UNIVERSIDAD DE CASTILLA - LA MANCHA

GUÍA DOCENTE

1. General information

Course: PHARMACEUTICAL BIOTECHNOLOGY
Type: CORE COURSE
Degree: 376 - UNDERGRADUATE DEGREE PROGRAMME IN PHARMACY
Center: 14 - FACULTY OF PHARMACY
Year: 4
Main language: Spanish
Use of additional languages:
Web site:

Code: 14334
ECTS credits: 6
Academic year: 2023-24
Group(s): 10
Duration: C2
Second language: English
English Friendly: Y
Bilingual: N

Lecturer: **MARIA FRANCISCA GALINDO ANAYA** - Group(s): **10**

Building/Office	Department	Phone number	Email	Office hours
Facultad de Farmacia 2.17	CIENCIAS MÉDICAS	967599200	maria.galindo@uclm.es	Monday to Wednesday 16:00-19:00. Confirm appointment by email

Lecturer: **JOAQUIN GONZALEZ FUENTES** - Group(s): **10**

Building/Office	Department	Phone number	Email	Office hours
Facultad de Farmacia AB. Despecho 3.8	CIENCIAS MÉDICAS	2236	joaquin.gfuentes@uclm.es	Monday to Wednesday 16:00-19:00. Confirm appointment by email

Lecturer: **MARIA VICTORIA LOZANO LOPEZ** - Group(s): **10**

Building/Office	Department	Phone number	Email	Office hours
Facultad Farmacia. 2.4	CIENCIAS MÉDICAS	8238	mvictoria.lozano@uclm.es	Monday to Wednesday 16:00-19:00. Confirm appointment by email

Lecturer: **MANUEL JESUS SANTANDER ORTEGA** - Group(s): **10**

Building/Office	Department	Phone number	Email	Office hours
Facultad Farmacia. 3.1	CIENCIAS MÉDICAS	2239	manuel.santander@uclm.es	Monday to Wednesday 16:00-19:00. Confirm appointment by email

2. Pre-Requisites

There are no prerequisites, but it is recommended:

Basic training in Structural and Metabolic Biochemistry to know the characteristics and properties of chemical products, bases of the physical and physicochemical processes necessary in the sequence of operations for the manufacture of medicines.

Basic training in Immunology and Microbiology necessary for understanding new therapeutic strategies in the design of vaccines and monoclonal antibodies.

Basic training in Molecular Biology which will be necessary for a better understanding of new experimental modalities such as gene therapy, stem cell treatments and antisense nucleotides.

Basic training in Pharmaceutical Technology I and II which will be necessary for the understanding of the formulation processes of biotechnological drugs.

If there are any changes in the schedule due to unforeseen circumstances, students will be notified of such changes through the virtual campus.

3. Justification in the curriculum, relation to other subjects and to the profession

Pharmaceutical Biotechnology is a discipline that provides the knowledge for the design and development of new medicines such as biotechnological medicines.

These include faster, more effective and safer medicines and personalised treatments through the use of active ingredients produced through the use of recombinant DNA technology, the design of biotechnological vaccines together with the knowledge of new therapies (cellular, gene therapy).

All these characteristics are related to subjects such as Biopharmacy and Pharmacokinetics, Pharmaceutical Technology I and II, leading the student to acquire the necessary training to successfully deal with the administration of drugs with effective, safe and stable pharmaceutical forms.

4. Degree competences achieved in this course

Course competences

Code	Description
B01	Proficiency in a second foreign language at level B1 of the Common European Framework of Reference for Languages.
B02	Knowledge of Information and Communication Technologies (ICT).
B03	A correct oral and written communication
B04	Ethical commitment and professional deontology.
B05	Ability to develop those learning skills necessary to undertake further studies.
EB01	Know the structures of biomolecules and their transformations into the cell.
EB03	Estimate the biological risks associated with the use of substances and processes of laboratories involved.

