COURSE GUIDE – extended form

Academic year 2026 – 2027

1. Program information

1.1 University	*Université de Rouen Normandie*
1.2 Faculty	*Engineering School for Innovative Technologies (ESITech)*
1.3 Department	*Biological Engineering*
1.4 Field	*Pharmaceutical Technology*
1.5 Study level	*Master of Science in Engineering*
1.6 Specialization	*Chemical and Biochemical Process Technology - CBPT*

2. Course information

2.1.1 Course name				**Biological and Sterile Medicinal Products: industrial context and implementation**			
2.1.2 Course code				607	2.1.3. Course category Fundamental/Specialized/Complementary)		
2.2 Course instructor				C Duclairoir Poc, A Morin, C Rozé			
2.3 Course instructors for applied activities (S, L, P, Pr)				C Duclairoir Poc, C Rozé, A Chane			
2.4 Year of study [2]	2	2.5 Semesterl[3]	3	2.6 Evaluation type[4]	R/P	2.7 Course type [5]	DOB

3. Amount of time estimated for course activities (hours / term)

3.1 Hours /week	3	3.2 course	1.5	3.3a sem.	1.5	3.3b laboratory	1.5	3.3c project		3.3.d. practice	1
3.4 Total hours from curriculum[6]	42	3.5 course	21	3.6a sem.	21	3.6b laboratory		3.6c project			

Time spent for related activities[7]	Hours
Study of recommended books, course support, scientific papers and course notes	30
Study in library and practical skills development	20
Preparation of seminars / laboratory works / project phases / home works / presentations	12
Evaluation[8]	2
Other activities:	

3.7 Total hours of individual study [9]	62
3.8 Total hours per semestre[10]	108
3.9 Number of credits	4

4. Prerequisites (optional)

4.1 curriculum[11]	A solid understanding of basic concepts at the undergraduate level in biology, physics, chemistry is required to successfully follow this course.
4.2 learning outcomes	Introduce students to technological, formulation, control quality, and regulatory approaches relevant to industrial pharmaceutical technologies in areas of interest, with a focus on production aera and GMPs compliance.

5. Requirements

5.1 Conditions for course delivery[12]	Blackboard, video projector.

	All digital course materials and resources will be provided through the university's virtual learning environment (UniversiTICE).
5.2 Seminar / Laboratory / Project delivery requirements[13]	All digital course materials and resources will be provided through the university's virtual learning environment (UniversiTICE). Some learning activities and coursework may involve frequent use of digital tools, virtual reality, computer-based resources, as well the technological pharmaceutical hall with pilot plants used in aseptical or sterile pharmaceutical processes.

6. Overall objective of the course

This course aims to raise students' awareness of the production of biopharmaceuticals in sterile or aseptic processes. In particular, the biotechnological process (USP+DSP) used to obtain recombinant proteins or monoclonal antibodies will be supplemented by the stages of formulation, filling, and even freeze-drying in compliance with drug or biopharmaceutics' Good Manufacturing Practices (GMPs).

By the end of the course, students will be able to manage a biopharmaceutical production process in compliance with various standards, including current Good Manufacturing Practices (cGMPs).

7. Learning outcomes

Knowledge	The student / graduate will be able to: - Understand and master biopharmaceuticals process - Understand how obtain and preserve biopharmaceutical biosafety - Demonstrate knowledge of methods and strategies used for the control and quality assessment of biopharmaceutical products; - Understand the operating principles and applications of pilot bioreactors in biopharmaceutical processes.
Skills	The student / graduate: Implements the right process in regards of the desired biopharmaceuticals forms Manage to control their efficacy and biosafety
Responsibility and autonomy	The student / graduate: respect biopharmaceutical regulations and specifications in the correct and timely completion of professional tasks, by adopting a rigorous, efficient, and responsible work strategy in decision-making and problem-solving; assumes responsibility for contributing to professional knowledge and practices and/or for reviewing the strategic performance of teams; engages in continuous professional development in their field by appropriately using effective lifelong learning methods and techniques.

8. Teaching methods

The teaching process will involve participatory lectures and debates, supported by PowerPoint presentations made available to students. These presentations include images and diagrams to make the information easier to understand and assimilate.

The teaching method is also based on discovery technological practices, facilitated through both direct and indirect exploration of reality (*e.g.,* experiments, demonstrations, virtual reality). Additionally, action-based methods will be employed, such as practical exercises, hands-on activities, and problem-solving tasks.

9. Course content

9. 1. Courses[15]	**Teaching methods**	**Time allocation**
9.1.1. Aseptic production	*Interactive lecture*	4 hours
9.1.2. Biological medicinal production 1 : USP		2 hours

9.1.3. Biological medicinal production 2 : DSP.	*Guided discussions* *Clarifying explanations*	4 hours
9.1.4. Additional manufacturing operation : freeze-drying		2 hours
9.1.5. Manufacturing constaints 1 : clean room		4 hours
9.1.6. Manufacturing constaints 2 : water management		2 hours
9.1.7. Specific Good Manufacturing Practices & focus on qualification/validation		2 hours
Course bibliography: All sources, documents, and references used during the course sessions (including articles, book excerpts, presentation slides, videos, etc.) will be made available to students through the designated platform. This includes both required readings and supplementary resources intended to deepen understanding of the topics covered in class. Students are encouraged to consult these materials regularly to support their learning and active participation.		
9.2b Laboratory	Working methods [17]	
9.2.b.1 Serious game : virtual bioreactor management		4 hours
9.2.b.2 Implementation of sterile medicinal process : Biocleaning, Manufacturing, global quality control (product and environment)		16 hours
Bibliography for applied activities (seminar / laboratory / project): All sources, documents, and references used during the course sessions (including articles, book excerpts, presentation slides, videos, etc.) will be made available to students through the designated platform. This includes both required readings and supplementary resources intended to deepen understanding of the topics covered in class. Students are encouraged to consult these materials regularly to support their learning and active participation.		

10. Evaluation

Activity type	10.1 Evaluation criteria	10.2 Evaluation method		10.3 Percentage of the final grade *(recommended to be proportional to the number of hours allocated to each type of activity)*
10.4 Type of evaluation: Final Exam / Assessment	Completeness and correctness of knowledge. Logical coherence, fluency, strength of argumentation. Capacity for analysis, personal interpretation, originality, creativity. Degree of mastery of specialized terminology and communication skills. Ability to apply acquired skills. Ability to process data and solve given problems.	Systematic observation of students (individual/team assignments – assignments must be completed during the week between lectures, preparation of a report – case study).	100%	40%
		Formative assessment test (ongoing evaluations throughout the semester).		
		Summative assessment test (final evaluation).		
10.5b Laboratory	Laboratory activity – Ability to work in a team, ability to apply learned knowledge in practice, in different contexts. Capacity for analysis, personal interpretation, originality, and creativity.	Completion of laboratory sheets (all lab works must be completed, allowing the makeup of only one missed lab work); Assessment test (laboratory colloquium).		60%
10.6 Conditions for passing				
The final evaluation result for a course is determined by considering the scores and weights assigned to each activity within the course. Whole-number grades from 10 to 1 will be awarded, with a grade of 5 certifying the achievement of the minimal learning outcomes required for the course and the awarding of the corresponding study credits.				

Date:

Course instructor: C Duclairoir Poc, A Morin, C Rozé

Course instructors for applied activities: C Duclairoir Poc, C Rozé, A Chane

Date of approval by the department: C Rozé Head of Department

Date of approval by the Faculty Council: Dean,