



IDENTIFYING DATA

Operations and Quality in Bio-Industries

Subject	Operations and Quality in Bio-Industries			
Code	V02M123V01116			
Study programme	(*)Máster Universitario en Ciencias Biológicas: Biología Molecular, Computacional e Ambiental e Bio-Industrias			
Descriptors	ECTS Credits	Type	Year	Quadmester
	6	Optional	1st	1st
Language				
Department				
Coordinator	Leao Martins, Jose Manuel			
Lecturers	Deive Herva, Francisco Javier Leao Martins, Jose Manuel Moldes Moreira, Diego			
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Web	http://webs.uvigo.es/biologicalsciences/			
General description	The subject is focused on technical executives in scientific instrumentation with a good approach on specific issues to be found in bioindustries and who acquired the basic requirements of Quality Control in Bioindustries process.			

Competencies

Type A	Code	Competences Specific
	A1	(*)To know the scientific method and the correct use of the scientific terminology as well as to acknowledge the contribution that scientific research provides to the overall knowledge and professional practice.
	A2	(*)Ability to describe and to analyse biological diversity, the mechanisms determining the interactions with the biotic and abiotic environment and being able to select those which might have technical applications.
	A3	(*)Ability to manage and/or to develop basic tools for validating and analysing data by means of statistics and bioinformatics.
	A4	(*)To know the ethical and legal aspects governing the collection and the handling of biological samples, organisms and habitats.
	A5	(*)Ability to design, evaluate and implement models of biological structures, systems and processes.
	A6	(*)To learn the sampling techniques and the instrumental methodologies, in the field and laboratory, for their application in the Biological Sciences
	A7	(*)To have an integrated view of the R&D processes and their possible transfer to the industrial sector. Planning and supervising facilities together with managing their human and economic resources.
	A8	(*)Ability to classify, evaluate, conserve, restore and manage natural and productive systems. Developing and implementing land management and sustainability plans.
	A9	(*)To understand and know how to apply quality control systems and safety protocols in any biological laboratory of the public or private sector.
	A10	(*)To acquire the professional ability to teach and spread Biology and to offer expertise advice for elaborating scientific, technical and socioeconomic biology reports. Address environmental consulting.

A11 (*)To perform an individual Master Project (critical and in-depth study) under the supervision of a tutor in a research or working environment demonstrating that skills have been acquired.

Type B Code Competences Transversal

B1	(*)Dissemination of results and conclusions of the biological studies, in oral and written English, through complex presentations that address ideas related with R&D in Biology.
B2	(*)Managing computational, laboratory, field and industrial techniques in order to obtain, process and apply the acquired information.
B3	(*)Disseminating and broadcasting ideas in contexts both academic and non-specialised.
B4	(*)Reflecting on social and ethical responsibilities.

Learning aims

Subject competences	Typology	Competences
To be able to design a basic process of biological production	know Know How Know be	A5 A7
To know the potential and limits of biomanufacturing as a production tool and to recognize the future trends in biomanufacturing	know Know How Know be	A5 A7
To know the basic facilities and equipment in biomanufacturing companies	know Know How Know be	A5 A7
To know the integration of units to achieve a correct design of a given industrial bioprocess.	know Know How Know be	A5 A7
To acquire abilities for bioindustries simulation by means of the use of specific comercial software such as SuperPro Designer	know Know How Know be	A5 A7 B2
To know the planned and systematic activities implemented in a quality system and the quality requirements for a product or service.	know Know How Know be	A3 A9 B2
How to carry out observation techniques and activities in order to fulfill the quality requirements	know Know How Know be	A3 A9 B2

Contents

Topic	
Biomanufacturing Operations	Technical considerations Steps Design Equipment Organization Facilities
Biorefineries	Overview Types Technical considerations
Analysis and design of processes in bioindustries	Conceptual design Fundamentals of hierarchical design Design of process flowsheet diagram
Simulation of processes in bioindustries by means of comercial software	Units of operation Operation conditions Bioreactor Separation unitis Raw materials pretreatment

