Master of Science in Biotechnology
Program Handbook

Academic year 2022/23

The cultural horizon
The M.Sc in Biotechnology (Class LM-8 – Industrial Biotechnology) offers a program that combines biochemistry, molecular biology, genetics, pharmacology and microbiology with fundamentals of economics and ecology. The teaching staff includes professionals from the world of industrial and clinical research, in order to link the knowledge of the fundamental elements of science and technology with the skills necessary for their application at industrial and clinical level and prepare second level graduates to a wide range of jobs in the biotechnology sector.

The course in brief
The Degree Course includes two distinct curricular courses:

The first curriculum, called **Applied Biotechnology,** provides a preparation aimed at developing a deep knowledge of the theory and fundamentals of biotechnology and developing the necessary skills to perform different roles in the laboratories of public research institutions or private laboratories engaged in research or development of biotechnological products.

The second curriculum, called **Clinical Research**, aims at training professional figures such as the Clinical Monitor (also known as CRA, Clinical Research Assistant), the Auditor or the staff assigned to regulatory activities, who perform organizational, managerial and control roles in the field of clinical trials of new drugs. The course aims to provide a set of basic knowledge that makes the new graduate uniquely and immediately recognizable and interesting in his profile for the Human Resources offices of the reference companies in the Clinical Research area

Further information can be found on the course web page: http://www.biotechuniroma2.it/

It should be noted that the lessons of the academic year 2022/2023 will be held in the classroom unless there are justified educational needs that require the use of distance learning

Access procedures
A maximum of 60 students can be admitted. Either citizens from Italy and from other EU or non-EU countries can be admitted to the selection, with a reserve of 20 places for foreign students.
To be admitted to the Master's Degree course in Biotechnology it is necessary to have a first-level degree or a three-year university degree or other qualification obtained abroad recognized as suitable. It is also necessary to certify the knowledge of the English language at a level at least equal to B2. A preliminary evaluation phase of the possession of the curricular requirements is foreseen for all applicants (see below).

The access procedures for students residing in the European Community are different from those provided for foreign students who need an entry visa. The access procedures for Italian students or students resident in the EU are described in the Call for Enrollment (http://www.biotechuniroma2.it/wp-content/uploads/2022/05/Avviso-immatricolazione-CdL-Magistrali-_-accesso-libero-SCIENZE-MM.FF_.NN_.-2022-2023.pdf).

Based on the regulations established by the Ministry of University and Research (MIUR) in accordance with the Ministry of the Interior and the Ministry of Foreign Affairs, the enrollment of non-EU candidates who are not resident in Italy involves 3 basic steps:

- The qualification assessment for the selected course
- An online pre-enrollment application through the Universitaly portal
- Obtaining an entry visa from the Italian Embassy or Consulate in their country

For admission into the M.Sc. in Biotechnology, the prospective student must have:sufficient **background** in the following topics: ***Mathematics, Chemistry and Physics; Biochemistry, Cell Biology, Molecular Biology, Genetics, Immunology, Animal and Plant Physiology, Microbiology, Virology, Basic economy and Bioethics.***
Applicants, therefore, should preferentially have a Bachelor's degree in **Biology** or **Biotechnology**. In the event the official transcript of exams does not demonstrate the passing of exams related to all the subjects listed above, the applicant must contact the coordinator to evaluate the possibility to fulfill the requirements prior to enrollment.

Admission of students in possession of other university degrees (Pharmacy, Chemistry …) is subject to an evaluation of the previous academic career by an ad hoc Commission. Such applicants are asked to provide documentation proving that they have a solid grounding in **all** subjects deemed essential

Priority will be given to the applicants who have obtained the bachelor's degree in the **last five years.**

We require:

- A **Bachelor's degree** from an accredited institution with a minimum grade point average (GPA) of 3.0 or B+ or 75 % depending on the system (95/110 for Italian students). Students with a lower GPA may submit a request of special evaluation of their application. Official Transcripts of all post-secondary colleges or universities attended are needed.
- A B2 Common European Framework (CEF) or Test of English as a Foreign Language (TOEFL IBT > 80; TOEFL PBT > 550) or an IELTS > 6.5 or B2 **certificate of English**. Alternatively, they must demonstrate that medium of administration of their previous studies was English.
- Students interested in the Clinical Research Curriculum, must also possess an at least B2 level knowledge of the Italian language and possess documented skills in statistics

Students in possession of a Bachelor's degree issued by an EU country can access the request for evaluation of qualifications according to the procedures described in the above-mentioned Call for Enrollment.

Non-EU students holding an International foreign title (BSC) interested to apply to The Master of Science in Biotechnology must preliminarily undergo a two-step assessment of their qualification:

The **preliminary assessment** of admission requirements must be requested through an online procedure at http://delphi.uniroma2.it. At this stage, the student must provide a copy of their university degree diploma, the complete transcripts of the exams, a copy of the identity document, and any other document useful for assessing the qualification (Syllabus of the course, letters of recommendation, CV, indications about previous laboratory experiences and any document proving additional experiences).