EB05	Develop skills to identify therapeutic targets and biotechnological production of drugs, as well as the use of gene therapy.
EB06	Know and understand the microbiological control of medications
EFT01	Using statistical analysis applied to pharmaceutical sciences
EFT02	Apply both computational and data processing techniques, for getting information about physical, chemical and biological data
EFT03	Know the processes of release, absorption, distribution, metabolism and excretion of drugs, and factors that condition the absorption and disposal according to their routes of administration.
EFT04	Evaluation of scientific data related to medicines and health products
EFT05	Using statistical analysis applied to pharmaceutical sciences
EFT06	Design, optimize and elaborate the pharmaceutical forms guaranteeing their quality, including the formulation and quality control of medicines, the development of master formulas and officinal preparations.
EFT07	Able to apply the quality control process to medical devices, dermopharmaceutical and cosmetic products and package materials.
EFT10	Demonstrate knowlege of the physicochemical and biopharmaceutical properties of drugs and excipients, as well as the possible interaction between them
G01	Identify, design, obtain, analyze, control and produce drugs and medicines, as well as other products and raw materials of sanitary interest for human or veterinary use.
G04	Design, prepare, supply and dispense medicines and other products of health interest.
G13	Develop communication and information skills, both oral and written, to deal with patients and users of the centre where they carry out their professional activity. Promote the capacity to work and collaborate with multidisciplinary teams and those related to other health professionals.
G14	Know the ethical and deontological principles according to the legislative, regulatory and administrative provisions governing professional practice, understanding the ethical implications of health in a changing social context.
G15	Recognise own limitations and the need to maintain and update professional competence, with particular emphasis on self-learning of new knowledge based on scientific evidence.
T01	Critical thinking skills based on the application of the scientific method
T02	Ability to manage quality scientific information, bibliography, specialized databases and resources accessible through the Internet.
T03	Handling of basic and specific software for the treatment of information and experimental results.
T04	Motivation for quality, safety at work and awareness of environmental issues, with knowledge of the internationally recognised systems for the correct management of these aspects.
T05	Organizational, planning and implementation skills.
T06	Ability to address human resources decision-making and management.
T07	Ability to work as a team and, where appropriate, exercise leadership functions, encouraging entrepreneurship.
T08	Develop interpersonal skills and the ability to function in an international and multicultural context.

5. Objectives or Learning Outcomes

Course learning outcomes

Description

Understanding the checks necessary to ensure the quality of pharmaceutics skin products, sanitary products, and cosmetics.

Ability to work under standards of good laboratory practice (GLP).

Ability to design a pharmaceutical laboratory in response to their facilities and processes necessary to ensure the quality of the products manufactured.

Ability to plan, design and develop preformulation studies of the different pharmaceutical forms and to interpret the results.

To know and to develop good manufacturing practiques (GMP) for the different activities to develop in Pharmaceutical Industry, pharmacy and hospital Pharmacy Service.

Understanding the mechanisms of production of drugs using genetic recombination technology.

Know and understand the fundamentals of the Pharmaceutical Technology

Develop drugs regarding its qualitative and quantitative composition and select the optimal technological processes to be used in its manufacture.

6. Units / Contents

Unit 1: INTRODUCTION TO PHARMACEUTICAL BIOTECHNOLOGY

Unit 1.1 INTRODUCTION TO PHARMACEUTICAL BIOTECHNOLOGY

Unit 2: BIOTECHNOLOGICAL TOOLS

Unit 2.1 Concepts. Omic sciences in biotechnology. Data mining and bioinformatics.

Unit 3: VACCINES AND BIOTECHNOLOGY

Unit 3.1 Obtaining vaccines by biological methodologies.

Unit 3.2 Genetically engineered vaccines.

Unit 4: MONOCLONAL ANTIBODIES

Unit 4.1 Introduction. Antibody engineering. Generation of human monoclonal antibodies. Mechanism of action.

Unit 5: BIOTECHNOLOGICAL MEDICINAL PRODUCTS. BIOEQUIVALENCE. BIOTHERAPY.

