



### INDUSTRIAL BIOTECHNOLOGIES

Enrollment year	2020/2021
Academic year	2021/2022
Regulations	DM270
Academic discipline	CHIM/11 (CHEMISTRY AND BIOTECHNOLOGY OF FERMENTATIONS)
Department	DEPARTMENT OF BIOLOGY AND BIOTECHNOLOGY "LAZZARO SPALLANZANI"
Course	ADVANCED BIOTECHNOLOGY
Curriculum	PERCORSO COMUNE
Year of study	2°
Period	1st semester (01/10/2021 - 14/01/2022)
ECTS	6
Lesson hours	48 lesson hours
Language	Italian
Activity type	ORAL TEST
Teacher	SELVA ENRICO (titolare) - 3 ECTS UBIALI DANIELA - 3 ECTS
Prerequisites	The course is intended for students who have achieved the final stage of their education programme and are thus ready to apply the theoretical knowledge acquired so far to the development of autonomous and original ideas for the proposal/optimization of industrial projects concerning biotechnological processes/products.
Learning outcomes	Introducing the students to approaches, problems and trade-off situations typical of industrial workplaces in the biotech sector. Provide the students with the tools and knowledge necessary to analyze and develop an industrial research project in the biotech area. Provide students with experience of team working in interdisciplinary contexts by creating tailor-made case studies for open discussion in the classroom.



The course aims at introducing the students to approaches typical of the biotech industry by examining industrial cases of research and development of bioactive molecules.

Starting from a case-study of a well-known antibiotic, the interdisciplinary and complex discovery process of bioactive molecules produced by microorganisms will be examined. The process development for the supply of a bioactive microbial product will be then presented by examining fermentation, down processing and strain development. The multiple interactions of these approaches will be discussed, along with the issues of process management, industrial organization, team working and intellectual property.

Some case-studies of process development for the synthesis of APIs (Active Pharmaceutical Ingredients) by biocatalysis will be presented. Advantages and disadvantages of using isolated enzymes as biocatalysts in organic chemistry will be discussed, with a focus on the most used enzymes in industry (hydrolases, transferases, oxidoreductases). The pipeline of the development of a biocatalytic process will cover the selection of the enzyme, the “transformation” of the selected enzyme into a biocatalyst active and stable under the operative conditions dictated by the specific industrial process, the enzymatic reaction set up, the scale-up of the biotransformation and the product downstream.

The product development process will be subsequently examined in view of regulatory requirements and emerging medical needs. Cases of anti-infective drugs will be examined, from the development stage to their therapeutic use. The life-cycle of a drug and the business models of Big Pharma and Biotech companies will be also discussed.



Lectures. Prof. Selva and Prof. Ubiali will be always in the classroom at the same time in order to maximize the interaction with the audience. Seminars of experts from research centres and chemical companies will be also given. Simulations of industrial cases and problems will be run during the course and the impact assessment of the solutions proposed by the students will be analyzed. Real-life cases from different industrial backgrounds which reflect different process/product development stages will be proposed. A particular emphasis will be given to the multidisciplinary approach required by a biotech process developed to obtain new bioactive molecules or APIs, either by fermentation or by biocatalysis.

Case-studies from scientific literature will be presented to stimulate class discussions about approaches, issues and decision processes typical of the industrial environment.

**Recommeneded or required  
readings**

Slides used during lectures and papers (provided as pdf files, also available in the Kiro website).

K. Faber "Biotransformations in Organic Chemistry – A textbook"  
Springer Ed.





Oral exam.

Mode: Simulation of a meeting in a biotech company with the professors in the role of R&D directors.

Starting from recent scientific publications selected by the professors, students are required to organize themselves as a research team, and to analyze the publication by using a multidisciplinary approach, thus highlighting background, aim of the work, results, conclusions, strength-points and weaknesses of the paper.

The team is required to give a short presentation (ppt file) about the paper (flash talk, max 10 minutes).

Each student of the team is required to analyze an experimental protocol of the paper and write down it in his/her lab notebook (either paper notebook or electronic notebook) for the individual discussion with the R&D directors.

After the technical analysis of the paper, a discussion about the potential industrial application of the results achieved in the paper will take place.

Following the guidelines given by the professors before the exam, the team is required to identify a customer potentially interested in product/process derived from the paper. Accordingly, the team will identify the desirable product/process specifications to fit the customer (unanswered) needs and, starting from the state of the art, the team will develop a realistic work plan of what needs to be done in a proposed timeframe (Gantt chart) to get the target product/process/service.

Each student of the team has a specific role in the project and is required to present his/her contribution to the R&D directors.

The final goal is to assess the Stop/Go status of the project developed by the team.

Evaluation criteria: individual assessment of the contribution of each student to the technical analysis of the paper, the personal elaboration of the selected experimental protocol, and to the industrial development of the project. The individual evaluation will be integrated with the evaluation of the overall work of the team.



None.



The contents of this course comply with the goals 6, 12, 13, 14, 15 and 17 of the 2030 Agenda (<https://asvis.it/agenda-2030/>).

[Sbl legenda sviluppo sostenibile](#)