It is generally possible to submit documents for the evaluation of qualifications in the period between the beginning of February and mid-June. The exact dates are however indicated on the course website

Students who will pass this preliminary step will be admitted to an **online test** aimed at verifying the actual skills in the subjects defined as fundamental for admission. The test is based on multiple choice questions on: Biochemistry, Genetics, Cell Biology, Molecular Biology, Microbiology, Immunology, and Human and Plant Physiology.

Students who participate in the test answering correctly less than 40% of the questions will not be admitted to the course in any case (regardless of the reserve of 20 places for foreign students). In the event that the test highlights training deficiencies in specific subjects, the student admitted to the course will be required to agree on a study path for the acquisition of the missing skills to be agreed with the course teachers. Overcoming these shortcomings is mandatory for the attendance of the course.

Students admitted to the course will receive, within a few days after the test, a letter of acceptance necessary to complete the subsequent procedures necessary to make admission to the course effective.

Dates for finalizing enrollment in the master's degree course:
First semester: from 10 June 2022 to 30 December 2022
Second semester: from 1 February 2023 to 31 March 2023

Possibility of part-time enrollment
It is possible to apply for part-time enrollment, paying university fees at a reduced rate with longer learning path times, in order to avoid to go off course. The option is not open to out-of-course students.
The part-time regulation is available at http://delphi.uniroma2.it using the link "enrollment as a part-time student" together with the tables and procedures required for this type of enrollment.

Transfers from other universities
The transfer from other universities of students with the appropriate requirements can be accepted based on logistical possibilities. It will be possible to request the recognition of any credits earned in the previous career. Students must submit a preliminary application within the deadlines indicated on the call for enrollment.

PROGRAM GOALS
The Master of Science in Biotechnology aims to train graduates who have adequate expertise in applying the scientific method to biological systems, with particular reference to the use of tools and skills in different sectors of biotechnological disciplines to solve problems, produce goods and offer services. Through this program, students will be able to develop a deep knowledge of the theory and fundamentals of biotechnology and develop biotechnology laboratory skills, with a comprehension of the real-world biotech business and clinical research. The course is provided entirely in English, thus allowing students to achieve greater competitiveness on the national and international labor market.

Expected learning outcomes, expressed through the Dublin descriptors

Applying knowledge and understanding
Graduates in Biotechnology must:
- possess in-depth knowledge of biochemistry, microbiology, molecular biology, plant physiology, immunology, pharmacology and of the industrial applications of this knowledge and its economic impact. Graduates with a specialization in clinical research must also have a thorough knowledge of all the technical and regulatory aspects related to the development of clinical trials.
- have a thorough understanding of the current applications of biotechnology and possible developments in the sector in the near future.
- knows how to use the main methodologies and instruments that characterize biotechnologies
- develop the ability to apply knowledge related to biological systems to solve problems and generate new applications

These skills are developed during the courses and through the development of the experimental thesis and are verified during the exams and graduation exam.

Making judgements
Graduates must: be able to independently perform observations and experiments in the biotechnology fieldr; Develop the ability of critical reasoning and evaluation of data to rationalize them in an interpretative model.
L'acquisizione di capacità autonome di giudizio è sviluppata tramite il coinvolgimento dello studente in esercitazioni e seminari organizzati che possono prevedere presentazioni individuali degli studenti stessi, nonché nella preparazione di elaborati eventualmente redatti sotto la supervisione di un 'Tutor'. La verifica dell'effettiva acquisizione dell'autonomia di giudizio è affidata, oltre che alla valutazione delle prove d'esame associate alle succitate attività formative, alla valutazione della relazione redatta dallo studente sulla propria attività di tirocinio per la prova finale.

Communication skills
A key objective of this degree course is to provide graduates with the communication skills essential to operate in the world of work. In this regard, we believe that the choice to provide teaching in English is fundamental to developing a better knowledge of the reference language in the scientific field.
In addition, the graduate must acquire:
- the ability to work in an interdisciplinary team;
- - the ability to communicate in a clear and unambiguous way the knowledge/ results of one's research, both in written and oral form, adapting the level of communication to the interlocutors to whom it is addressed;
These skills will be acquired during the courses, through specific activities such as the elaboration of presentations starting from scientific articles, during the preparation of the thesis and through participation in seminars.

Learning skills
Master's degree graduates must:
- acquire skills that favor the development and continuous deepening of knowledge;
- knowing how to learn independently by drawing on advanced texts,

consultation of databases and other information online;
These skills are acquired progressively during the teachings, in the exercises and in the internships, also through the study of specific research problems, and during the thesis work.
They are checked in progress during the exams.

