UNIVERSITA' DEGLI STUDI DI MILANO
PROGRAMME DESCRIPTION - ACADEMIC YEAR 2026/27
IN
SAFETY ASSESSMENT OF XENOBIOTICS AND BIOTECHNOLOGICAL PRODUCTS (Classe LM-9 R)
Immatricolati nell'a.a. 25/26

HEADING

Degree classification - Denomination and code:	LM-9 R
Degree title:	Dottore Magistrale
Length of course:	2 years
Credits required for admission:	180
Total number of credits required to complete programme:	120
Course years currently available:	2nd
Access procedures:	
Course code:	EBB

PERSONS/ROLES

Head of Study Programme

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Degree Course website

https://safetyassessment.cdl.unimi.it

Contact

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Student Desks

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Suggestions to improve

Email: didattica.disfeb@unimi.it

CHARACTERISTICS OF DEGREE PROGRAMME

General and specific learning objectives

The aim of the Master Course is to present provision of training program in risk assessment based on common European and international criteria, easily adoptable by institutions across Europe and worldwide and focusing on Risk Assessment methodology and procedure.

The Master provides the methodological background, knowledge and skills necessary to apply current methodologies and generate novel protocols, to acquire competence in problem-solving, to assess risks arising from production and use of chemicals and biotechnological products, with particular attention to the implementation of European Regulations through the integrated development of different areas including legislation, chemistry, toxicology and pharmacology, biotechnology and risk analysis. The graduates will have specific expertise in the areas of:

- community law, national and international legislation on chemicals, risk and safety;
- toxic and eco-toxic properties of chemicals and biotechnological products;
- methods and procedures for the characterization of chemical substances and biotechnological products;
- computational techniques for the estimation of the chemical and toxicological properties of substances;
- procedures for registration of chemicals under various European regulations;
- evaluation of risks inherent to the production and use of chemicals and biotechnological products;
- evaluation of new materials such as those produced by nanotechnologies and new processes;
- strategies of synthesis and production of alternatives to the toxic and/or eco-friendly;
- basis on risk perception and risk communication.

The project focuses on understanding the profile and training requirements of risk assessors in order to design a degree covering a range of disciplines in risk assessment and providing a model to establish a recognition of risk assessors. To this end, the Master degree in "Safety Assessment of Xenobiotics and Biotechnological Products" (SAXBi) has been certified (the first one in Europe), according to the Standard UNI EN 16736 and to the AICQ SICEV Regulation RG 06-1, that well define the formation for risk assessors.

The Master level "Safety assessment of xenobiotics and biotechnological products" (SAXBi) is equivalent to the second-level higher education award that refers to the second cycle in the Qualifications Framework of the European Higher Education Area (EHEA), designed by the Bologna Accords (1999) which refers to level 7 of the European Union's European Qualifications Framework. The degree requires 120 European Credit Transfer System (ECTS), and the expected learning outcomes will meet those specific to the second Dublin descriptor.

Expected learning outcomes

The Master course is designed to provide students with interdisciplinary knowledge and the ability to manage complex projects. The program emphasizes the connections between various disciplines, particularly chemistry, biology, and economics/law. Courses are designed to promote the exchange of methodological and technological knowledge, as well as to prepare students for the job market. Practical exercises associated with basic courses are considered highly relevant. The curriculum includes internships at university or other public or private institutions, aimed at completing the student's cultural and professional training. These internships provide hands-on experience in evaluation, biotechnology, IT, and regulatory and managerial fields. This also helps develop critical thinking, teamwork, and communication skills. The application of risk assessment for human health protection is covered within courses that explain the regulatory pathways for different substances and products. Graduates will develop critical thinking skills necessary for applying risk assessment tests and methodologies, and for creating innovative protocols in the fields of pharmaceutical biotechnology and related areas. They will also be able to independently evaluate the socio-economic impact of regulations, methodologies, and new risk assessment protocols. This development is facilitated through seminars and workshops that encourage critical evaluations of published work and scientific research. Graduates will be able to communicate complex information clearly and effectively, both with specialists and non-specialists. They will also be capable of presenting progress and innovations in risk assessment in English. The training received, including workshops and seminars, will allow them to communicate with audiences of diverse scientific backgrounds. Graduates will be able to independently acquire new knowledge through scientific articles, databases, and online resources, especially within formal courses and internships. They will also develop the ability to prepare and execute protocols, write reports, and conduct research in risk assessment and related fields.

