**UNIVERSITA` DEGLI STUDI DI ROMA TOR VERGATA**

Dipartimento di Biologia

# Master of Science in Biotechnology

## **P**rogram **H**andbook 2019-2020

20 – June 2020

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## CONTACT INFORMATION

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## 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 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.

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 50-80 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 |
|---|---|---|
| Structural and Industrial Biochemistry (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 12.

## 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 2019-20 the following Elective Courses are proposed:

| **Course** | **CFU** |
|---|---|
| Plant micropropagation | 4 |
| High-Throughput technologies in drug discovery | 2 |
| European pharmaceutical legislation | 5 |
| Food Chemistry | 5 |
| Modern techniques of protein identification and Molecular Recognition Methods | 3 |
| Methods for genetic modification of bacteria: application in basic and applied research | 2 |
| Genes and Nutrition | 2 |
| Laboratory Quality Control | 2 |
| Medical Device Regulations and Development | 2 |
| Pharmacovigilance | 2 |
| CRO Management | 1 |
| Protein-protein Interactions:Phage-display methodology | 2 |
| Experimental approaches to study neoplastic transformation | 3 |

The description of elective courses can be found on the webpage http://www.biotechuniroma2.it/courses/.

## 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 2019-2020

**FIRST SEMESTER** September 30, 2019 – December 20, 2019.
**SECOND SEMESTER** March 9, 2020 – May 29, 2020.

**First Exam session:** January 13, 2020– March 6, 2020
**Second Exam session**: June 8, 2020 – September 25, 2020

The detailed *Lessons Schedule* and *Exams Schedule* will be available online in September 2018.

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

**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 | 6 | SECS-S/02 |
| Pharmacology and Pharmaceutical Chemistry (2 modules) | 6+6 | BIO/14, CHIM/08 |
| Structural and Industrial Biochemistry (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 | 6 | MED/01 + SECS-P/10 |
| B. Drug design and development | 6 | CHIM/09 |
| B. Clinical Data Quality management | 6 | MED/09 |
| Applied Immunology | 6 | MED/04 |
| Pharmaceutical applications of plant metabolites | 6 | BIO/04 |
| **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 | |
| **TOTAL 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
- 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.

## 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). Non-EU candidates not residing in Italy must proceed first with the **assessment** of their previous studies and then with the **pre-enrollment** procedure at the Italian Embassy or Consulate in their country, before the opening of the online application.

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, Virology, 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.
- 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, and must have passed an exam of Statistics during their Bachelor studies

## ADMISSION PROCEDURE

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

General information (Guida dello studente) can be found at
http://web.uniroma2.it/modules.php?name=Content&navpath=STD&section_parent=442

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

*Foreign students*: Detailed instructions for enrollment can be found on the website
http://internationalstudents.uniroma2.it/

Preliminary **assessment** of requisites must be requested via online procedure at http://delphi.uniroma2.it/totem/jsp/homeStudenti.jsp?language=EN > Assessment
where 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 in February-June 2019.
Upon positive outcome of this assessment, Foreign Students will receive an email and a letter (in Italian) 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)-

**Enrollment** usually takes place between September and December of each year. In the academic year 2019/2020 the Call will be out in July 2019.

For information on preliminary procedures Foreign students may refer to the
Ufficio studenti stranieri – Via Orazio Raimondo,18 – 00173 ROMA
(email: studenti.stranieri@uniroma2.it)
Office Hours:
Mondays: from 9,00 a.m. to 12,00 a.m.
Wednesdays: from 9,00 a.m. to 12,00 a.m. - 14,00 p.m. to 16,00 p.m.
and Fridays from 9,00 a.m. to 12,00 a.m.

