

# UNIVERSITA' DEGLI STUDI DI ROMA TOR VERGATA

Dipartimento di Biologia

# **Master of Science in Biotechnology**

Program Handbook 2021-2022

10 - October 2021

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#### PROGRAM CONTACT INFORMATION

Coordinator of the Degree: Prof. Andrea Battistoni email <u>andrea.battistoni@uniroma2.it</u>
Vice-coordinator of the Degree: Prof. Maurizio Fraziano email <u>fraziano@uniroma2.it</u>

#### **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.

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
- Clinical Research
- Teaching (in Italy, A-50 Natural, chemical and biological sciences high schools)

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

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

#### **DEGREE REQUIREMENTS**

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 lectures is strongly recommended and is a central element for having an excellent success 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. 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 have to learn 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 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 pathways, sharing the following core courses

Core Courses	CFU	SSD
Industrial Biochemistry and Bioinformatics (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

The description of core courses can be found at page 11.

#### **ELECTIVE COURSES**

Students must attend Elective Courses to totalize 9 or more CFU, choosing among those listed below. As Elective Courses students can also choose to attend **any core course** offered by the MacroArea of Science, University of Tor Vergata (subject to previous approval of the Coordinator of the degree courses in Biotechnology).

For the year 2020-21 the following Elective Courses are proposed:

Course	CFU
Plant micropropagation	4
Regenerative medicine for central nervous system diseases: approaches and future directions	2
Experimental and bioinformatics tools to study protein protein interactions	3
Food Chemistry (taken from Pharmacy)	5
Protein-protein Interactions: Phage-display methodology	3
Experimental approaches to study neoplastic transformation	3
Nutrigenomics	2
Medical Device Regulations and Development	2
Pharmacovigilance	2
CRO Management	1
Digital Health and Therapeutics	1

The description of elective courses can be found on the webpage <a href="http://www.biotechuniroma2.it/courses/">http://www.biotechuniroma2.it/courses/</a>.

#### **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

## **COURSES SCHEDULE 2020-2021**

**FIRST SEMESTER** October 4, 2021 – December 23, 2021. **SECOND SEMESTER** March 7, 2022 – May 27, 2022.

First Exam session: January 10, 2022– March 4, 2022 Second Exam session: June 6, 2022 – September 23, 2022 The detailed *Lessons Schedule* and *Exams Schedule* are available at <a href="http://www.biotechuniroma2.it/schedule/">http://www.biotechuniroma2.it/schedule/</a>

Courses will be organized as follows (courses common to the two curriculum are in red):

#### FIRST VFAR

FIRST YEAR			
		CFU	SSD
FIRST SEMESTER			
A. Plant Biomass and Phytotechnologies		6	BIO/01
A. Applied Ecology		6	BIO/07
B. Applied Physiopathology		6	MED/04
B. Clinical Research Methodology (2 modules)		4+2	SECS-S/02
Pharmacology and Pharmaceutical Chemistry (2 modules	5)	6+6	BIO/14, CHIM/08
Industrial Biochemistry and Bioinformatics (2 modules)		8+3	BIO/10, BIO/11
SECOND SEMESTER			
A. Biosensor Technology		6	CHIM/01
A. Gene expression and regulation		6	BIO/18
A. Microbial Technology		6	BIO/19
B. Clinical research development and management (2 mg	odules)	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
Pharmaceutical applications of plant metabolites		6	BIO/04
1	TOTAL CFU, 1st Year	65	
SECOND YEAR			
		CFU	SSD
FIRST SEMESTER (beginning in the first week of October	)		
A. Applied Economics		6	SECS-P/06
B. Regulatory activities		6	IUS/09
Nanobiotechnology		6	BIO/13
Elective courses		9	
Internship and Dissertation		34	
Т	OTAL CFU, 2nd Year	55	
	TOTAL CFU	120	

#### 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

1<sup>st</sup> session, July (end of the second year)
 2<sup>nd</sup> session, October (end of the second year)
 any other later session
 points
 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.

#### **ADMISSION REQUIREMENTS**

A maximum of 65 students will be admitted.

Citizens from Italy, other EU countries and non-EU countries are equally admitted to the selection. All students must request preliminary assessment of their previous studies (see below).

For admission into the M.Sc. in Biotechnology, the prospective student must have:

- Sufficient background in the following:
- Mathematics, Chemistry and Physics; Biochemistry, Cell Biology, Molecular Biology, Genetics, Animal and Plant Physiology, Immunology, Microbiology, Statistics, Basic economy and Bioethics
- Therefore, they should have a Bachelor's degree in **Biology** or **Biotechnology**. Admission of students possessing other university first level degrees is possible upon preliminary assessment of their previous academic career by an *ad hoc* Committee. Preference will be given to students having received their degree in the last five years.
- 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 have knowledge of the **Italian language** at a B2 level, in order to make possible their internship in Clinical research Organizations outside the University.

#### **ADMISSION PROCEDURE**

*Italian students*: Preliminary assessment of requisites must be requested via the online procedure at <a href="http://delphi.uniroma2.it">http://delphi.uniroma2.it</a> > Richiesta verifica requisiti curriculari.

