

[GBM105] MEDICAL CERTIFICATIONS AND STANDARDS

GENERAL INFORMATION

Studies	DEGREE IN BIOMEDICAL ENGINEERING		Subject	New Products Engineering
Semester	2	Course	3	Mention / Field of specialisation
Character	COMPULSORY		Language	CASTELLANO
Plan	2017	Modality	Adapted Face-to-face	Total hours
Credits	4,5	Hours/week	3.97	71.5 class hours + 41 non-class hours = 112.5 total hours

PROFESSORS

AZPI-FORTEA MENDEZ, EIDER

REQUIRED PREVIOUS KNOWLEDGE

Subjects	Knowledge
(No specific previous subjects required)	(No previous knowledge required)

SKILLS

VERIFICA SKILLS

SPECIFIC

GBCE26 - Understanding, applying and assessing regulations, certifications and legal aspects in solving Biomedical Engineering problems.

GENERAL

GBCG10 - To be familiar with and apply the relevant laws and regulations concerning the professional activity of Biomedical Engineering.

GBCG6 - Ability to work with mandatory specifications, regulations and standards.

CROSS

GBCTR2 - To be able to do their job in cooperative, participatory environments, with awareness of social responsibility.

BASIC

G_CB3 - To be capable of gathering and interpreting relevant data (normally within their field of study) in order to make judgements, reflecting on relevant matters of a social, scientific or ethical nature

G_CB4 - To be able to communicate information, ideas, problems and solutions to both expert and lay audiences

LEARNING RESULTS

RG301 Assumes responsibilities in the work team, organizing and planning the tasks to be developed, facing the contingencies and encouraging the participation of its members.

LEARNING ACTIVITIES

Development and writing of records, reports, presentations, audiovisual material, etc. on projects/work experience/challenges/case studies/experimental investigations carried out individually and/or in teams

CH	NCH	TH
3 h.	2 h.	5 h.

EVALUATION SYSTEM

Reports on the completion of exercises, case studies, computer exercises, simulation exercises, laboratory exercises, term projects, challenges and problems

W
100%

MAKE-UP MECHANISMS

(No mechanisms)

CH - Class hours: 3 h.

NCH - Non-class hours: 2 h.

TH - Total hours: 5 h.

RG302 Analyze the intervening variables in the problem and propose actions for a stable situation.

LEARNING ACTIVITIES

Development and writing of records, reports, presentations, audiovisual material, etc. on projects/work experience/challenges/case studies/experimental investigations carried out individually and/or in teams

CH	NCH	TH
3 h.	2 h.	5 h.

EVALUATION SYSTEM

Reports on the completion of exercises, case studies, computer exercises, simulation exercises, laboratory

W
100%

MAKE-UP MECHANISMS

(No mechanisms)

exercises, term projects, challenges and problems

CH - Class hours: 3 h.
NCH - Non-class hours: 2 h.
TH - Total hours: 5 h.

RG304 Define the problem, develop the solution and present the conclusions in a efficient manner, arguing and justifying each one of them in writing.

LEARNING ACTIVITIES

	<i>CH</i>	<i>NCH</i>	<i>TH</i>
Development and writing of records, reports, presentations, audiovisual material, etc. on projects/work experience/challenges/case studies/experimental investigations carried out individually and/or in teams	3 h.	1 h.	4 h.

EVALUATION SYSTEM

W

Reports on the completion of exercises, case studies, computer exercises, simulation exercises, laboratory exercises, term projects, challenges and problems

100%

MAKE-UP MECHANISMS

(No mechanisms)

CH - Class hours: 3 h.
NCH - Non-class hours: 1 h.
TH - Total hours: 4 h.

RG305 Define the problem, develop the solution and present the conclusions in a efficient manner, arguing and justifying each one of them in spoken form.

LEARNING ACTIVITIES

	<i>CH</i>	<i>NCH</i>	<i>TH</i>
Development and writing of records, reports, presentations, audiovisual material, etc. on projects/work experience/challenges/case studies/experimental investigations carried out individually and/or in teams	3 h.	1 h.	4 h.

EVALUATION SYSTEM

W

Reports on the completion of exercises, case studies, computer exercises, simulation exercises, laboratory exercises, term projects, challenges and problems

100%

MAKE-UP MECHANISMS

(No mechanisms)

CH - Class hours: 3 h.
NCH - Non-class hours: 1 h.
TH - Total hours: 4 h.