Unit 5.1 Biotherapy and biotechnological medicinal products. Legal regulation of biotechnological medicinal products. Biosimilar medicines. Biosimilars versus innovators.

Unit 6: BIOTECH DRUGS

Unit 6.1 Insulin

Unit 6.2 Growth Hormone, Interferon and Haematopoietic Growth Factors.

Unit 7: BIOTECHNOLOGICAL BIOSENSORS

Unit 7.1 Technological bases involved in detection processes.

Unit 7.2 Biosensors. Applications in the diagnosis and treatment of diseases. Applications in industry.

Unit 8: PRE-FORMULATION OF BIOTECH PRODUCTS

Unit 8.1 Biomaterials. Classification and strategies to modulate their properties.

Unit 8.2 Preformulation of biotechnological products. Chemical and physical instability. Strategies in early stage preformulation.

Unit 9: FORMULATION OF BIOPHARMACEUTICALS

Unit 9.1 Development of liquid formulations of biotech products.

Unit 9.2 Drying methods for biotech products: spray drying and freeze drying.

Unit 10: NANOTECHNOLOGY AND BIOTECHNOLOGY

Unit 10.1 Nanoparticles and microparticles in biotechnology: general concepts and applications for the oral route.
Unit 10.2 Nanoparticles and microparticles in biotechnology: other routes of administration.

Unit 11: GENE THERAPY

Unit 11.1 Formulation in gene therapy: active ingredients and their formulation in viral and synthetic vectors.

Unit 12: TISSUE ENGINEERING

Unit 12.1 Concepts and strategies in tissue engineering. Application of tissue engineering for tissue and organ reconstruction.

Unit 13: PHARMACOKINETICS OF BIOTECHNOLOGY PRODUCTS

Unit 13.1 ADME processes in biotechnological therapy
Unit 13.2 Pharmacokinetic characteristics of protein and peptide therapy I
Unit 13.3 Pharmacokinetic characteristics of protein and peptide therapy II
Unit 13.4 Pharmacokinetics of monoclonal Antibodies
Unit 13.5 Pharmacokinetic characteristics of vaccines
Unit 13.6 Pharmacokinetic characteristics of gene and cell therapy

7. Activities, Units/Modules and Methodology

Training Activity	Methodology	Related Competences (only degrees before RD 822/2021)	ECTS	Hours	As	Com	Description
Class Attendance (theory) [ON-SITE]	Combination of methods	B01 B02 B03 B04 B05 EB01 EB03 EB05 EB06 EFT01 EFT02 EFT03 EFT04 EFT05 EFT06 EFT07 EFT10 G01 G04 G13 G14 G15 T01 T02 T03 T04 T05 T06 T07 T08	1.44	36	Y	N	The availability of teaching resources will be accessible on the Moodle platform before the start of the activities. In addition, students will have access to complementary bibliographic and audiovisual material (books, review articles, videos) in the university library on the Albacete campus. The teaching methodology through the combination of methods will contemplate the expository method/lecture together with case studies. Active student participation in face-to-face teaching in workshops and seminars will be assessed using ICT tools. Cooperative work both in and out of the classroom will be materialised in the preparation and defence of assignments as well as in the resolution of problems and/or cases that will be presented orally. The marks obtained in these activities will be taken into account in the final assessment of the course.
Class Attendance (practical) [ON-SITE]	Practical or hands-on activities	B01 B02 B03 B04 B05 EB01 EB03 EB05 EB06 EFT01 EFT02 EFT03 EFT04 EFT05 EFT06 EFT07 EFT10 G01 G04 G13 G14 G15 T01 T02 T03 T04 T05 T06 T07 T08	0.8	20	Y	Y	Practical teaching will be given in small groups within periods established in the academic calendar that do not coincide with other teaching activities. They will be carried out in classrooms and/or laboratories, all of which are equipped with the appropriate means to achieve the proposed objectives. These activities are MANDATORY, so that the student will not be able to pass the course if they are not carried out properly.
Study and Exam Preparation [OFF-SITE]	Self-study	B01 B02 B03 B04 B05 EB01 EB03 EB05 EB06 EFT01 EFT02 EFT03 EFT04 EFT05 EFT06 EFT07 EFT10 G01 G04 G13 G14 G15 T01 T02 T03 T04 T05 T06 T07 T08	3.6	90	Y	N	Students may request personal tutorials on the contents of the subject by arranging an interview in advance with the corresponding teacher.
Formative Assessment [ON-SITE]	Assessment tests	B01 B02 B03 B04 B05 EB01 EB03 EB05 EB06 EFT01 EFT02 EFT03 EFT04 EFT05 EFT06 EFT07 EFT10 G01 G04 G13 G14 G15 T01 T02 T03 T04 T05 T06 T07 T08	0.16	4	Y	Y	Specific dates have been set aside in the academic calendar for assessment tests that do not coincide with other teaching activities.
		Total:	**6**	**150**			
		Total credits of in-class work: 2.4					**Total class time hours: 60**
		Total credits of out of class work: 3.6					**Total hours of out of class work: 90**