Importance of analytical quality management on industrial manufacturing efficiency and profit

Quality Management
Quality Control Tools
Total Quality Concept
Principles of Quality Assurance
Acreditation /Certification

Quality Manual Preparation

Bioindustries organization
Documentations
Management
Audits
Customers
Process control
Inspections
Records
Training
Services

Planning

	Personalized attention	Assessment	Ordinary class hours A	Face-to-face hours outside the classroom Guided academic environment B	Student's work factor C	Outside the classroom hours D	Total hours (A+B+D) E
Master Session	<input checked="" type="checkbox"/>	<input type="checkbox"/>	12	0	3.5	42	54
Case studies / analysis of situations	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	8	0	4	32	40
Practice in computer rooms	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	6	0	3	18	24
Introductory activities	<input type="checkbox"/>	<input type="checkbox"/>	1	0	0	0	1
Short answer tests	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	1	0	9	9	10
Jobs and projects	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	3	0	6	18	21
Total hours E:							150
Work load in UVIGO ECTS credits:							6

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

Methodologies

	Description
Master Session	Presentation of the contents of the subject, including main principles and tools to be used in the case studies and analysis of situations. The contents will be explained with the support of PowerPoint slides and they will be provided before presentations.
Case studies / analysis of situations	Different real situations and problems will be tackled by the students in order to get further insight in the process design and quality principles underlying them. The lecturer will help them by giving several clues and instructions at different moments of the process development. Several case studies will be presented with videos, articles or any other media.
Practice in computer rooms	The use of comercial simulation software will be prioritized as a means of helping the students to understand a model case study of bioindustrial process. The use of computers for quality control data processing and chart representations.
Introductory activities	The lectures will provide the students with an overview of the subject, the contents to be tackled, the evaluation and learning aims that will be assessed

Personalized attention

	Description
Master Session	All the teaching activity will be complemented group and individual tutorship. More specifically, during practice in computer rooms, the students will be guided through the steps required to achieve a complete process design, from raw materials registration to equipment design and mass and energy balances performance.
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Jobs and projects	All the teaching activity will be complemented group and individual tutorship. More specifically, during practice in computer rooms, the students will be guided through the steps required to achieve a complete process design, from raw materials registration to equipment design and mass and energy balances performance.

Assessment

	Description	Qualification
Case studies / analysis of situations	The case studies/analysis of situations will be assessed on a daily basis.	10
Practice in computer rooms	The daily performances of each student will be taken into account together with their personal homework out of the classroom	30
Short answer tests	These tests will be used as a tool to evaluate the knowledge acquired during the master session	30
Jobs and projects	The end of the course, students will deliver a project report and will make Project oral defense	30

Other comments and second call

Sources of information

Michael J. Roy, Biotechnology Operations-Principles and Practices, 1st (2011), CRC Press, Taylor & Francis Group

Birgit Kamm, Patrick R. Gruber, Michael Kamm, Biorefineries-Industrial Process and Products, 2006, Wiley-VCH GmbH & Co. Weinheim

E. M. T. El-Mansi, Fermentation Microbiology and Biotechnology, 2nd (2007), CRC Raylor & Francis

Pauline M. Doran, Bioprocess Engineering and Biotechnology, 1st (1995), Elsevier Science & Technology Books

G. D. Najafpour, Biochemical Engineering and Biotechnology, 1st (2007), Elsevier, The Netherlands

Amitava Mitra, Fundamentals of Quality Control and Improvements, 3rd Edition (2008), John Wiley & Sons Inc.

Douglas C. Montgomery, Introduction to Statistical Quality Control, 7 th Edition (2012), John Wiley & Sons Inc.

Dale Besterfield, Quality Improvement, 9th Edition (2014), Pearson Education Limited

Recommendations

Subjects that are recommended to be taken simultaneously

Human Resources Management and Leadership/V02M123V01213

Subjects that it is recommended to have taken before

Introduction to Bio-Industries Management and Business Development in Life Sciences/V02M123V01114

Statistical and Mathematical Methods in Bioinformatics/V02M123V01112