UNIVERSITA' DEGLI STUDI DI MILANO
MANIFESTO DEGLI STUDI A.A. 2020/21
LAUREA MAGISTRALE IN
SAFETY ASSESSMENT OF XENOBIOTICS AND BIOTECHNOLOGICAL PRODUCTS (Classe LM-9)
For students enrolled from 2015/16 academic year

GENERALITA'

Classe di laurea di appartenenza:	LM-9 BIOTECNOLOGIE MEDICHE, VETERINARIE E FARMACEUTICHE
Titolo rilasciato:	Dottore Magistrale
Durata del corso di studi:	2 anni
Crediti richiesti per l'accesso:	180
Cfu da acquisire totali:	120
Annualità attivate:	1° , 2°
Modalità accesso:	Libero con valutazione dei requisiti di accesso
Codice corso di studi:	E52

RIFERIMENTI

Presidente Collegio Didattico

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Docenti tutor

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Sito web del corso di laurea

https://safetyassessment.cdl.unimi.it/en

Contact

Email: saxbi@unimi.it

Enrolment and Admission

https://www.unimi.it/en/study/enrolment

Student Desks

Via Celoria 18, Milano Tel. 02 5032 5032 https://www.unimi.it/en/node/360 https://www.unimi.it/en/node/359

Student Office of the Department of Pharmacological and Biomolecular Sciences dr.ssa Antonella Masi

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Suggestions to improve

Email: saxbi@unimi.it

CARATTERISTICHE DEL CORSO DI STUDI

Premessa

The industrial revolution has resulted in a profound and irreversible transformation that starts from the productive system to involve the economic as the entire social system.
This has resulted in the need to regulate the complex world of chemicals both as regards their use and, above all, their safety. The rapid evolution of the productive system has not been followed by the generation of professionals with the competence and skills necessary to ensure the efficient and continuous monitoring of the environment and food chain.
As a result, the need to train professionals who can fit authoritatively in the complex process of risk assessment and possibly also in its management is imperative not only in the national, but also in the international context. The recent implementation of regulatory frameworks for chemicals, plant protection products, biocides, pharmaceuticals, food contaminants, and cosmetics by the European Commission and other interested bodies have resulted in a demand for trained health risk assessors across the world. Not only are more trained professionals needed to work in regulatory affairs such as European agencies and national and international authorities, but also industry, research and the academic setting need such professionals.
In Europe this issue has become even more relevant in view of the activity of the agencies such the European Food Safety Authority (EFSA), European Chemical Agency (ECHA) and European Medicine Authorithy (EMA) and the application of the European regulations which requires authorities and private companies to collect, to select and to correctly evaluate the data of effect and exposure for a large number of chemicals.
Today, only a limited number of training courses specifically in human health risk assessment are available in Europe as shown from data collected by the University of Milan in a EU-sponsored market survey “Mapping existing courses relevant to risk assessment in Europe" and although some basic training in health risk assessment is part of most toxicology university programs, the preparation is often not enough to provide excellent candidates to become risk assessors.
The Master Degree in “Safety Assessment of Xenobiotics and Biotechnological Products” (SAXBi) integrates chemical, biological and toxicological disciplines with a particular focus on the regulatory field.
The Department of Pharmacological and Biomolecular Sciences at the Università degli Studi di Milano is the reference point and the main Institution responsible for the SAXBi Master Degree.

Obiettivi formativi generali e specifici

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 focusing on Risk Assessment methodology and procedure. 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.

Risultati di apprendimento attesi

The Master Course provides specific knowledge in the analysis and assessment of risk, taking into account the international regulations. In addition, the ambition of the course is to provide the students with a multidisciplinary background sufficient to initiate research on the novel methodologies to be applied in the field of risk assessment. It is believed that the professional profiles formed will find employment in the European and international Institutions and Agencies dealing with the protection of health of consumer and the environment, as well as in companies operating in the chemical, agrochemical, pharmaceutical and food field.
As mentioned in the program of activity of ECHA “In the evaluation of dossiers ECHA produces scientific judgments. These judgments must be based on scientific principles accurate and require well-trained and competent experts. A number of scientific disciplines, such as toxicology, chemistry, epidemiology, occupational hygiene, environmental fate and effects on the environment, exposure assessment and characterization and risk management, must come to comprehensive evaluation results from the scientific point of view.”
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.

Profilo professionale e sbocchi occupazionali

The professional profiles generated will be employed by:
- 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.

Conoscenze per l'accesso

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 areas L2 or L29;
- 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 December 2020 can also apply for admission to the Master in SAXBi.