As: Assessable training activity
Com: Training activity of compulsory overcoming (It will be essential to overcome both continuous and non-continuous assessment).

8. Evaluation criteria and Grading System

Evaluation System	Continuous assessment	Non-continuous evaluation*	Description
Test	70.00%	70.00%	Theoretical knowledge is evaluated, as well as its application to the resolution of problems and practical cases.
Laboratory sessions	20.00%	20.00%	Attendance to the practical laboratory classes is compulsory. The grade obtained will account for 20% of the final grade for the subject. The application in the laboratory of the knowledge previously learnt, the student's attitude and the adequate preparation of the laboratory notebook individually will be assessed. The practical notebook will be graded as PASS/FAIL. It is essential to obtain a PASS in the practical notebook in order to pass the practical block of the subject, whose final grade will be the grade obtained in the practical exam. In the event that the student does not pass the practical block in the ordinary exam, he/she will have another opportunity in the final exam of the extraordinary exam to pass the subject. Once the practical block has been passed, the grade obtained will be retained for the following two academic years.
Assessment of active participation	10.00%	10.00%	The lecturer advises the student to regularly attend the face-to-face activities during the course. The resolution of questions and problems by the student, the presentation and public defence of work, as well as their active participation and attitude in class and tutorials will be positively valued. These activities are not compulsory.
Total:	**100.00%**	**100.00%**	

According to art. 4 of the UCLM Student Evaluation Regulations, it must be provided to students who cannot regularly attend face-to-face training activities the passing of the subject, having the right (art. 12.2) to be globally graded, in 2 annual calls per subject , an ordinary and an extraordinary one (evaluating 100% of the competences).

Evaluation criteria for the final exam:

Continuous assessment:

In this modality, the subject will follow a continuous evaluation system, adapted to the regulatory norms of the University of Castilla-La Mancha.
The final grade will take into account, proportionally, the average of the written tests (70%), the completion of laboratory practices (20%) and participation in seminars or other activities proposed in class (10%).
It will be assumed that all students opt for the continuous modality, unless otherwise informed (non-continuous modality) by means of a email addressed to the professor responsible for the subject until 50% of all the evaluable activities have been completed or the class period has ended.
The subject will be passed as long as a final average grade equal to or greater than 5 out of 10 is obtained among the different blocks (Theoretical, Practical and
Stake). It will be possible to add the marks obtained from the Theoretical and Practical block from a mark of 4 out of 10.
THEORETICAL MODULE EVALUATION (70% of the final mark). It will consist of a partial test (continuous assessment) and a final test. Both may include theoretical concepts, topics covered in practices or in different teaching activities, problems or clinical cases, etc. The student who pass a 4 in the partial test, you can decide whether to take an exam for the entire subject, or eliminate the contents corresponding to the partial test to the final test, in this case each test will have a value of 50%. This decision will have to be notified to the professor responsible for the subject via email at least 2 weeks before the date of the second final test. In order to be able to add the note corresponding to the theoretical block of the subject through continuous evaluation, a minimum grade of 4 must be obtained in each of the tests.
PRACTICAL MODULE EVALUATION (20% of the final mark). Attendance at practices is MANDATORY. It will be evaluated by presenting a laboratory notebook and a knowledge test, although the attitude in the laboratory, compliance with safety regulations and management of residues may also be considered in the qualification. To pass the practical module, a qualification of AT LEAST 5 POINTS must be obtained in order to keep it for the following two academic years. The
The grade may be kept for the following two academic years, if the student so states in writing to the responsible professor. For
To be able to choose to add the grade from the practical block to the rest of the blocks, a minimum grade of 4 must be obtained in this block of the subject.
EVALUATION OF THE ACTIVITIES MODULE (10% of the final mark). Its evaluation will be in the classroom by carrying out the proposed activities by the teacher. They are NON-MANDATORY. It will only be taken into account once the theoretical-practical block has been passed. The rating can be retain it for the next two academic years, if the student states so in writing to the responsible professor. If a student could not carry out any of the evaluable activities of the block of activities in person, for justified reasons, you can ask the teacher for the carrying out another non-contact activity, of which they will be evaluated, to achieve the competencies.
In the event that the student does not reach the grade required to pass the ordinary call, and has to take the extraordinary one, the qualification of the Theoretical and practical blocks can only be retained if a minimum score of 4 points has been reached. The activity note is not subject to this rule.
It is recalled that the material prepared by the teacher and made available to students on the Virtual Campus platform is the property of the teacher, so taking it out of that context and making it available to people outside that platform will be considered plagiarism. Likewise, carrying out different tests with unauthorized aid or material will be considered fraud. In accordance with the provisions of the Evaluation Regulation of the student, the test in which fraud has been detected will be considered invalid and will be graded with fail (0), including as a fraudulent act any type of plagiarism detected.

Non-continuous evaluation:

The subject can follow a non-continuous evaluation system, adapted to the regulatory norms of the University of Castilla-La Mancha.
The final grade will take into account, proportionally, the average of the written tests (70%), the completion of laboratory practices (20%) and participation in seminars or other activities proposed in class (10%).
The subject will be passed as long as a final average grade equal to or greater than 5 out of 10 is obtained among the different blocks (Theoretical, Practical and
Stake). It will be possible to add the marks obtained from the Theoretical and Practical block from a mark of 4 out of 10.
THEORETICAL MODULE EVALUATION 70% of the final mark. It will consist of 1 FINAL TEST that may include theoretical concepts, practical cases, problems etc
PRACTICAL MODULE EVALUATION (20% of the final mark). Attendance at practices is MANDATORY. It will be evaluated by presenting a laboratory notebook and a knowledge test, although the attitude in the laboratory, compliance with safety regulations and management of residues may also be considered in the qualification. To pass the practical module, a qualification of AT LEAST 5 POINTS must be obtained and the
The grade may be kept for the following two academic years, if the student so states in writing to the responsible professor.

EVALUATION OF THE ACTIVITIES MODULE (10% of the final mark). Its evaluation will be in the classroom by carrying out the proposed activities by the teacher. They are NON-MANDATORY. It will only be taken into account once the theoretical-practical block has been passed. The rating can be retain it for the next two academic years, if the student states so in writing to the responsible professor. If a student could not carry out any of the evaluable activities of the block of activities in person, for justified reasons, you can ask the teacher for the carrying out another non-contact activity, of which they will be evaluated, to achieve the competencies.
In the event that the student does not reach the grade required to pass the ordinary call, and has to take the extraordinary one, the qualification of the Theoretical and practical blocks can only be retained if a minimum score of 4 points has been reached. The activity note is not subject to this rule.
It is recalled that the material prepared by the teacher and made available to students on the Virtual Campus platform is the property of the teacher, so taking it out of that context and making it available to people outside that platform will be considered plagiarism. Likewise, carrying out different tests with unauthorized aid or material will be considered fraud. In accordance with the provisions of the Evaluation Regulation of the student, the test in which fraud has been detected will be considered invalid and will be graded with fail (0), including as a fraudulent act any type of plagiarism detected.

