Industrial Production of Bioproducts. Design and Operation of Bioprocesses in Pilot Plant

Code: 42907
ECTS Credits: 9

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Gloria González Anadón
José Luis Montesinos Seguí
Xavier Garcia Ortega
Laura Cervera Gracia

Use of Languages
Principal working language: **Spanish** (spa)

Prerequisites
To follow the module it is necessary to have a basic formation in Biochemical Engineering, in fundamental aspects of Bioprocess Engineering, in Bioreactors and some very basic concepts of recombinant DNA and Genetic Engineering.

Objectives and Contextualisation
The objective of this module is to familiarize the student with the most important tools used in a bioprocess, and its application in the design and operation of bioprocesses in their future professional careers. In order to achieve this objective, different cellular factories will be explored, designed, integrated and optimized for producing industrial biotechnological products, integrating the production and purification of the bioproduct in a reproducible way (BIOPAT concept) and economically viable Bioprocess Engineering. The quality and safety regulations of bioproducts from different fields will also be explained and the principles on which the scale up of a bioprocess is based will be presented.

Competences
- Continue the learning process, to a large extent autonomously.
- Integrate knowledge and use it to make judgements in complex situations, with incomplete information, while keeping in mind social and ethical responsibilities.
- Solve problems in new or little-known situations within broader (or multidisciplinary) contexts related to the field of study.
- Synthesise, weigh up alternatives and engage in critical discussion.
- Use acquired knowledge as a basis for originality in the application of ideas, often in a research context.
• Use advanced biotechnology tools in combination to solve problems in emerging areas of biotechnology.
• Use and manage bibliography and IT resources related to biotechnology responsibly.
• Work in a multidisciplinary team.

Learning Outcomes

1. Continue the learning process, to a large extent autonomously.
2. Define and protocolise experimenting and production in accordance with BPL, ISO and GMP norms.
   Write standard working protocols.
3. Describe PAT methodology.
4. Describe and apply the norms on correct production to safeguard human and animal health.
5. Describe and apply the quality norms of a bioprocess.
6. Design and select the optimal operation strategy in bioreactors.
7. Design and select the optimal operation strategy in conventional bioreactors.
8. Design the main separation and purification operations in bioprocesses.
9. Identify the advantages, disadvantages and engineering of the bioprocess of mammal cells as a cell factory.
10. Identify the advantages, disadvantages and engineering of the bioprocess of the eukaryotic cell factory P. pastoris.
11. Identify the advantages, disadvantages and engineering of the bioprocess of the prokaryotic cell factory E. coli.
12. Integrate knowledge and use it to make judgements in complex situations, with incomplete information, while keeping in mind social and ethical responsibilities.
13. Recognise the problem of change of scale in biotechnology.
14. Recognise the work of a pilot fermentation plant and apply its working rules.
15. Solve problems in new or little-known situations within broader (or multidisciplinary) contexts related to the field of study.
16. Synthesise, weigh up alternatives and engage in critical discussion.
17. Use acquired knowledge as a basis for originality in the application of ideas, often in a research context.
18. Use and manage bibliography and IT resources related to biotechnology responsibly.
19. Work in a multidisciplinary team.

Content

1.- Introduction to the industrial production of bioproducts. Scale up in bioreactors

2.- Bioprocess design based on quality.

2.1.- Quality by Design (QbD) / Process Analytical Technology (PAT)

2.2.- Good Manufacturing Practice (GMPs). Good Laboratory Practices (BPLs),

3.- Cell factories: Animal cell culture

4.- Cell factories: Pichia pastoris.

5.- Cell factories: Escherichia coli.

6.- Laboratory work at Fermentation Pilot Plant

Methodology

Lectures on the topics of the syllabus.
Seminars on aspects of the industrial world of Biotechnology by experts invited from the sector.

Elaboration of group works. Group activity. Students will prepare a report on a topic related to the contents, at the teacher's proposal. These works will be exposed and defended in public.

Laboratory work. The students will carry out practices in the pilot plant of fermentation, consisting of the follow-up of a process of production of a recombinant protein.

**Activities**

<table>
<thead>
<tr>
<th>Title</th>
<th>Hours</th>
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<th>Learning Outcomes</th>
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</thead>
<tbody>
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<tr>
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<td>1.34</td>
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<td>seminars</td>
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<td><strong>Type: Supervised</strong></td>
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<td>Laborator reports</td>
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<td><strong>Type: Autonomous</strong></td>
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<td>16, 12, 15, 17, 19, 18</td>
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<td>writing work and oral exposure</td>
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<td>0.98</td>
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**Assessment**

**Evaluation of the theoretical part of the module:**

**Continuous assessment**

Individual written evaluation: It is 70% of the final grade. Four partial tests corresponding to different subjects of the course are carried out with a weight of 25% each of them. If in the individual written evaluation the student obtained a grade lower than 3/10, he will not pass the module.

Evaluation of the defense and oral presentation of a research paper (30%)

**Final evaluation:**

Students who do not pass the continuous assessment will have a global test of written individual final recovery. Whenever this test is exceeded with a grade higher than 3/10, it will be done with the grade of the oral presentation.

**Global evaluation of the module**

Evaluation of laboratory practices in a fermentation pilot plant (25%).

Evaluation of the theoretical part of the module (75%). Minimum note of this part to approve the module 3.5/10
Assessment Activities

<table>
<thead>
<tr>
<th>Title</th>
<th>Weighting</th>
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<th>Learning Outcomes</th>
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Bibliography

The bibliography needed to follow the module can be consulted through the virtual platform. In parallel, the student will have to carry out searches and specific bibliographical consultations for the elaboration of their group work.