Employment areas envisaged for graduates
Graduates will acquire the competence needed to work in the field of:

- Research in gene manipulation and production of proteins
- Creation and monitoring of genetically modified organisms
- Pharmacology
- Food industry and food control
- Industrial and environmental quality control
- Molecular diagnostics and Clinical Research
- Teaching (in Italy, class 60/A – high schools)

They can also get access to Ph.D. programs and to other secondary specialization schools.

It is worth underlying that the Biotechnology sector in Italy (as in the rest of the world) is constantly expanding, with the continuous growth of business initiatives, as indicated by the data provided by Assobiotec (https://assobiotec.federchimica.it/attiv/dati-e- analysis/biotechnology).

Didactic structure
The degree course lasts for two academic years. To complete the program, a total of 120 credits (CFU) must be acquired. 1 CFU is conventionally set as corresponding to 8 hours of lessons plus 17 hours of personal study, or to 12 hours of laboratory experience plus 13 hours of personal study. **Since the ambition of our courses is to provide cutting-edge information, not yet codified in conventional textbooks, attendance at courses is strongly recommended and is a central element for having excellent results in studies.**

Of the 120 CFU, 77 credits are from Core Courses and 9 credits are from Elective Courses. The final 34 CFU must be acquired by the students performing original research work (usually in a 6-8 months internship project), writing a 60-80 pages dissertation on its results and defending the dissertation. The internship is mandatory. The internship is aimed at allowing graduates to acquire additional skills necessary for their proper inclusion in research or production activities. In fact, the student will participate to a research project, learning how to elaborate a project, defining its aims, techniques and feasibility, and reshaping it in relation to the results. The results of this study must be reported in an original paper (thesis), prepared under the guidance of a supervisor, which will then be illustrated and discussed in the presence of a graduation commission.
The internship can be carried out both in the university and in external research institutes (with which an agreement must exist or be stipulated). In this second case, the student will be followed by an external supervisor (or researcher not included among those who teach in the biological area courses of the University of Rome Tor Vergata). The thesis work and the drafting of the report will also be followed by an internal supervisor to whom the student must refer with regular updates. A teacher of the CdS crtically oversees the work and the written paper (Opponent). The discussion of the thesis takes place in a public session in front of a commission of teachers who express the overall evaluation

CORE COURSES (with the number of CFU and the relative scientific discipline (SSD) according to Italian regulations). Some courses are administered in two modules.

The Program offers two curricola, sharing the following core courses

Core Courses	CFU	SSD
Industrial Biochemistry and Bioinformaticsc(two modules)	11	BIO/10 - BIO/11
Applied Immunology	6	MED/04
Nanobiotechnology	6	BIO/13
Pharmaceutical applications of plant metabolites	6	BIO/04
Pharmacology and Pharmaceutical Chemistry (two modules)	12	BIO/14 - CHIM/08

Students can then choose between

A - Curriculum Applied Biotechnology

Plant Biomass and Phytotechnologies	6	BIO/01
Applied Ecology	6	BIO/07
Applied Economics	6	SECS-P/06
Microbial Technology	6	BIO/19
Gene expression and regulation	6	BIO/18
Biosensor Technology	6	CHIM/01

B - Curriculum Clinical Research

Applied Physiopathology	6	MED/04
Clinical Data Quality Management (two modules)	6	MED/09
Clinical Research Development and Management (two modules)	6	MED/01 + SECS-P/10
Clinical Research Methodology (two modules)	6	SECS-S/02
Drug Design and Development	6	CHIM/09
Regulatory Activities	6	IUS/09

ELECTIVE COURSES
Students must attend Elective Courses to totalize 9 (or more) CFU. Elective activities are intended as an opportunity **to deepen, complete and personalize the training path, in harmony with the training objectives of the course**

In accordance, the following principles must orient the choice of elective courses in the M.Sc. in Biotechnology:

1) Students are preliminarly invited to attend the Elective courses included in the Educational program of this Master of Science (see below). These courses have been specifically designed to complement the training goals of this M. Sc.

2) As a complement students may choose Elective Courses offered by the related course in Pharmacy;

3) in compliance with the principle that this course is provided in English, attendance of elective courses or activities in Italian must be discussed with the coordinator, justified by clear educational reasons and, in any case, kept to a minimum (no more than 2 CFU);

4) Students willing to attend a curricular course (i.e. compulsory exams in other courses of study, including Pharmacy) in place of Elective courses, **MUST preventively discuss with the coordinator** of this possibility, in order to evaluate its coherence with the training goals and/or possible overlaps with our courses .

