UNIVERSITA' DEGLI STUDI DI MILANO
PROGRAMME DESCRIPTION - ACADEMIC YEAR 2018/19
MASTER DEGREE IN
SAFETY ASSESSMENT OF XENOBIOTICS AND BIOTECHNOLOGICAL PRODUCTS (Classe LM-9)
For students enrolled from 2015/16 academic year

HEADING

Degree classification - Denomination and code:	LM-9 Pharmaceutical, veterinary and medical biotechnologies
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:	1st , 2nd
Access procedures:	open, subject to entry requirements
Course code:	E52

PERSONS/ROLES

Head of Study Programme

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Tutors - Faculty

Prof. Marina Marinovich

Prof. Paolo Magni

ERASMUS Coordinator

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Degree Course website

www.farmacia.unimi.it

aSUGGESTIONS TO IMPROVE AND KIND COMPLAINS

Email: saxbi@unimi.it

bEnrolment and Admission

http://www.unimi.it/studenti/matricole/77648.htm

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CHARACTERISTICS OF DEGREE PROGRAMME

Introduction

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
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) and European Chemical Agency (ECHA) and the application of the new European regulations (for examples, REACH, Regulation (EC) No. 1223/2009 on cosmetic products, Regulation 1107/2009 on pesticides, etc.), 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, to be carried out in the next decade.
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 EUROTOX European Registered Toxicologists (ERTs).
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.

Access
To be admitted to a 2nd course/level degree course, a 1st level degree or a suitable equivalent foreign qualification is required (see below for details).

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 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 in accordance to a well-defined and properly acknowledged training standard that will be available and adopted in 2015 in all European Countries by the Committee for Standardization CEN member states (CEN TC/416).
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 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.

Professional profile and employment opportunities

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.

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

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

Teaching block Via Golgi 19

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

Teaching block Via Golgi 19

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.

Libraries

Centralized library of the University of Milan, Library of Scienze del Farmaco, via Balzaretti 9

biblio.scienzedelfarmaco@unimi.it, http://www.sba.unimi.it/Biblioteche/48.html

Tutoring

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.

Compulsory attendance

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 http://www.unimi.it/studenti/tasse/78557.htm

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 Sifa online Service.

Procedures for exam registration and admittance

Exam registration is compulsory and must be carried out through the SIFA-on-line site available at http://www.unimi.it/ .

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 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.

Internship criteria

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.

Degree programme final exam

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.
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.

Criteria for admission to degree course final exam

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.

Lecture timetable

http://www.unimi.it/corsi_istituti/corsiUrlb.jsp
Download "Lezioniunimi", LaStatale app for Android, iOS and Windows phone

EXPERIENCE OF STUDY ABROAD AS PART OF THE DEGREE PROGRAM

The University of Milan supports the international mobility of its students, offering them the opportunity to spend periods of

study and training abroad, a unique opportunity to enrich their curriculum in an international context.

Study and internships abroad

Thanks to mobility programs such as Erasmus +, Erasmus Placement, and Erasmus Mundus, the Master Course in SAXBi offers its students the opportunity to spend periods of training abroad. The Erasmus Placement Program also offers 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.

http://www.farmacia.unimi.it/CorsiDiLaurea/4114_ITA_HTML.html to page 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, namely:

- 30 credits for an academic semester:
- 20 credits for an academic quarter.

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

How to participate in Erasmus mobility programs

To gain access to mobility programs for study purposes, lasting 3-12 months, the enrolled students of the University of Milan must attend a public selection that starts usually around the month of February each year through the presentation of specific competition announcements, which contain information on available destinations, respective duration of the mobility, requirements and deadlines for submitting the online application.

The selection, aimed at evaluating the proposed study abroad program of the candidate, knowledge of a foreign language, especially when this is a preferential requirement, and the motivations behind the request, is performed by specially constituted commissions.

Each year, before the expiry of the competition announcements, the University organises information sessions for the specific study course or groups of study courses, in order to illustrate to students the opportunities and participation rules.

To finance stays abroad under the Erasmus + program, the European Union assigns to the selected students a scholarship that - while not covering the full cost of living abroad - is a useful contribution for additional costs as travel costs or greater cost of living in the country of destination.