The Master course anticipates that graduates will find employment in European and international institutions that deal with the protection of health and the environment, as well as companies in the chemical, agrochemical, pharmaceutical, and food sectors. The program also points out the importance of scientific expertise in risk evaluation and decision making, requiring professionals with expertise in areas such as toxicology, chemistry, epidemiology, environmental fate, exposure and risk management.

Professional profile and employment opportunities

SAXBI offers various career opportunities for graduates, with roles in research, safety evaluation, production, and quality certification. These positions span both public and private sectors and involve tasks such as designing scientific experiments, analyzing data, and ensuring regulatory compliance. More specifically:

Research roles are available in public and private research institutions. These positions require skills in experimental design, data analysis, and scientific communication, as well as knowledge of safety regulations for chemical and biological products. Specific employers include universities, the Istituto Superiore di Sanità, and various governmental agencies.

Safety evaluation roles involve gathering toxicological data, assessing risks, and establishing health-based guidance values. These roles require critical thinking, knowledge of safety regulations, and the ability to work in teams. Employment opportunities exist in the biotechnology, pharmaceutical, diagnostic, food, cosmetic, and chemical industries.

Production roles encompass production management, quality control, and formulation development. These positions require managerial and planning skills, as well as knowledge of safety regulations. The same industries that employ safety evaluators also employ production specialists.
Quality certification roles involve verifying quality management systems, analyzing company processes, and defining work procedures that comply with regulations. This requires knowledge of safety regulations and the ability to interface with various professionals. Opportunities are available in consulting firms and various industries.
The resultant job profiles will be available for recruitment in:
- public administration for the control, implementation and management of human health and environmental protection;
- industry Associations (Food, Cosmetics, Pharma, Chemicals);
- pharma Companies in the sector of drug development;
- biotech Companies;
- contract Research Organization for the drug toxicity testing;
- food and Chemical Companies in Quality Control divisions;
- bioremediation Companies;
- innovative energy plants;
- public and Private Companies for the implementation and application of appropriate RA procedures;
- private sectors as consultants for RA of chemicals, food contaminants, water and air pollutants;
- public and Private Research Institutions;
- universities and secondary schools;
- researcher at public and private research institutions;
- researcher in industry (research and development sector); - risk assessor in public and private organizations;
- quality certifier.

Pre-requisites for admission

Admission Requirements
To be admitted to a 2nd course/level degree course, a 1st level degree or a suitable equivalent foreign qualification is required (see also the "Admission criteria" section).
Access to the Master in "Safety Assessment of Xenobiotics and Biotechnological Products" (SAXBi) is open to:
- graduates with Italian degree (ex. DM 270/04 or equivalent ex. DM 509/99) in the classes L-2 or L-29;
- graduates from areas other than the above listed, provided they have earned the following credits:
- at least 9 credits (ECTS) in disciplines of CHIM/01, CHIM/03 or CHIM/06 (analytical chemistry; general and inorganic chemistry; organic chemistry);
- at least 5 credits in disciplines BIO/09 (physiology);
- at least 12 credits in disciplines BIO/10, BIO/11 or BIO/13 (biochemistry; molecular biology; applied biology);
- at least 6 credits in disciplines BIO/14 (pharmacology/toxicology);
Students with foreign qualification recognised as equivalent may access to the Master in SAXBi if they can demonstrate background knowledge and skills in biology, chemistry, biochemistry, pharmacology, toxicology and physiology, equivalent to those listed above. A committee of teachers appointed by the Board of Faculty will check the presence of these requirements.

