COURSE GUIDE – extended form

Academic year 2026 – 2027

1. Program information

1.1 University	*Université de Rouen Normandie*
1.2 Faculty	
1.3 Department	*UFR Sciences et technologies*
1.4 Field	*Biomaterials*
1.5 Study level	*Master*
1.6 Specialization	*Chemical and Biochemical Process Technology - CBPT*

2. Course information

2.1.1 Course name	**Material-product compatibility and biological risk**						
2.1.2 Course code		2.1.3. Course category Fundamental/Specialized/Complementary)					DS
2.2 Course instructor	C Egles, E Gosse, B Labat						
2.3 Course instructors for applied activities (S, L, P, Pr)	n/a						
2.4 Year of study [2]	2	2.5 Semesterl[3]	3	2.6 Evaluation type[4]	E	2.7 Course type [5]	DOB

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

3.1 Hours /week	6	3.2 course	3	3.3a sem.	3	3.3b laboratory		3.3c project		3.3.d. practice	
3.4 Total hours from curriculum[6]	84	3.5 course	42	3.6a sem.	42	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	30
Preparation of seminars / laboratory works / project phases / home works / presentations	14
Evaluation[8]	4
Other activities:	

3.7 Total hours of individual study [9]	74
3.8 Total hours per semestre[10]	162
3.9 Number of credits	6

4. Prerequisites (optional)

4.1 curriculum[11]	Basic concepts of (bio)materials
4.2 learning outcomes	

5. Requirements

5.1 Conditions for course delivery[12]	Blackboard, video projector
5.2 Seminar / Laboratory / Project delivery requirements[13]	Blackboard, video projector, optimization software (EXCEL, GAMS or similar)

6. Overall objective of the course

The course aims to provide students with a foundational understanding ofbiomaterials, biomaterials testing and biocompatibility

7. Learning outcomes

Knowledge	- Definitions, properties and applications of nanomaterials in industries - Approach of risks related to nanomaterials (human and environmental) - Definition of Medical Devices (classes, rules, criteria...) - European and international standards for obtaining the CE marking of medical devices - Biological evaluation of biomaterials and medical devices according to ISO 10993 - Regulatory aspect (GHS, CLP and REACh) and impacts of these new regulations within industries, deciphering of labels (pictograms, hazard statements, cautionary advice and mention of warning) and MSDS. - Explanation of the methods of handling and storing chemicals including the notions of incompatibility) - Collective and individual protective equipment - prevention and hygiene measures. - Different routes of penetration are presented as well as the associated impacts. - During tutorial sessions, MSDS are requested, as well as a simulation of a reaction with dangerous and reactive chemicals.
Skills	Skills **Advanced and specialized uses of digital tools** - Identify the digital uses and the impacts of their evolution on the fields concerned by the mention - To use advanced digital tools in an autonomous way for one or several professions or research sectors of the field - Use digital tools in compliance with computer security rules **Development and integration of highly specialized knowledge** - Mobilize highly specialized knowledge, some of which is at the forefront of knowledge in a field of work or study, as a basis for original thinking - Develop a critical awareness of knowledge in a field and/or at the interface of several fields - Conduct a reflective and distanced analysis taking into account the stakes, the problems and the complexity of a request or a situation in order to propose adapted and/or innovative solutions in compliance with the evolutions of the regulation **Support for transformation in a professional context** - Respect the principles of ethics, deontology and environmental responsibility **Scientific and technical mastery** - Identify and apply knowledge and tools related to basic science in health engineering - Provide solutions in terms of continuous improvement of the performance of processes, products and services related to health through the knowledge and understanding of scientific and technical fields - Collect and interpret data using appropriate methods and tools to identify and solve problems **Regulatory and contextual issues** - Appreciate the economic stakes, the respect of the quality, the competitiveness and the productivity, the commercial requirements, the economic intelligence - Conduct a complex project in compliance with quality systems and taking into account the standards and legislation in force - Take into account societal and environmental issues. - Apply national and international regulations
Responsibility and autonomy	The student / graduate: respects ethical principles, standards, and values 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. Each lecture will begin with a brief review of the topics covered in the previous session.

The teaching method is also based on discovery learning models, facilitated through both direct and indirect exploration of reality (e.g., experiments, demonstrations, modelling). 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. Techniques and models in the regulatory framework (C. Egles)	*Interactive lecture* *Guided discussions* *Clarifying explanations*	9 hours
9.1.2. Industrial risk - REACH (E. Gosse)		5 hours
9.1.3. Nanomaterials (B. Labat)		10 hours
9.1.4. Medical Devices (B. Labat)		13 hours
9.1.5. Biocompatibility (B. Labat)		4 hours

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 %	100%
		Formative assessment test (ongoing evaluations throughout the semester).		
		Summative assessment test (final evaluation).		
10.6 Conditions for passing				
A minimum grade of ECTS' E or up is the minimal learning outcomes required for the course and the awarding of the corresponding study credits.				

Date:

Course instructor:

Course instructors for applied activities:

Date of approval by the department: Head of Department

Date of approval by the Faculty Council: Dean,