacy of the proposals in relation to the stated objectives, the development of the practical work, the degree of autonomy of the students, as well as the choice and monitoring of compliance with the regulations will be assessed. During the practical work, compulsory periodical deliveries and individual and/or group meetings could be considered.	20	A3 B7 D1 A4 B8 D3 A5 B12	
Report of practices, practicum and external practices	At the end of the course, a complete technical report of the results obtained during the practical sessions of each block of the subject must be prepared. In this report, which may be joint or divided into each block, the processes carried out in each block of exercises must be described and the technical documentation procedure followed must be highlighted. Among other aspects, the compliance of the proposal with the regulations, the technical writing, and the clarity of the explanation of the stages to be followed will be assessed. Other aspects that will be taken into consideration are the technical and content-related presentation, the student's participation in class and in the work, the adaptation to the deadlines and the presentation and defence of the solution obtained, which is compulsory.	30	A3 B7 D1 A4 B8 D3 A5 B10	

Other comments on the Evaluation

The assessment of the subject will include the lecturer's assessment of the student's work, both individual and group, whether face-to-face or remote, weighted as indicated in the Assessment section.

To determine the grade for all the assessment tests, a numerical grading system will be used, with values ranging from 0.0 to 10.0 points, in accordance with current legislation (R.D. 1125/2003, of 5 September, BOE. No. 224, of 18 September). In any case, the subject is considered passed if the grade obtained is at least 5.0 out of 10.

The subject offers two different evaluation modalities in its first evaluation period: continuous evaluation and non-continuous or global evaluation. In the second period, the evaluation is carried out exclusively by means of the corresponding global examination.

Comments for the First Assessment Period / Ordinary Exam Period

The student may follow the above modalities:

- Continuous evaluation modality

In this modality, the student will pass the subject if he/she obtains a minimum of five points (5.0) out of 10 without having to take the corresponding ordinary period examination. Each assessment test is worth 10 points. It is necessary to obtain a minimum of 5.0 points out of 10 in each of the assessment tests and in each part or subpart of those tests in order to pass the subject. Students who do not pass the continuous assessment, i.e. who do not pass each and every one of the assessment tests set, will be required to take the corresponding additional tests and, if applicable, to take the second period examination. This is subject to the considerations and clarifications deemed appropriate by the teacher.

- Non-continuous or global evaluation modality

At the beginning of the course, enrolled students have a deadline set by the School of Industrial Engineering to explicitly opt out of continuous evaluation. In this case, the enrolled student must inform the professor as soon as this has been requested and confirmed.

A student who opts out of continuous evaluation in order to pass the subject must take a single final examination on the date set by the School for the first assessment period, covering all the theoretical and practical content of the subject, including short answer questions, long answer questions, problem solving and the development of practical scenarios. Additionally, it will be necessary to demonstrate sufficient applied knowledge of the certification process and the intellectual and industrial protection of medical products, as well as the integral management of R&D&i in the healthcare sector. In order to pass the subject, students must achieve an overall mark of at least 5.0 out of 10 in each of these tests.

Comments for the Second Assessment Period / Extraordinary Exam Period

Students who have not passed the subject in the ordinary period by any of the above modalities will have a second opportunity to pass the subject by taking the second period examination on the date set by the School of Industrial Engineering.

The second period examination will cover all the theoretical and practical content of the subject, including short answer questions, long answer questions, problem solving and the development of practical cases. Additionally, it will be necessary to demonstrate sufficient applied knowledge of the certification process and the intellectual and industrial protection of medical products, as well as the integral management of R&D&i in the healthcare sector. In order to pass the subject, students must achieve an overall mark of at least 5.0 out of 10 in each of these tests.

Ethical Behavior

Students are expected to demonstrate appropriate ethical behaviour. In the event of unethical behaviour (cheating, plagiarism, use of unauthorized electronic devices, etc...) it will be assumed that the student does not meet the necessary requirements to pass the subject. In this case, the overall grade for the current academic year will be a fail (0.0). The use of teaching aids or electronic devices during examinations is not permitted unless specifically authorized. Bringing unauthorized materials or electronic devices into the examination room will be considered grounds for failing the subject for the current academic year and the overall grade will be a fail (0.0).

Sources of information

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Organización Mundial de la Propiedad Intelectual (OMPI), **Tratado sobre el Derecho de Patentes**, 2000

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Owen, R., Bessant, J.R. y Heintz, M., **Responsible innovation: managing the responsible emergence of science and innovation in society**, John Wiley & Sons, 2013

Gonzalez-Pifiero, M., Cano, E., Mafianas, M., Villanueva, J., y Magrans, P., **Knowledge Management and Open Innovation in a Bioengineering Research Case**, 1 (158), Case Studies in Innovation, 2012

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Recommendations

Subjects that are recommended to be taken simultaneously

(*)Organización do sistema sanitario e enxeñaría de procesos nos servizos sanitarios/V04M192V01303

Other comments

A review of the regulations contained in the bibliography is recommended to students as well as practice in information search methods.