Knowledge Assessment
Students meeting the above minimum requirements are invited to an interview for admission (in English) with the Commission for Admittance to the Master, composed by teaching members appointed by the Teaching Board. The interview, done remotely via electronic devices if necessary, is aimed at verifying the above mentioned skills and the knowledge of the English Language equivalent to B2 level.

Students who have not yet graduated but who expect to graduate by 31st of October of the same year can also apply for admission to the Master in SAXBi, on the understanding that enrolment will only be finalised once the required qualification has been obtained.

Programme structure

The 2nd cycle course, also known as a Laurea Magistrale (qualification Dottore Magistrale), provides the student with advanced education and training for professions in specific fields that require a high level of qualification. The course lasts two years, and each year is subdivided into two semesters. To obtain the qualification (2nd level degree) it is necessary to accumulate 120 credits. Each credit corresponds to a standard student workload of 25 hours, including:
- 8 hours of lectures followed by 17 hours of individual study;
- 16 hours of practical labs followed by 9 hours of individual study;
- 25 hours of training activities related to the thesis
- 25 hours of individual study.
The SAXBi Master Degree integrates chemical, biological and toxicological disciplines with a particular focus on the regulatory field.
The Department of Pharmacological and Biomolecular Sciences “Rodolfo Paoletti” of the Università degli Studi di Milano is the reference point and the main institution responsible for the SAXBi Master Degree.

ATTENDANCE
Recommended to the course, see section "Compulsory attendance" for the labs.

STUDY PLAN DEFINITION AND SUBMISSION FOR APPROVAL

The student must provide an individual study plan indicating the elective course units for a total of 8 credits. These will be chosen freely from all courses provided by the University of Milan if they are consistent with the educational project, after consulting the Study Programme committee. As an alternative, the student can also choose the Laboratory of Risk assessment (8 CFU). This laboratory aims to deepen the theoretical and practical aspects of the research topic of the thesis,and it will be agreed with the thesis tutor.

Other training activities (3 ECTS)

To facilitate the completion of cultural and professional training of students, activities of orientation to the career are also planned, including meetings and seminars of experts in various fields inherent to the degree.

The credits obtained in these activities ("Other training activities" in the study plan) must be cumulated to reach 3 ECTS= (including at least 20 hours of lectures).

Students are expected to provide certificates of participation in activities and to give short presentations of the activities they have participated in on specific days scheduled during the academic year.

Foreign students have also the opportunity to acquire 3 CFU of additional language skills in Italian (for more details, refer to the Language courses section).

The study plan must be submitted online in the 1st year, within the deadline set by the Direzione Segreteria Studenti. For information on dates and procedures for submitting the official study plan, please visit the relevant section of the UNIMI website available at https://www.unimi.it/en/study/bachelor-and-master-study/following-your-programme-study/plan-study. After the approval of the study plan, the student can independently take further exams in addition to his/her educational path. In addition, activities included in the University project for the development of soft skills can be chosen: https://www.unimi.it/en/study/bachelor-and-master-study/following-your-programme-study/soft-skills. These educational activities have a compulsory attendance, a limited number of places is available and they can be included in the study plan, under the “Elective activities”, only if they have been subscribed to by the Course of Study. For more details, please refer to the following webpage: https://safetyassessment.cdl.unimi.it/en/courses/soft-skills

TESTING AND ASSESSMENT PROCEDURES

Course exams must be passed, with grades calculated on a 30-point scale, to obtain course credits, with 18/30 being the minimum pass grade. The assessment will consist of an oral or written exam. For courses structured into modules, a head lecturer will be identified as the coordinator, and evaluation procedures for course outcomes and the registration of examination grades will be agreed by all associated teaching members.