For the year 2022-23 the following Elective Courses are proposed:

Course	CFU	SSD
○ Fundamental of production for sterile products: biological and small molecules	3	BIO/14
○ Plant micropropagation	4	BIO/01
○ Regenerative medicine for central nervous system diseases: approaches and future directions	2	BIO/10
○ Experimental and bioinformatics tools to study protein protein interactions	3	BIO/18
○ Protein-protein Interactions:Phage-display methodology	3	BIO/11
○ Experimental approaches to study neoplastic transformation	3	BIO/18
○ Nutrigenomics	2	BIO/10
○ Medical Device Regulations and Development	2	CHIM/09
○ Pharmacovigilance	2	BIO/14
○ Digital Health and Therapeutics	1	MED/46

EXAMS
Exams may be in the form of a written or spoken test, or both. Details on the mode of exam are provided by each teacher at the beginning of the course.

Marks are based on the following :

0-17 /30	FAILED
18-21 /30	PASSED
22-24 /30	GOOD
25-27 /30	VERY GOOD
28-29 /30	EXCELLENT
30 or 30 with honors	OUTSTANDING

CRITERIA TO CALCULATE THE FINAL GRADUATION MARK

The final mark may vary from 66/110 (pass) to 110/110 *cum laude* (outstanding).

It will be assigned adding the following:

1. Starting vote: average of marks from exams, expressed on 110 (e.g. 27/30 = 99/110)

2. points awarded to the final report and thesis defense by the **Commission** (7 members + President) **0-8 points**

3. bonus (optional):
a. number of years to obtain the degree: graduation in the
- 1st session, July (end of the second year) **3 points**
- 2nd session, October (end of the second year) **1 point**
- any other later session **0 points**

b. Erasmus or other stage in a foreign country (**max 3 points**) calculated according to the following criteria:

b1. Passing exams abroad **1-3 points**

6-11 CFU:	1 point
12-17 CFU:	2 points
> 18 CFU:	3 points

b2. Laboratory training abroad **3 points**

c. For **each exam** passed **with honors**, excluding elective courses: **0.2 points**

The notation "with honors" (cum laude) **may** be given **unanimously** by the Commission to students who have achieved a final score of at least 112/110.

COURSES SCHEDULE 2022-2023

FIRST SEMESTER: October 3, 2022 – December 22, 2022.
SECOND SEMESTER: March 6, 2023 – May 26, 2023.

First semester exam session: January 16, 2023 – March 3, 2022
Second semester exam session: June 12, 2023 – September 29, 2022

The detailed *Lessons Schedule* and *Exams Schedule* can be found at http://www.biotechuniroma2.it/schedule/.

Courses will be organized as follows (courses common to the two curriculum are in red, [A] Applied Biotechnology; [B] Clinical research):

FIRST YEAR

	CFU	SSD
FIRST SEMESTER		
A. Plant Biomass and Phytotechnologies	6	BIO/01
A. Gene expression and regulation	6	BIO/18
B. Applied Physiopathology	6	MED/04
B. Clinical Research Methodology (2 modules)	4+2	SECS-S/02
Pharmaceutical Chemistry (module of Pharmacology and Pharmaceutical Chemistry)	6	CHIM/08
Applied Immunology	6	MED/04
Industrial Biochemistry (module of Industrial Biochemistry and Bioinformatics)	8	BIO/10
SECOND SEMESTER		
A. Biosensor Technology	6	CHIM/01
A. Applied Ecology	6	BIO/07
A. Microbial Technology	6	BIO/19
B. Clinical research development and management (2 modules)	3+3	MED/01 + SECS-P/10
B. Drug design and development	6	CHIM/09
B. Clinical Data Quality management (2 modules)	3+3	MED/09
Applied Immunology	6	MED/04
Pharmacology (module of Pharmacology and Pharmaceutical Chemistry)	6	BIO/14
Bioinformatics for Biotechnology (module of Industrial Biochemistry and Bioinformatics)	3	BIO/11
Pharmaceutical applications of plant metabolites	6	BIO/04
TOTAL CFU, 1st Year	**65**	

SECOND YEAR

	CFU	SSD
FIRST SEMESTER		
A. Applied Economics	6	SECS-P/06
B. Regulatory activities	6	IUS/09
Nanobiotechnology	6	BIO/13
Elective courses	9	
Internship and Dissertation	34	
TOTAL CFU, 2nd Year	**55**	
TOTAL CFU	**120**	

TUITION FEES AND SCHOLARSHIPS

Tuition fees at the University of Rome Tor Vergata for the AY 2020/2021 will be based on the student's family income and no extra-fee will be charged for courses taught in English. Non-EU students unable to submit a regular ISEE, will be asked to pay a fixed annual tuition fee. Additional Information is available at the site http://en.uniroma2.it/admissions/tuition-fees/

Fees do not cover the costs of living and study materials.

The Fee for each Academic Year must be paid in three installments. Late enrollment is subjected to penalty fees.