Specifications for the resit/retake exam:

The final grade will take into account, proportionally, the average of the written tests (70%), the completion of the laboratory practices (20%) and the participation in seminars or other activities proposed in class (10%).
The subject will be passed as long as a final average grade equal to or greater than 5 out of 10 is obtained among the different blocks (Theoretical, Practical and Stake). It will be possible to add the marks obtained from the Theoretical and Practical block from a mark of 4 out of 10.
THEORETICAL MODULE EVALUATION 70% of the final mark. It will consist of 1 FINAL TEST that may include theoretical concepts, practical cases, problems etc
PRACTICAL MODULE EVALUATION (20% of the final mark). For those students who have failed the practical module, they will be able to repeat the exam of practical knowledge in the EXTRAORDINARY CALL. A grade of AT LEAST 5 POINTS is required to pass the practical module and keep it for the following two academic years.
EVALUATION OF THE ACTIVITIES MODULE (10% of the final mark). THE QUALIFICATION OBTAINED DURING THE CALL IS MAINTAINED ORDINARY. It will only be taken into account once the theoretical-practical block has been passed. The qualification can be kept during the two academic years following, if the student manifests it.
It is recalled that the material prepared by the teacher and made available to students on the Virtual Campus platform is the property of the teacher, for taking it out of that context and making it available to people outside of that platform will be considered plagiarism. Likewise, the realization of the different Testing with unauthorized aid or material will be considered fraud. In accordance with the provisions of the Student Assessment Regulations, the test in the one that has been detected fraud will be considered invalid and will be qualified with suspense (0), including any type of plagiarism as a fraudulent act detected.

Specifications for the second resit / retake exam:

Only students who meet the requirements set out in the Student Assessment Regulations of the University of Castilla-La-Mancha will be eligible for this call and will be assessed in accordance with the criteria applied in the extraordinary call.

9. Assignments, course calendar and important dates

Not related to the syllabus/contents

Hours	hours
Class Attendance (theory) [PRESENCIAL][Combination of methods]	36
Class Attendance (practical) [PRESENCIAL][Practical or hands-on activities]	20
Study and Exam Preparation [AUTÓNOMA][Self-study]	90
Formative Assessment [PRESENCIAL][Assessment tests]	4

Global activity

Activities	hours
Class Attendance (theory) [PRESENCIAL][Combination of methods]	36
Class Attendance (practical) [PRESENCIAL][Practical or hands-on activities]	20
Study and Exam Preparation [AUTÓNOMA][Self-study]	90
Formative Assessment [PRESENCIAL][Assessment tests]	4
Total horas:	150

10. Bibliography and Sources

Author(s)	Title/Link	Publishing house	Citv	ISBN	Year	Description
Crommelin D., Sindelar R.	Pharmaceutical Biotechnology: An Introduction for Pharmacists and Pharmaceutical Scientist	Springer		978-04-152-8501-8	2013	
Herráez Sánchez A.	Texto ilustrado e interactivo de biología molecular e ingeniería genética + StudentConsult en español. 2ª edición	Elsevier			2012	
Jameel F, Hershenson S.	Formulation and Process Development Strategies for Manufacturing Biopharmaceuticals	Wiley		978-0-470-11812-2	2010	
Kayser O., Warzecha H.	Pharmaceutical Biotecnology: Drug Discovery and Clinical Applications. 2nd Edition	Wiley		978-3-527-32994-6	2012	
Martínez Burraco A.	Texto Ilustrado de Biología Molecular e Ingeniería Genética. Avances recientes en Biotecnología Vegetal e Ingeniería Genética de Plantas	Reverte			2005	
Zhang J., Hoshino K.	Molecular Sensors and Nanodevices. Principles, Designs and Applications in Biomedical Engineering	Elsevier		978-1-4557-7631-3	2013	