The schedule of the examination sessions for the assessment of the learning outcomes is available through the online service available at https://www.unimi.it/en/node/134/

Exam registration is compulsory and must be carried out through the online service available at https://www.unimi.it/en/node/130/

TEACHING CALENDAR AND LECTURE TIMETABLE

- 1st Semester: September 28th, 2026 - January 22nd, 2027
- 2nd Semester: March 1st, 2027 - June 18th, 2027

Teaching is delivered in a blended mode.

The degree program employs a mixed teaching approach, a flexible approach that allows the teachers, from a student-centered perspective, to adapt teaching methods to the specific needs of courses and students, many of whom are international and may face temporary visa issues. For each course in the study plan, up to 50% of instructional activities can be conducted online (one-third of which is synchronous), within the permitted maximum hours. The program uses technologies that promote active learning, with technical and applied skills supported by virtual labs or environments. A key feature of this teaching method is the "Learning in Action" project, designed to integrate theory with practice. This strategy includes digital learning resources that enrich the learning experience of learning content and skills, enabling a more dynamic, engaging interactions between students and between students and teachers. Through this teaching methodology, students engage in hands-on activities that apply the theoretical knowledge gained in class. This not only fosters a deeper understanding of key concepts but also helps develop essential practical skills for their future careers.

The student and teacher will be supported for online activities by qualified tutors and Faculty Development's Ambassador for Innovative Teaching.

Exams take place mainly during February and July-September sessions, and in other dates to be agreed with the students, possibly not in conjunction with lessons. The lecture timetable is available at https://www.unimi.it/en/node/128/; download “Lezioniunimi”, LaStatale app for Android, iOS and Windows phone.

Conscientious objection policy

The teaching activities do not include laboratories involving the use of animals. In case students during their internship period for thesis will attend a laboratory activity involving the use of animals, the Teaching Board of SAXBi acknowledges the uncontested right of conscientious objection according to the Italian law n. 413, October 12, 1993, "Norme sull'obiezione di coscienza alla sperimentazione animale".

Campus

Città Studi teaching facilities

Lectures are held in the classrooms indicated in the timetable of the courses of Università degli Studi di Milano.

All the classrooms are accessible to students with disabilities.

Laboratories

Città Studi teaching facilities

Laboratory activities are held in the labs of the School of Pharmacy, according to the timetable of the courses of Università degli Studi di Milano.

Libraries

The Biomedical Library of Città Studi, Valvassori Peroni Street, n. 21 (Milan) offers texts, scientific journals and collections for consultation.

More info: https://sba.unimi.it/en/libraries/biomedical-sciences-library-citta-studi

Tutoring

Tutors are available to help the students

i) learn the material in individual courses;

ii) understand how to use the syllabus, through regular meetings with students, throughout the semester.

Students can contact the tutors, whose names appear on the first page of the official programme description.

Language test / computer literacy test

Additional Language Skills: Italian (foreign students)

Among the electives, those who do not hold an Italian high school diploma or degree can obtain 3 credits in Additional language skills: Italian by demonstrating A2 level in Italian per the Common European Framework of Reference for Languages (CEFR). This level can be assessed in one of the following ways:

- by submitting a certificate of A2 or higher level issued no more than three years prior to the date of submission. You will find the list of language certificates recognized by the University at https://www.unimi.it/en/node/349/. The language certificate must be uploaded through http://studente.unimi.it/uploadCertificazioniLingue.

- by an entry-level test administrated by SLAM that can be taken only once and is compulsory for all students who do not have a valid language certificate. Those who fail to reach A2 level will have to attend one or more than one 60-hour Italian course(s) geared to their level. Those who do not take the entry-level test or fail to pass the end-of-course test after six attempts will have to obtain language certification privately in order to earn the 3 credits of Additional language skills: Italian. As an alternative, they can modify their course programme by choosing a different elective.

Compulsory attendance

Mandatory to the labs, recommended to the courses.

Students who are working

If the student is enrolled in working activities in laboratories in which techniques that are subject of the teaching laboratories are used, he/she is entitled of a partial/total exemption from laboratory attendance.