Foreign students and Italian students not resident in Rome may apply for a LAZIODISCO scholarship. Information can be found at
http://www.laziodisco.it/

HOUSING

Students can apply for a room in the University Residence **Campus X**.
The University of Rome Tor Vergata has a University Residence inside the Campus, where Italian and International students can live. The residence provides flats with single rooms where students share a kitchen and toilet. Campus X is a residential structure to be enjoyed, with green areas, study halls, sports facilities, minimarket, canteen, gym and spa.
For further information you can visit:
http://internationalstudents.uniroma2.it/ - Section Services
or
http://www.campusx.it/cxroma/international/

FURTHER BENEFITS

The University of Tor Vergata offers to students the possibility to benefit from a number of discounts in shops, restaurants, gyms and others. Offers can be found at
http://agevola.uniroma2.it/

DIRECTIONS

The Department of Biology is located in Via della Ricerca Scientifica 1 (Roma - 00133), outside the ring road "GRA - Grande Raccordo Anulare", in the Building of the Facoltà di Scienze MM.FF.NN (now called MacroArea di Scienze).

By public transportation
Metro + Bus: take the subway line A and get off at the end of the line ("Anagnina" station), take the bus 500 or 046 and get off at the stop "Facoltà di Scienze".

By car
Take the "GRA - Grande Raccordo Anulare", exit to "La Romanina" (exit 19-20), follow the signs to "Tor Vergata - Facoltà di Science MM.FF.NN".

DESCRIPTION OF CORE COURSES

Applied Ecology
Prof. Eleonora Ciccotti
Aims: The course aims at giving the cultural background and methodology to understand the environmental effects at various levels resulting from the application of technology and management processes, and deal with them with a view to the principles of ecology and sustainability.
Program: 1. The reference framework: some definitions, from ecology to environmental science, key issues. The natural capital: resources and processes, ecosystem services. Atmosphere, hydrosphere, lithosphere and biosphere: patterns of exploitation, environmental consequences of production and exploitation patterns, approaches to sustainability. Role of biotechnology in solving environmental issues.
2. Atmosphere: Climate: Climate change, consequences of climate change. Air pollution.
3. Hydrosphere: water as a renewable resource. Water usage, water demand and water quality. Water pollution. Oceans and their status.
4. Lithosphere: patterns of exploitation of mineral resources, non-renewable resources. Environmental effects of the extraction of mineral resources. Soil as a renewable resource, soil use and land use.
5. Agriculture: global trends, relationship with human demography . Types of agriculture. The Green revolution. Sustainable agriculture vs industrial agriculture. GMOs and agriculture.
6. Living resources: living resources and their exploitation. Living aquatic resources: trends of exploitation, over-exploitation. Biodiversity and conservation: biodiversity loss as an environmental issue of key concern.
7. Ethical and social issues associated with applications of biotechnology for alleviating the environmental concerns. Risk assessments and regulatory frameworks in environmental management related issues and biotechnology applications.

Applied Economics
Prof. Alessio D'Amato
The course is ideally divided in three parts. The first part aims at introducing students to the broad concept of Sustainable Development, underlying its foundations and showing examples of interlinkages and trade-offs across different Agenda 2030 objectives. This part will also highlight measurement methodologies and issues related to Sustainability.
The second part will be devoted to the microeconomic foundations of policy design and evaluation, focusing both on efficiency and on fairness issues. Topics covered in this part will include:
- drivers of supply and demand
- measuring welfare and equity
- from market and government failures to policy design and implementation
- how does economic policy work in real life? The cases of energy and environmental policies

Finally, the third part will focus on the investigation of innovation and innovation policies, with specific attention to eco-innovation. This part will include:
- some basics on the economics of innovation
- drivers of eco-innovation and its role in sustainable development
- case studies on eco-innovation: empirical analysis on drivers and consequences

Applied Immunology
Prof Carla Montesano
Aims: The aim of the course is to provide the scientific and technological knowledge in the field of immunological diagnostics, vaccines and immunotherapy.
Program: Cellular and molecular components of the innate and adaptive immune response. Immunopathology. Immune response in infectious diseases. Poverty related diseases and neglected infectious diseases. Monoclonal antibodies: production and use in research, diagnosis and therapy. Isolation of peripheral blood mononuclear cells and purification of cell subsets. Phenotypic and functional characterization of T and B lymphocytes. Development strategies of diagnostic tools for infectious diseases.
Vaccines: recombinant vaccines, DNA vaccines, live attenuated vaccines. Adjuvancy: microbial and natural adjuvants. Vaccine delivery. Reverse vaccinology. Identification of T and B epitopes: from phage libraries to bioinformatic analysis. Immunotherapeutic strategies in: chronic inflammation diseases, autoimmunity, transplant rejection and cancer

Applied Physiopathology
Prof. Camilla Palumbo/ Prof Michelangelo Campanella
Aims: Purpose of the course is to provide students with tools needed to define the different pathologic conditions in relation to the underlying causes and main pathogenic mechanisms, operating at the cellular, tissue and systemic levels. The knowledge acquired during the course is a prerequisite for a rational approach to biotechnology applications in clinical settings and for the critical evaluation of clinically relevant experimental data.

