



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

#### **GENERALITA'**

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

#### **RIFERIMENTI**

**Presidente Collegio Didattico Interdipartimentale**

Prof.ssa Marina Marinovich

**Sito web del corso di laurea**

[www.farmacia.unimi.it](http://www.farmacia.unimi.it)

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#### **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. At the base of the phenomenon that has allowed the development of modern technology are the great discoveries of modern chemistry.

This has resulted in the need to regulate the complex world of chemicals both as regards their use and, above all, their safety. While the pharmaceutical field has developed in the last two decades a solid frame of rules and legislation aimed at limiting undesired effect of drugs, 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 scenario.

The recent implementation of regulatory frameworks for chemicals, plant protection products, biocides, pharmaceuticals, food contaminants, and cosmetics by the European Commission have resulted in a demand for trained health risk assessors across Europe. Not only are more trained professionals needed to work in regulatory affairs such as European agencies and national authorities, but also industry, research and the academic setting need such professionals.

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).

#### 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).

### **Obiettivi formativi generali e specifici**

The aim is to present provision of training program in risk assessment based on common European 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.

### **Abilità e competenze acquisite**

The aim of this master course is to provide specific knowledge in the analysis and assessment of risk, taking into account the European 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 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 proposal aims to provide 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 and national 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

### **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. To obtain the qualification (2nd level degree) it is necessary to accumulate 120 credits.

### **Area didattica**

Teaching block Via Golgi 19

### **Laboratori didattica**

Teaching block Via Golgi 19

### **Biblioteche**

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

### **Tutorato**

Tutors and coaches will help the students i) to learn the material in individual courses; ii) how to be successful in school and iii) understanding how to use the syllabus, by means of meetings with the students, regularly throughout the semesters. Coaches will directly work with students in all kinds of situations. Tutoring may even be used for the whole duration of the degree course.

### **Obbligo di frequenza**

Suggested to the course, mandatory to the labs.

### **Formulazione e presentazione piano di studi**

The student must provide the Study Plan with the indication of the optional course for a total of 8 credits, chosen freely among all the activated courses, offered by the University, provided that they are consistent with the educational project. The terms of presentation will be provided by the Faculty.

### **Caratteristiche Tirocinio**

In order to facilitate the completion of cultural and professional training of students, are also planned activities of orientation to the career, consisting of meetings and seminars of experts in various fields of industrial and environmental biotechnology.

### **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 about 60 credits.

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.

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

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.

### **Cosa offre il corso di studi**

Thanks to mobility programs such as Erasmus +, Erasmus Placement, and Erasmus Mundus, the CdS of the 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/3125\\_ITA\\_HTML.html](http://www.farmacia.unimi.it/CorsiDiLaurea/3125_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:

- 60 credits for one academic year;
- 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.

### **Modalità di partecipazione ai programmi di mobilità - mobilità Erasmus**

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](http://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](mailto:mobility.out@unimi.it)

Desk opening hour: Monday-friday 9 - 12

## **MODALITA' DI ACCESSO: 1° ANNO PROGRAMMATO**

### **Informazioni e modalità organizzative per immatricolazione**

The Master of Science in Safety Assessment of Xenobiotics and Biotechnological Products has limited access according to the Law August 2, 1999, n. 264.

Can apply to the admission test, the candidates with Italian degree (ex. DM 270/04 or equivalent ex. DM 509/99) in the areas L2 or L29.

For graduates from areas other than the above listed, the curricular prerequisites to sustain the admission test for the SAXBi Master's Degree Course are the following:

- 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 may sustain the admission test if they have the minimum requirements equivalent to those required for students with Italian qualifications. A committee of teachers appointed by the Board of Faculty will check the presence of minimum requirements.

In some cases it may be scheduled an admission test remotely via electronic devices. Details in the post [www.unimi.it](http://www.unimi.it)

The ranking for admission to the first year of the course is based on the outcome of a mandatory test in English that candidates have to take prior to registration, as provided by the academic regulations of the course. Mandatory testing is designed to verify the level of knowledge of the candidates and is based on multiple-choice questions concerning different topics such as biology, chemistry, biochemistry, toxicology, physiology and pathology and the knowledge of English language.

If coming from another university or other degree program, admission to second year of the course will be possible on the basis of the number of seats available, the positive outcome of the entrance test and evaluation of previous career by competent organs of the course.

N° posti riservati a studenti extracomunitari non soggiornanti in Italia  
15

N° posti assegnati  
45

Data, Ora e Sede prova  
15-07-2015

1° ANNO DI CORSO Attività formative obbligatorie				
Erogazione	Attività formativa	Modulo/Unità didattica	Cfu	Settore
1 semestre	Development Biology and Differentiation		6	BIO/13
1 semestre	Functional, Metabolic and Epigenetic Biochemistry		6	BIO/10
1 semestre	Methods of analysis of chemicals in water, air, biological fluids, tissues, food (tot. cfu:6)	Methods of analysis of chemicals (1 semestre)	3	CHIM/01, CHIM/06
		Physical-chemical characterization, identity (1 semestre)	3	CHIM/01, CHIM/06
1 semestre	Organ Physiopathology and Histopathology (tot. cfu:10)	Organ Physiology and Pathology (1 semestre)	7	BIO/09, MED/04
		Lab of Comparative Histopathology (1 semestre)	3	VET/03
2 semestre	Bioremediation (tot. cfu:7)	Environmental Microbiology and Biotechnological Remediation (2 semestre)	3	BIO/13, BIO/19
		Laboratory of Cell Biology (2 semestre)	4	BIO/13, BIO/19
2 semestre	Biotechnology and Pharmacotoxicology (tot. cfu:10)	Biotechnology and Pharmacology (2 semestre)	5	BIO/14
		Genotoxicology, Cancerogenicity, Reproductive and Developmental Toxicity (2 semestre)	5	BIO/14
2 semestre	Regulatory Aspects in toxicology (tot. cfu:6)	Regulatory Aspects of Medicaments, Medical Devices and Health products (2 semestre)	3	CHIM/09, IUS/14
		Legislation in European Union (2 semestre)	3	CHIM/09, IUS/14
Totale CFU obbligatori			51	
2° ANNO DI CORSO (da attivare a partire dall'a.a. 2016/17) Attività formative obbligatorie				
Erogazione	Attività formativa	Modulo/Unità didattica	Cfu	Settore
1 semestre	Databases and Exposure scenarios (tot. cfu:6)	Informatics and Data Base (1 semestre)	3	INF/01, SECS-S/01
		Statistics applied to Epidemiology (1 semestre)	3	INF/01, SECS-S/01
1 semestre	Quantitative Chemical Structure and activity relationship (tot. cfu:10)	Methods of analysis applied to water, air, biological fluids, tissues, food and In Silico Methods in Toxicology (1 semestre)	5	CHIM/08
		Structural Bioinformatics (1 semestre)	5	BIO/10
1 semestre	System Toxicity and Risk Assessment (tot. cfu:7)	Risk Assessment (1 semestre)	4	BIO/14
		System Toxicity (1 semestre)	3	BIO/14
2 semestre	Pharmacogenetics and Epigenetics in Toxicology		6	BIO/14
Totale CFU obbligatori			29	
Altre attività a scelta				
Students have to choose optional course for 8 credits.				
Attività conclusive				
	Other training activities		3	
	Thesis		29	
Totale CFU obbligatori			32	