To take advantage of such concession, the student has to present to the Secretariat of the Teaching Committee copy of the job contract and timetable at the beginning of each academic year.

Alternatively, the students who are working are entitled to enrol as part-time students (see below).

Part-time students

In agreement with the University of Milan rules, students who cannot attend classes with academic continuity and take exams within the regular duration of the course, can be granted the possibility to follow a specific path based on the particular situation and can be enrolled as part-time students.

For further information, please visit the website https://www.unimi.it/en/node/113/

Internship criteria

The final exam requires an internship (thesis) during the degree course, in academic, private or governmental institutions with expertise in health risk assessment, to acquire the expected 29 ECTS.

A minimum of 51 ECTS must be earned in order to begin the internship (thesis).

In addition to the expected 29 ECTS, the Laboratory of Risk Assessment (8 ECTS) offers the possibility to the students to add their free credits to the scheduled credits for the preparation of their thesis, with the evaluation of the student's performance based on the experimental thesis period.

Otherwise, students can acquire 8 ECTS choosing courses among those offered by the University of Milan, relevant to SAXBi programmes.

Internships and traineeships carried out in external organizations and companies are managed through agreements signed

with COSP and require the student to activate a procedure through a dedicated platform. More information is available on the website https://www.unimi.it/en/node/483/

Degree programme final exam

The final examination requires a previous internship (thesis).
The final examination consists of written thesis, oral presentation and defence of a risk assessment exercise conducted on a case- study, agreed by the tutor and the candidate.
The objective of the examination is to assess the students' broader and deeper knowledge and skills to independently apply the knowledge presented in the taught courses and be able to perform a full risk assessment integrating the different elements of the risk-assessment-process.
To be admitted to the final examination, students must have achieved all the credits required by all the topic listed in the second cycle program, except those reserved to the final examination.

EXPERIENCE OF STUDY ABROAD AS PART OF THE DEGREE PROGRAM

The University of Milan supports international mobility by providing its students with the opportunity to spend study and internship periods abroad. It is a unique chance to enrich your educational path in a new exciting environment.

The agreements entered into by the University with over 300 universities from the 27 EU member countries under the European Erasmus+ programme allow regularly enrolled students to carry out part of their studies at one of the partner universities or to undertake internships at companies, training and research centres and other organisations.

Similar international mobility opportunities are provided outside Europe, through agreements with a number of prestigious institutions.

The University of Milan is a member of the 4EU+ European University Alliance that brings together eight public multidisciplinary universities: University of Milan, Charles University of Prague, Heidelberg University, Paris-Panthéon-Assas University, Sorbonne University of Paris, University of Copenhagen, University of Geneva, and University of Warsaw. The 4EU+ Alliance offers integrated educational pathways and programmes to promote the international mobility of students (physical, blended and virtual).

Study and internships abroad

Thanks to mobility Erasmus programs and other Mobility opportunities, the Master Course in SAXBi offers its students the opportunity to spend periods of training abroad. The Programs also offer the opportunity to play an internship abroad at companies, universities or other organizations. Universities and Institutions partners involved in these programs offer the possibility to engage in a wide range of areas. In the mobility period, the student can:
- carry out the thesis.

Each student is followed by a tutor identified within the Course. The url https://www.unimi.it/en/node/12879/ lists all the information related to the fields of study and training opportunities offered by the host locations. Procedure for the recognition of study periods abroad: each student must propose a Learning Agreement regarding training activities that lead to the recognition of a number of credits adequate to the period spent abroad.
The activity of the thesis or internship will be valid only after acquisition of all credits. For students who have accomplished satisfactorily the training program, there are appropriate incentives, proposed by the teacher in charge, will be paid by the Faculty in the diploma achievement session. It provides additional points to the final degree mark varying from a minimum of 1 to a maximum of 3 points depending on the duration of the study period, the amount of credits attained, and the overall results obtained by the student.