RGB324 [!] *Conoce y comprende las peculiaridades en cuanto a normativas y certificaciones de los productos sanitarios*

LEARNING ACTIVITIES

	<i>CH</i>	<i>NCH</i>	<i>TH</i>
Development and writing of records, reports, presentations, audiovisual material, etc. on projects/work experience/challenges/case studies/experimental investigations carried out individually and/or in teams	2,5 h.	1,5 h.	4 h.
Conducting tests, giving presentations, presenting defences, taking examinations and/or doing checkpoints		5,75 h.	5,75 h.
Presentation by the teacher in the classroom, in participatory classes, of concepts and procedures associated with the subjects	9,5 h.		9,5 h.

EVALUATION SYSTEM

W

Reports on the completion of exercises, case studies, computer exercises, simulation exercises, laboratory exercises, term projects, challenges and problems

30%

MAKE-UP MECHANISMS

Individual written and oral tests to assess technical skills of the subject

Presentation and defence of exercises, case studies, computer practical work, simulation practical work, laboratory practical work, term projects, end of degree project, master's thesis, challenges and problems	20%
Individual written and/or oral tests or individual coding/programming tests	50%

CH - Class hours: 12 h.
NCH - Non-class hours: 7,25 h.
TH - Total hours: 19,25 h.

RGB325 [!] *Aplica los conocimientos sobre certificaciones y normativas a la hora de diseñar productos sanitarios para su posterior comercialización*

LEARNING ACTIVITIES

	CH	NCH	TH
Development and writing of records, reports, presentations, audiovisual material, etc. on projects/work experience/challenges/case studies/experimental investigations carried out individually and/or in teams	3 h.	1 h.	4 h.
Conducting tests, giving presentations, presenting defences, taking examinations and/or doing checkpoints	1 h.	5 h.	6 h.
Presentation by the teacher in the classroom, in participatory classes, of concepts and procedures associated with the subjects	7 h.		7 h.

EVALUATION SYSTEM

W

MAKE-UP MECHANISMS

Reports on the completion of exercises, case studies, computer exercises, simulation exercises, laboratory exercises, term projects, challenges and problems	30%	Individual written and oral tests to assess technical skills of the subject
Presentation and defence of exercises, case studies, computer practical work, simulation practical work, laboratory practical work, term projects, end of degree project, master's thesis, challenges and problems	20%	
Individual written and/or oral tests or individual coding/programming tests	50%	

CH - Class hours: 11 h.
NCH - Non-class hours: 6 h.
TH - Total hours: 17 h.

RGB326 [!] *Conoce y aplica los conocimientos sobre gestión de la calidad a diferentes sistemas del ámbito sanitario*

LEARNING ACTIVITIES

	CH	NCH	TH
Development and writing of records, reports, presentations, audiovisual material, etc. on projects/work experience/challenges/case studies/experimental investigations carried out individually and/or in teams	15 h.	7 h.	22 h.
Conducting tests, giving presentations, presenting defences, taking examinations and/or doing checkpoints		14,75 h.	14,75 h.
Presentation by the teacher in the classroom, in participatory classes, of concepts and procedures associated with the subjects	21,5 h.		21,5 h.

EVALUATION SYSTEM

W

MAKE-UP MECHANISMS

Reports on the completion of exercises, case studies, computer exercises, simulation exercises, laboratory exercises, term projects, challenges and problems	30%	Individual written and oral tests to assess technical skills of the subject
Presentation and defence of exercises, case studies, computer practical work, simulation practical work, laboratory practical work, term projects, end of degree project, master's thesis, challenges and problems	20%	
Individual written and/or oral tests or individual coding/programming tests	50%	

CH - Class hours: 36,5 h.
NCH - Non-class hours: 21,75 h.
TH - Total hours: 58,25 h.

CONTENTS

- 1.Context.
- 2.European legislative framework
- 3.AEMPS
- 4.Introduction
- 5.What is a medical device?
- 6.Various definitions
- 7.Economic agents: manufacturers, importers, distributors, authorised representatives and notified bodies
- 8.The UDI
- 9.Process of marketing a product in EU
 - 1.Operating license
 - 2.Product classification.
 - 3.Technical documentation
 - 4.Risk management
 - 5.Clinical evaluation
 - 6.Quality management system
 - 7.Conformity assessment procedures
 - 8.EC (EU) declaration of conformity and CE marking
 - 10.EUDAMED Database
 - 11.Infringements and sanctions.

LEARNING RESOURCES AND BIBLIOGRAPHY

Learning resources

Subject notes
Moodle Platform

Bibliography

Reglamento 745/2017 del Parlamento Europeo y del Consejo, de 5 de abril de 2017 sobre los productos sanitarios.
UNE-EN-ISO 13485:2016 Sistemas de gestión de calidad. Requisitos para fines reglamentarios
UNE-EN-ISO 14971:2019 Gestión de riesgo de productos sanitarios PS1/2019 Instrucciones para la licencia de funcionamiento.