The monthly amount of the communitarian scholarship is established annually at national level; additional contributions may be provided to students with disabilities.

In order to enable students in economic disadvantaged conditions to participate in Erasmus+ program, the University of Milan assigns further additional contributions; amount of this contributions and criteria for assigning them are established from year to year.

The University of Milan promotes the linguistic preparation of students selected for mobility programs, organising every year intensive courses in the following languages: English, French, German and Spanish.

The University in order to facilitate the organisation of the stay abroad and to guide students in choosing their destination offers a specific support service.

More information in Italian are available on www.unimi.it > Studenti > Studiare all'estero > Erasmus+

For assistance please contact:
Ufficio Accordi e relazioni internazionali
via Festa del Perdono 7 (ground floor)
Tel. 02 503 13501-12589-13495-13502
Fax 02 503 13503
E-mail: mobility.out@unimi.it
Desk opening hour: Monday-Friday 9 - 12

ADMISSION CRITERIA: 1ST YEAR OPEN, SUBJECT TO ENTRY REQUIREMENTS

Application and enrolment information and procedures

Application form

Both Italian and foreign students must submit admission applications by the deadlines indicated in the "student area" of the University web portal. Undergraduates who intend to graduate by 31st December 2018 may also apply.

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.
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 2018 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 grade;
-up to 25/100 for the curriculum (type of degree, free courses, others…)
-up to 50/100 for the interview
The minimum requirement for admission is 60/100.

If coming from another university or other degree program, admission to second year of the course will be possible on the basis of the evaluation of previous career by competent organs of the course.

N° of places reserved to non-EU students resident abroad

15

1st COURSE YEAR Core/compulsory courses/activities

Scheduling	Learning activity	Module/teaching unit	Ects	Sector
1	Development Biology and Differentiation		6	BIO/13
1	Functional, Metabolic and Epigenetic Biochemistry		6	BIO/10
1	Methods of analysis of chemicals in water, air, biological fluids, tissues, food (Total number of ects:6)	Methods of analysis of chemicals	3	(3) CHIM/01, (3) CHIM/06
		Physical-chemical characterization, identity	3	(3) CHIM/01, (3) CHIM/06
1	Organ Physiopathology and Histopathology (Total number of ects:10)	Organ Physiology and Pathology	7	(7) BIO/09, (7) MED/04
		Lab of Comparative Histopathology	3	VET/03
2	Bioremediation (Total number of ects:7)	Environmental Microbiology and Biotechnological Remediation	3	(3) BIO/13, (3) BIO/19
		Laboratory of Cell Biology	4	(4) BIO/13, (4) BIO/19
2	Biotechnology and Pharmacotoxicology (Total number of ects:10)	Biotechnology and Pharmacology	5	BIO/14
		Genotoxicology, Cancerogenicity, Reproductive and Developmental Toxicity	5	BIO/14
2	Regulatory Aspects in toxicology (Total number of ects:6)	Regulatory Aspects of Medicaments, Medical Devices and Health products	3	(3) CHIM/09, (3) IUS/14
		Legislation in European Union	3	(3) CHIM/09, (3) IUS/14
		Total number of compulsory credits/ects	51	

2nd COURSE YEAR Core/compulsory courses/activities

Scheduling	Learning activity	Module/teaching unit	Ects	Sector
1	Databases and Exposure scenarios (Total number of ects:6)	Informatics and Database	3	(3) INF/01, (3) SECS-S/01
		Statistics applied to Epidemiology	3	(3) INF/01, (3) SECS-S/01

1	Quantitative Chemical Structure and activity relationship (Total number of ects:10)	In Silico Methods in Toxicology	5	CHIM/08
		Structural Bioinformatics	5	BIO/10
1	System Toxicity and Risk Assessment (Total number of ects:7)	Risk Assessment	4	BIO/14
		System Toxicity	3	BIO/14
2	Pharmacogenetics and Epigenetics in Toxicology		6	BIO/14
		Total number of compulsory credits/ects	29	

Elective courses

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

End of course requirements

	Other training activities *(i.e. meetings and seminars of experts in various fields inherent to the degree)*		3	NA
	Thesis		29	NA
		Total number of compulsory credits/ects	32	