Program: Cellular adaptations and responses to stress. Cell death. Overview of repair responses after injury and inflammation. Regeneration and fibrosis. Hemostasis disorders. Hemodynamic disorders. Thrombosis, embolism. Infarction. Shock. Hypertension, atherosclerosis. Heart pathophysiology. Heart failure. Cardiac hypertrophy. Ischemic heart disease. Angina pectoris. Myocardial infarction. Red blood cell disorders. Anemia. Classification of anemia. Decreased red blood cell production. Hemolytic anemias. Blood loss anemia. Liver pathophysiology. Hepatic failure. Cirrhosis. Portal hypertension. Ascites. Viral hepatitis. Bilirubin metabolism. Causes and classification of jaundice. Respiratory pathophysiology. Respiratory failure: causes and classification. Respiratory distress syndromes. Chronic obstructive pulmonary diseases. Interstitial lung disease.

Biosensor Technology
Prof Francesco Ricci
Aims: Knowledege of equilibria in solution. Ability to select and use biosensors
Program: Acid-base equilibria, Precipitation equilibria, complex and redox equilibria
Ion selective electrodes. Amperometric and potentiometric chemical sensors. Biosensors, immunosensors, DNA sensors. Electrochemical, optical, calorimetric, piezoelectric biosensors.
Applications in food, clinical and environmental areas with focus on industry

Clinical data quality management
Prof Annamaria Paparella/Prof Davide Integlia
Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible. (Introduction to ICH – International Conference on Harmonization – Guideline for Good Clinical Practice – GCP – June 1996).
The Course will explain the main features of an adequate system of Quality Assurance (All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with Good Clinical Practice (GCP) and the applicable regulatory requirement(s). - International Conference on Harmonization – Guideline for Good Clinical Practice – GCP – Glossary – June 1996) and the related activities of Quality Control - Auditing and Clinical Monitoring – (The operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial-related activities have been fulfilled. – International Conference on Harmonization – Guideline for Good Clinical Practice – GCP – Glossary – June 1996).

Clinical Research Methodology
Prof Stefano Vella/Prof Betty Polikar
The general aim of this course is to explain the basic principles of clinical research/clinical development and the methodological aspects needed to assure the validity of the data generated.
Upon an overview on research development from compound to drug, the first part of the course will guide students into clinical studies' classification(interventional/non interventional), clinical phases requested by regulatory authorities and in-depth examination of the contents and structure of a Study Protocol and related topics (common designs, study population, objectives, endpoints, randomization, blinding).
Further focus will be dedicated to particular study designs (adaptive design, basket studies, target therapy studies), relationship between clinical outcomes and patient-reported outcomes (PROs), meaning of efficacy and effectiveness, clinical studies on medical devices and neutraceuticals.
Biostatistics general principles will be also introduced in order to explain how to finalize an effective planning, collection, analysis and interpretation of clinical data.
The second part of the course will be structured as monothematic lessons, which will cover specific areas of clinical research, such as infectivology (the history of HIV treatment), oncology (multiple identities and multiple approaches), cardiovascular and rare diseases, providing real examples on design and execution of clinical trials.

Clinical research development and management
Prof Giovanabattista Leproux/Prof. Giovanni Assogna
Aims: The course introduce the student to the processes in new drug development and concerning regulations. The goal is a) to provide deep knowledge and understanding of Clinical research methodology and of the main regulations at national and international level and b) to provide the basis to operate in basic research and in structures operating in research and development of new drugs.
Program: Clinical development . Focus on the transition from pre-clinical to clinical development. Clinical protocol organization. Pharmacovigilance and relative Italian and EU rules. Ethics in Clinical Research. Pharma Company organization and main roles and activities within a Medical Department . Work organization: from hierarchical to lean organization

Drug Design and Development
Prof Tatiana Guzzo
Aims: To gain knowledge on the different phases of the drug discovery and development process. To understand deeply the pharmacodynamic and pharmacokinetic principles underlying the drug design and development process. To learn the key approaches and strategies of contemporary Drug Discovery
Program: Drug Discovery Phases, Molecular Drug Targets -Enzymes -Receptors -Ion Channels -Transporters , Pharmacodynamics and mechanism of Drug-Target Interaction, Pharmacokinetics, Design of New Chemicals Entities with potential biological activity, Rational Drug Design, Structure Activity Releationship, Pharmacophore, Bioisosterism

