Course unit English denomination	Design, Development and Delivery of Innovative Biopharmaceuticals
Teacher in charge (if defined)	GATTO Barbara, PASUT Gianfranco
Teaching Hours	24
Number of ECTS credits allocated	3
Course period	01-02/2025
Course delivery method	☐ In presence ☐ Remotely ☒ Blended
Language of instruction	English
Mandatory attendance	☒ Yes (75 % minimum of presence) ☐ No
Course unit contents	The course will focus on state-of-the-art approaches for the design, development, and delivery of biotech drugs, with the specific aim to stimulate students to cross-contaminate different disciplines in the field of molecular sciences. The course aims to enable students to develop a sound knowledge relative to the design and development of innovative biopharmaceuticals such as recombinant monoclonal antibodies and protein therapeutics. Aspects of production, characterization, handling and regulatory issues for these therapeutic agents will be described. Nucleic acids-based drugs will also be briefly described. The limitation of biotech drugs will be discussed taking into consideration their instabilities. Common solutions of protein formulation will be explained. Several advanced protein delivery approaches will be presented in detail. Particular emphasis will be dedicated to the field of polymer conjugation to proteins both with chemical or enzymatic methods. Other approaches, such as fusion proteins, hyper-glycosylation, lipidization will be presented.
Learning goals	Knowledge: design and development of innovative biopharmaceuticals such as recombinant monoclonal antibodies and protein therapeutics; meaning and methods of upstream and downstream processing, current challenges related to the development, regulation, approval and use of biological and biosimilars. Skills: ability to use the tools provided by EMA concerning the search, approval, identity and use of the biologicals in clinical use approved in Europe Competencies: understand and discuss current issues related to the manufacturing and use of biologicals and biosimilars
Teaching methods	Frontal teaching
Course on transversal, interdisciplinary, transdisciplinary skills	☒ Yes (interdisciplinary) ☐ No

Available for PhD students from other courses	☒ Yes ☐ No Students external to the PhD Course admitted upon evaluation of the CV by the teachers
Prerequisites (not mandatory)	Advanced knowledge of chemistry and biochemistry basic knowledge of molecular and cell biology
Examination methods	Moodle exam test
Study material	Slides/articles provided by the teacher
Additional information (not mandatory)	max 3750 caratteri