How to participate in Erasmus mobility programs

The students of the University of Milan can participate in mobility programmes, through a public selection procedure.
Ad hoc commissions will evaluate:
· Academic career
· the candidate's proposed study programme abroad
· his/her foreign language proficiency
· the reasons behind his/her application

Call for applications and informative meetings

The public selection for Erasmus+ mobility for study generally begins around February each year with the publication of a call for applications specifying destinations and requirements. Regarding the Erasmus+ Mobility for Traineeship, the University of Milan usually publishes two calls a year enabling students to choose a destination defined by an inter-institutional agreement or to find a traineeship position on their own.
The University organises informative meetings to illustrate mobility opportunities and rules for participation.

Erasmus+ scholarship

The European Union grants the winners of the Erasmus+ programme selection a scholarship to contribute to their mobility costs, which may be supplemented by the University funding for disadvantaged students.

Language courses
Students who pass the selections for mobility programmes can benefit from intensive foreign language courses offered each year by the University Language Centre (SLAM).
https://www.unimi.it/en/node/8/

Learn more at https://www.unimi.it/en/node/274/

For assistance, please contact:
International Mobility Office
Via Santa Sofia 9 (second floor)
Tel. 02 503 13501-12589-13495-13502
Contacts: InformaStudenti;
Student Desk booking through InformaStudenti

1st COURSE YEAR (Cancelled since academic year2026/27)Core/compulsory courses/activities

Scheduling	Learning activity	Module/teaching unit	Ects	Sector
	Development Biology and Differentiation		6	BIO/13
	Functional, Metabolic and Epigenetic Biochemistry		6	BIO/10
	Methods of analysis of chemicals in water, air, biological fluids, tissues, food		6	(3) CHIM/01, (3) CHIM/06
	Organ Physiopathology and Histopathology (Total number of ects:10)	Organ Physiology and Pathology	7	(4) MED/04, (3) BIO/09
		Lab of Comparative Histopathology	3	VET/03
	Bioremediation		7	(3) BIO/19, (4) BIO/13
	Biotechnology and Pharmacotoxicology		10	BIO/14
	Regulatory Aspects in toxicology		6	(3) IUS/14, (3) CHIM/09
		Total number of compulsory credits/ects	51	

2nd COURSE YEAR Core/compulsory courses/activities

Scheduling	Learning activity	Module/teaching unit	Ects	Sector
year	Quantitative Chemical Structure and activity relationship (Total number of ects:10)	In Silico Methods in Toxicology	5	BIO/14
		Structural Bioinformatics	5	BIO/10
1 semester	Databases and Exposure scenarios		6	(3) MED/01, (3) INF/01
1 semester	System Toxicity and Risk Assessment		7	BIO/14
2 semester	Pharmacogenetics and Epigenetics in Toxicology		6	BIO/14
		Total number of compulsory credits/ects	29	

Elective courses

STUDENTS MUST CHOOSE AN OPTIONAL COURSE OF 8 ETCS.
These will be freely chosen among all courses provided by the University of Milan if the are compatible with the educational project, after consulting the Study Programme Committee. As an alternative, the student can also choose the Laboratory of Risk assessment 8 ETCS. This laboratory aims to deepen the theoretical and practical aspects of the research topic of the thesis and it will be agreed with the thesis tutor.
In addition, activities included in the University project for the development of soft skills can be chosen.
https://www.unimi.it/en/study/bachelor-and-master-study/following-your-programme-study/soft-skills

	Laboratory of Risk assessment		8	NN

TO OBTAIN THE DEGREE, STUDENTS HAVE TO ACQUIRE AN ADDITIONAL 3 CREDITS (OTHER ACTIVITIES). More information in the "Study plan definition and submission for approval" and in "Language and Computer skills" above.

	Additional Language Skills: Italian (3 ECTS)		3	NN
	Other training activities *(i.e. meetings and seminars of experts in various fields inherent to the degree)*		3	NN

End of course requirements

	Thesis		29	NN
		Total number of compulsory credits/ects	29	