Interviews of applicants will be held according to a calendar proposed individually to each applicant.
The committee evaluates the candidate on a 100-point scale:
-up to 25/100 will be given for the graduation mark;
-up to 25/100 for the curriculum (free courses, others…) -up to 50/100 for the interview
The minimum requirement for admission is 60/100.

Struttura del corso

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 at the Università degli Studi di Milano is the reference point and the main Institution responsible for the SAXBi Master Degree.

Obiezione di coscienza

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".

Area didattica

Teaching block Via Golgi, 19 – 20133 MILAN
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.

Laboratori didattica

Teaching block Via Golgi, 19 – 20133 MILAN
Laboratory activities are held in the labs of the Faculty of Pharmacy, according to the timetable of the courses of Università degli Studi di Milano.

Biblioteche

At the Biomedical Library of Città Studi, Valvassori Peroni Street, n. 21 (Milan), texts, scientific journals and collections are available.
More info: http://www.sba.unimi.it/Biblioteche/bcittastudi/11688.html

Tutorato

Tutors are available to help the students
i) to learn the material in individual courses;
ii) understanding how to use the syllabus, by means of meetings with the students, regularly throughout the semesters.

Students can contact the tutors, whose names are listed in the first page of the programme official description.

Obbligo di frequenza

Recommended to the course, mandatory to the labs.

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:
- are working with a not occasional documented commitment (subordinate, autonomous or professional) of at least 6 months/year;
- are taking care of not self-sufficient relatives with a not-occasional commitment;
- have health problems or disabilities, which are hampering the normal study progression;
- are taking care of their own children or are pregnant;
- are enrolled in documented sport or artistic activities at national or international level
can be enrolled as part-time students.

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

Modalità di valutazione del profitto

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 on line service available at https://www.unimi.it/en/node/130/

Regole generali per iscrizione e ammissione agli appelli d'esame

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

Formulazione e presentazione piano di studi

The student must provide an individual study plan indicating the elective course units for a total of 8 credits. These will be chosen freely among all courses provided by the University of Milan if they are consistent with the educational project, after consulting the Study Programme committee. As 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.
The study plan must be submitted online in the 2nd Year, within the deadline set by the Segreteria Studenti, generally between December and March. For information on dates and procedures for submitting the official study plan, please visit the relevant section of the UNIMI website available in https://www.unimi.it/en/node/122/

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OTHER TRAINING ACTIVITIES (3 ECTS)

In order 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=24 hours.

Caratteristiche della prova finale

The final exam requires a previous internship (thesis) during the degree course, in academic, private or governmental institutions with expertise in health risk assessment, to acquire the expected 29 credits. Eligibility is based upon the acquirements of about 60 credits.The student can choose to convert the optional course in thesis, then period of the thesis will be prolonged of 8 ECTS (Laboratory of Risk assessment).

The final exam consists of: written text, 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.

Criteri di ammissione alla prova finale

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.

Orario lezioni

https://www.unimi.it/en/study/bachelor-and-master-study/following-your-programme-study/course-timetables

Download "Lezioniunimi", LaStatale app for Android, iOS and Windows phone

ESPERIENZA DI STUDIO ALL'ESTERO NELL'AMBITO DEL PERCORSO FORMATIVO

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 30 different 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 organizations.

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

Cosa offre il corso di studi

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:

- continue their studies by attending courses and the respective exams;
- carry out the thesis.

Each student is followed by a tutor identified within the Course. https://www.unimi.it/en/international/study-abroad/studying-abroad-erasmus/how-take-part-programme/erasmus-areas/erasmus-pharmacy 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 period of study abroad will be recognized as valid after obtaining at least 70% of the credits specified in the learning agreement, while 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 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

Modalità di partecipazione ai programmi di mobilità - mobilità Erasmus

The students of the University of Milan can participate in mobility programmes, which last 3 to 12 months, through a public selection procedure.

Ad hoc commissions will evaluate:

• 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 generally begins around February each year with the publication of a call for applications specifying the destinations, with the respective programme duration, requirements and online application deadline.

Every year, before the deadline for the call, the University organizes informative meetings to illustrate opportunities and rules for participation to students.

Erasmus+ scholarship
The European Union grants the winners of the Erasmus+ programme selection a scholarship to contribute to their mobility costs, which is 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.