Gene expression and regulation
Prof Daniela Barilà
Aims: Advanced knowledge on molecular mechanisms that ensure gene expression regulation and are involved in cellular homeostasis and cancer. Applications of technologies to study gene expression, using the identification of novel therapeutic targets in cancer as a model system.
The students will learn to develop and discuss a project related to the evaluation of gene expression regulation.
Program: References and insights on molecular mechanism that ensure the control of gene expression: epigenetic control, transcriptional and post-transcriptional control. Role of microRNAs. Translational and post-translational control.
Post-translational modifications and signal transduction: positive and negative feedback loop, redundancy and robustness.
Examples of technical strategies employed to study gene expression.
Examples of gene expression regulation.
Cancer as an example of gene expression deregulation: tumorigenesis, oncogenes and tumor suppressors, mutations. Analysis of signal transduction pathways to define novel therapeutic targets in cancer.

Microbial Technology
Prof Serena Ammendola
Aims: The course will provide insights on the main techniques currently used for the genetic manipulation of microbial strains, both for basic research and for the development of useful strains for biotechnology. Applications based on the use of microbial strains in the various fields of biotechnology will be presented.
Program : Searching for useful microbes: bioprospecting and in silico genome prospecting. Customizing a microbe: E. coli, Streptomyces, Bacillus; main features of plasmids used in biotechnology; classical strain improvement (random mutagenesis); site-directed mutagenesis and directed evolution. Genome editing of microbes: "Recombineering" (the lambda-red system; epitope tagging of chromosomal genes; plasmid – based gene knockout methods); Mobile Group II introns as gene editing tools and the TargeTron technology; the CRISPR-Cas immune system in bacteria; the CRISPR-Cas toolkit for KO mutants and for gene expression modulation; systems metabolic engineering.
Microbes in Biotechnology: Industrial Biotechnology (Production of Amino acids, Organic acids, Bioplastics, Vitamins); Food Biotechnology (Production of fermented foods; Starter cultures; Health promoting components; Probiotics; Bacteriocins; Elimination of allergens); Medical Biotechnology (Secondary metabolites production; Antibiotics; Antitumor agents; Live attenuated bacteria; Vaccines; Delivery vectors for therapeutics); Agricultural Biotechnology (Agrobacterium and genetic engineering of plants; Biotechnological use of symbiotic microbes; Biofertilizers; Biopesticides; Frost preventing); Environmental Biotechnology (Bioremediation of heavy metals and petroleum hydrocarbons contaminated environments); Arid soils Biotechnology (Biomineralization: improvement of arid soils and deserts); Marine Biotechnology (Discovery of bioactive compounds from deep oceans microbes).

Nanobiotechnology
Prof Lina Ghibelli
Aims: to provide the scientific and technological bases of the application of nanotechnology to the biomedical field.*Program:* Nanotechnology: terminology; materials science and engineering; properties of nanostrutured materials; size, shape, zeta potential, surface, aggregation, colloidal stability, functionalization, solubilty, ion release.
- Pharmacological exploitation of the intrinsic features of nanoparticles
- Interactions between nanoparticles and living matter: spontaneous functionalization and protein corona; biokinetics: routes of entry and excretion.
- Paradigms of nanotoxicology; nanoparticles relevant for human exposure; nanoparticulate pollution and occupational exposure; safety issues.
- Principles of nanomedicine: paradigms, expectations and perspectives; polyfunctional platforms; targeting; biocompatibility; smart materials.
- Drug delivery: capsules, micelles, polymers; differential release.
- Tissue engineering: generalities; scaffold; 3D cultures; stem cells;
- Nanobioinformatics: bioinformatics applied to biological function of nanoparticles and nanotoxicology.

Pharmaceutical applications of plant metabolites
Prof. Lorenzo Camoni
Aims: Knowledge of biochemistry of plant bioactive metabolites and of their properties and applications
Program:
Distribution and characterization of bioactive natural products in plants.
medicinal and officinal herbs: definition, classification and regulation
Role of secondary metabolites in plant defense against pathogens and herbivores.
Biosynthesis of phenolic compounds.
Biosynthesis of terpenes , from mono to tetraterpenes.
Nitrogen-containing compounds. Alkaloids, cyanogenic glucosides, glucosinolates.
Essential oils and herbal tincture.
Plants containing metabolites of each group will be described as well as their applications in pharmacology and nutrition.