General information (Guida dello studente) can be found at <a href="http://web.uniroma2.it/modules.php?name=Content&navpath=STD&section\_parent=442">http://web.uniroma2.it/modules.php?name=Content&navpath=STD&section\_parent=442</a>

If a certificate of English knowledge is not available, students must contact the Coordinator of the Degree, Prof. Andrea Battistoni via email <a href="mailto:andrea.battistoni@uniroma2.it">andrea.battistoni@uniroma2.it</a>, in order to set a date for a spoken English test.

Foreign students: Detailed instructions for enrollment can be found on the website https://en.uniroma2.it/campus-life/international-students/

Non-EU candidates not residing in Italy must proceed first with a preliminary assessment of their previous studies at this site <a href="https://delphi.uniroma2.it/totem/jsp/homeStudenti.jsp?language=EN">https://delphi.uniroma2.it/totem/jsp/homeStudenti.jsp?language=EN</a>. Here, students can register and upload their certificates. Both the exam transcript and English certificate must be uploaded (a single pdf is fine). Foreign Students are invited to ask for assessment of requisites between January and June. Upon positive outcome of this assessment, Foreign Students will receive an email and a letter that is needed in order to obtain two important documents both issued by the Italian Diplomatic Authorities in their own country: the Entry Visa and the Codice Fiscale (Fiscal Code).

The Codice Fiscale is necessary for all kinds of interaction with the Italian public administration and also to apply for the Regional scholarships awarded by Laziodisu (see below)-

To obtain the issuance of the Visa to enter Italy for study purposes from the Embassy or Consulate in their countries, students having received the letter of admission will have to fill out the pre-enrollment application online through the Universitaly Portal at the following link: <a href="https://www.universitaly.it/index.php/students/stranieri">https://www.universitaly.it/index.php/students/stranieri</a>. The pre-enrolment application will be verified by Tor Vergata University of Rome and forwarded to the Embassy or Consulate you have declared in your application.

In order to facilitate Visa issuing operations, we recommend that you request a statement of comparability of your High School/Bachelor Diploma from CIMEA by connecting directly to the following link: <a href="https://cimea.diplo-me.eu/torvergata/#/auth/login">https://cimea.diplo-me.eu/torvergata/#/auth/login</a>

**Enrollment** usually takes place between August and December of each year. In the academic year 2021-20222 the Call will be out in July 2021.

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For information on preliminary procedures Foreign students may refer to the Ufficio studenti stranieri – Via Cracovia, n. 50 - 00133 Roma Edificio D – piano 0 – stanza n. 001
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(email: studenti.stranieri@uniroma2.it)

Office Hours:

Mon to Thu: 9:00 - 12:00 / 14:00 - 16:00

Fri: 9:00 - 12:00

Enrollment application forms must be completed on-line at <a href="http://delphi.uniroma2.it">http://delphi.uniroma2.it</a> and then handed in to the Students' Secretary.

#### **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 <a href="http://en.uniroma2.it/admissions/tuition-fees/">http://en.uniroma2.it/admissions/tuition-fees/</a>

**Not submitting the ISEEU to the University** will imply for the student the payment based on the maximum rate of the yearly fee of the course (80% of the maximum rate for the students coming from low-income economies or lower-middle-income economies; 100% of the maximum rate for all the other international students).

#### 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.

Italian students not resident in Rome may apply for a LAZIODISCO scholarship. Information can be found at <a href="http://www.laziodisco.it/">http://www.laziodisco.it/</a>

Non-Italian Students may apply for a LAZIODISCO scholarship (as above) and for other fellowships, to be found at <a href="http://internationalstudents.uniroma2.it/">http://internationalstudents.uniroma2.it/</a> - Section Services

#### **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 <a href="http://agevola.uniroma2.it/">http://agevola.uniroma2.it/</a>

#### **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".

#### **ADDITIONAL INFORMATION**

All information relating to the M.Sc. in Biotechnology (professors, CVs, teaching programs, examination procedures, teaching regulations) can be found online.

Link to the M.Sc. website in Biotechnology: <a href="http://www.biotechuniroma2.it/">http://www.biotechuniroma2.it/</a>

The teaching regulations of the M.Sc. in Biotechnology can be found at the website: The teaching plan 2019/2020 of M.Sc. in Biotechnology was approved by the Council of Department of Biology on 17 April 2019.

The Manifesto (planned teaching) for the academic year 2019/2020 of the LM in Biotechnology is visible on the site: http://uniroma2public.gomp.it/manifesti/render.aspx?UID=33b4f2e8-3b14-456d-8715-d6c4ec82dd21http://www.biotechuniroma2.it/wp-content/uploads/2019/06/regolamento-didattico-biotechnology.pdf

Facebook page: <a href="https://www.facebook.com/biotechnologyuniroma2/">https://www.facebook.com/biotechnologyuniroma2/</a>

#### **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**

#### Profs. Alessio D'Amato and Giacomo Pallante

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).

#### 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.

#### **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 physicochemical 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: At the end of the course the student must have acquired competence related to basic applications of bioinformatics for the research in biotechnology.