Learn more at https://www.unimi.it/en/international/study-abroad/studying-abroad-erasmus

For assistance, please contact:
International Mobility Office
Via Santa Sofia 9 (2nd floor)
Tel. 02 503 13501-12589-13495-13502
E-mail: mobility.out@unimi.it
Desk opening hours: Monday to Friday 9 am - 12 noon

MODALITA' DI ACCESSO: 1° ANNO LIBERO CON VALUTAZIONE DEI REQUISITI DI ACCESSO

Informazioni e modalità organizzative per immatricolazione

All students must submit the application for the admission by the deadlines indicated in the "student area" of the University web portal (https://www.unimi.it/en/node/92/).
The admission application is mandatory and must be completed online from March 2020 to August 28, 2020.
Undergraduates who intend to graduate by 31st December 2020 may also apply.
See for all details the section above "Pre-requisites for admission"

If coming from another university or other degree program, admission to second year of the course will be evaluated by competent organs of the course.

Enrolment
At the end of the evaluation procedures, candidates admitted and already graduated must enrol online by September 30, 2020. Candidates who will graduate after September 30, 2020 can enrol by January 15, 2021.

N° posti riservati a studenti extracomunitari non soggiornanti in Italia

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1° ANNO DI CORSO Attività formative obbligatorie

Erogazione	Attività formativa	Modulo/Unità didattica	Cfu	Settore	Form.Didatt.
annuale	Development Biology and Differentiation		6	BIO/13	40 ore Lectures, 16 ore Laboratory individual activity
1 semestre	Functional, Metabolic and Epigenetic Biochemistry		6	BIO/10	48 ore Lectures
1 semestre	Methods of analysis of chemicals in water, air, biological fluids, tissues, food (tot. cfu:6)	Methods of analysis of chemicals	3	CHIM/01, CHIM/06	24 ore Lectures
		Physical-chemical characterization, identity	3	CHIM/01, CHIM/06	24 ore Lectures
1 semestre	Organ Physiopathology and Histopathology (tot. cfu:10)	Organ Physiology and Pathology	7	BIO/09, MED/04	48 ore Lectures, 16 ore Tutorials
		Lab of Comparative Histopathology	3	VET/03	16 ore Lectures, 16 ore Laboratory individual activity
2 semestre	Bioremediation (tot. cfu:7)	Environmental Microbiology and Biotechnological Remediation	3	BIO/13, BIO/19	8 ore Lectures, 32 ore Laboratory individual activity
		Laboratory of Cell Biology	4	BIO/13, BIO/19	16 ore Lectures, 32 ore Laboratory individual activity
2 semestre	Biotechnology and Pharmacotoxicology (tot. cfu:10)	Biotechnology and Pharmacology	5	BIO/14	40 ore Lectures
		Genotoxicology, Cancerogenicity, Immunotoxicology, Reproductive and Developmental Toxicity	5	BIO/14	32 ore Lectures, 16 ore Tutorials
2 semestre	Regulatory Aspects in toxicology (tot. cfu:6)	Regulatory Aspects of Medicaments, Medical Devices and Health products	3	CHIM/09, IUS/14	24 ore Lectures
		Legislation in European Union	3	CHIM/09, IUS/14	24 ore Lectures
		Totale CFU obbligatori	51		

2° ANNO DI CORSO Attività formative obbligatorie

Erogazione	Attività formativa	Modulo/Unità didattica	Cfu	Settore	Form.Didatt.
1 semestre	Databases and Exposure scenarios (tot. cfu:6)	Informatics and Database	3	INF/01, SECS-S/01	24 ore Lectures
		Statistics applied to Epidemiology	3	INF/01, SECS-S/01	24 ore Lectures
1 semestre	Quantitative Chemical Structure and activity relationship (tot. cfu:10)	In Silico Methods in Toxicology	5	CHIM/08	40 ore Lectures
		Structural Bioinformatics	5	BIO/10	32 ore Lectures, 16 ore Laboratory individual activity
1 semestre	System Toxicity and Risk Assessment (tot. cfu:7)	Risk Assessment	4	BIO/14	24 ore Lectures, 16 ore Tutorials
		System Toxicity	3	BIO/14	24 ore Lectures
2 semestre	Pharmacogenetics and Epigenetics in Toxicology		6	BIO/14	48 ore Lectures
		Totale CFU obbligatori	29		
Attività a scelta					
Students have to choose optional course for 8 credits. These will be chosen freely among all courses provided by the University of Milan if they are consistent with the educational project, after consulting the Study Programme committee. As 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.					
	Laboratory of Risk assessment		8	ND	Studio e pratica individuale
Attività conclusive					
	Other training activities *(i.e. meetings and seminars of experts in various fields inherent to the degree)*		3	NA	Studio Individuale
	Thesis		29	NA	Studio Individuale
		Totale CFU obbligatori	32		