Pharmacology and Pharmaceutical Chemistry
Pharmacology
Prof Robert Nisticò
Aims: The objectives of the course are to identify major drug classes, discriminate among major drug classes by their mechanism of action at the molecular, cellular and organism levels and describe the basis for drug action on specific cells, tissues, organs as a basis for decisions regarding application in human therapeutics
Program: Pharmacokinetics: the dynamic of drug absorption, distribution, metabolism and elimination. Routes of administration. Pharmacodynamics: Definition of drug. Drug-receptor interaction (pD2). Agonists, antagonists (pA2), inverse agonists. Potency and efficacy. Therapeutic index. Families of receptors and signaling pathways. Ion channels, G-protein-coupled receptor, receptor protein kinases, intracellular receptors. Transcription factors. Agonist and antagonist ligands. Regulation of receptors.
Drugs acting on the Peripheral Autonomic System. Drugs acting on the Central nervous system. Drugs affecting tissue responses. Drugs affecting gastrointestinal function. Drugs affecting respiratory function. Drugs affecting cardiovascular function. Drugs affecting renal function. Drugs affecting the endocrine system. Principles of chemotherapy.
Pharmaceutical Chemistry
Prof Orazio Nicolotti
Aims: This is a foundation course whose aims are to provide an introduction to the principles of Medicinal chemistry, including an understanding of drug structure-activity relationships, prediction of the physico-chemical properties of a drug, basic knowledge of the major pathways of drug metabolism, and factors that can contribute to drug-drug interactions. Students will be also shown how to predict the structure-activity relationships, basic synthesis routes for selected structures, metabolism and pharmacological activity/potency/safety of drug classes and individual members of classes based on the contribution of their functional groups to their structures. In particular H1 and H2 antagonists, cholinergic and adrenergic drugs as well as antineoplastic agents.
Program:
1- Target Class
2- Molecular Interaction and Drug Potency
3- Drug Metabolism
4- Physical Properties
5- Finding a Lead
6- Drug Design
7- Safety Assessment
8- NOSynthase Inhibitor
9- Cholinergics
10- Adrenergics
11- Antihistamines
12- Oncological chemotherapy

Plant Biomass and Phytotechnologies
Prof Cinzia Forni
Aims: The aims of the course are to foster a fast paced immersion into some aspects of plant biotechnologies. Students will merge their interdisciplinary knowledge with the learning about phytotechnologies and on how to recognize, understand and find solutions to some of the global problems related to feed, fuel and ecosystem management in an environmentally friendly and sustainable manner.
Program: Plant biomass production and methods of yield evaluation. Biomass utilization for energy production. Woody biomass. First and second generation biofuels. Biomass, carbon sequestration and climate change.
Tools of plant biotechnology to enhance sustainable and profitable agricultural production systems.

Plant cell and tissue cultures. Micropropagation. Somatic embryos. Somaclonal variation. Control mechanisms of plant cell fate. Chromatin remodelling in plant development.
Plant cells cultures as a tool for the production of useful compounds. From lab bench to industrial scale. Bioreactors. Protoplasts and somatic hybrids.
Germplasm preservation. Methods of ex situ germplasm preservation.
Production of biopharmaceuticals, bioplastics. Molecular pharming and transgenic plants. Phytotechnologies and environment.

Regulatory activities:
Prof: Salvatore Caruso
Aims: to provide students with a general knowledge on "regulatory" matters, which is indispensable for orienting oneself in the complex authorization procedures concerning clinical trials of medicinal products for human use.
Program: The main rules in force and the main national and international reference documents will be illustrated, with particular attention to the ethical-scientific issues at the origin of the aforementioned rules and documents. At the end of the course the student will have acquired the indispensable tools to orientate himself in the context of different authorization processes and will be able to recognize and evaluate various problems (scientific and ethical) that the subject involves.

Industrial Biochemistry and Bioinformatics
Industrial Biochemistry
Prof Andrea Battistoni
Aims: The course aims at highlighting some of the main applications of biochemistry in the industrial, medical and food preparation fields.
Program: Fermentations and their applications. Biotechnologies and biofuel production. Analysis of the different applications of protein in the pharmaceutical field, in food industry, in analytical chemistry, in agriculture and animal husbandry and in other applicative areas. Procedures for the production and isolation of proteins of biotechnological interest. Discussion of issues concerning the relationships between protein structure and function. Modification of enzymes and proteins aimed to their improved use in the industrial and pharmaceutical fields. Immobilized enzymes. Biosensors.
Bioinformatics for Biotechnology
Prof Federico Iacovelli
Aims: advanced knowledge in bioinformatics: basic notions, databases (nucleotide and protein sequences, structures, functional motifs, scientific literature), bioinformatic algorithms (search for similar sequences with exaustive and euristic methods), protein structure prediction, molecular docking, molecular dynamics, miRNA target prediction.
Program: Databases of nucleic acids, proteins, biomedical literature. Proficient search methods into biological databases. Exhaustive and euristic methods for sequence alignment. Substitution matrices. Multiple sequence alignments. Functional motifs. Classification and comparison of protein structures. Inference of protein secondary and tertiary structure. Homology modelling, threading, ab initio methods. Computational methods for the inference of protein interactions. Molecular docking. Molecular dynamics. miRNA target prediction algorithms.