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

## TUITION FEES AND SCHOLARSHIPS

Tuition fees at the University of Rome Tor Vergata for the AY 2019/2020 will be based on the student's family income. Information will be available at the site http://en.uniroma2.it/admissions/tuition-fees/

Application requires to submit the student's last family income declaration (referred to 2018 incomes) and the composition of his/her family (referred to 2018). EU and non-EU foreign students' income and assets are based on the records which must be issued by the authorities of the country in which such income has been earned. **Such records must be translated and stamped by the Italian Embassy at home-country**.

These certified documents need to be brought to any CAF Office (Italian Tax Service Centres) after arriving in Rome. The CAF office will deliver to the student the ISEEU module necessary to determine the student's yearly tuition fee.

**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.
Please refer to the Students Office for up-to-date information about tuition and fees.

Italian students not resident in Rome may apply for a LAZIODISU scholarship. Information can be found at http://www.laziodisu.it/bando/

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

Further information about Laziodisu scholarship is available on the following website: http://www.laziodisu.it/wp-content/uploads/2017/05/Bando-Diritto-allo-Studio-2017-2018-ENGLISH-VERSION.pdf.

## PART-TIME REGISTRATION

students that can not devote full time to studies, can apply for part-time enrollment or part-time registration to the subsequent academic year. In this way, they will pay a lower enrollment fee and obtain an extension of the educational path, avoiding to go off course. The part-time request must be properly motivated and certified (for example, work-related problems, family problems, or medical problems). working, family, medical and similar). The option request for a part-time regime can be presented only once and cannot be reversed during the year. On the site http://delphi.uniroma2.it, using the link "enrollment as a part-time student", it is possible to consult the regulations, the tables and procedures for this type of registration.

## 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".

## 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: http://www.biotechuniroma2.it/

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: https://www.facebook.com/biotechnologyuniroma2/

## DESCRIPTION OF CORE COURSES

### APPLIED ECOLOGY

**Teacher: 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:* 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.

Atmosphere: Climate: Climate change, consequences of climate change. Air pollution.

Hydrosphere: water as a renewable resource. Water usage, water demand and water quality. Water pollution. Oceans and their status.

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.

Agriculture: global trends, relationship with human demography . Types of agriculture. The Green revolution. Sustainable agriculture vs industrial agriculture. GMOs and agriculture.

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. 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.

**Suggested Textbook**: W. Cunningham & M.A. Cunningham. Environmental Science: a global concern, McGraw-Hill, 12th Edition, 613 pp.

### APPLIED ECONOMICS

**Teacher: Barbara Martini**

*Aims:* The aim of the course is twofold. The aim of the first part, concerning sustainable development, is to develop the economic framework concerning the use of natural resources in a sustainable way. Special attention is dedicated to the economic analysis of the renewable resources. The second part concerns the evaluation projects. Special attention is devote to the cost and benefit analysis and to the R&D projects. The third part concerns sanitary economics.

*Program:* Part I: Sustainable development; sources of energy; Demand of energy; Renewable energy: the European approach; Energy market in Italy; Hydro energy; Geothermal energy; Wind energy; Solar energy; Biomass; Smart cities

Part II: Biotec in Italy; the evaluation of investment projects; cost-benefit analysis; the theory of real options. Research and Development: definition, problems and prospects; Methods of financing R&D.

Part III: Sanitary economics

**Textbooks**: Materials provided by the teachers

### APPLIED PHYSIOPATHOLOGY

**Teachers: Camilla Palumbo and Carla Montesano**

*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. Kidney patophysiology. Acute renal failure and chronic renal failure. Nephritic syndrome and nephrotic syndrome. Glomerulonephritis. Tubulo-interstitial diseases. Obstructive diseases. Endocrine system pathophysiology. General mechanisms of hormonal hypofunction and hyperfunction. Diabetes mellitus. Diabetes insipidus.

**Suggested textbooks:** Robbins &Cotran. Pathologic Basis of Disease; Rubin's Pathology: Clinicopathologic Foundations of Medicine

## APPLIED IMMUNOLOGY

**Teacher: 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

**Suggested Textbooks:** Kenneth M Murphy; Allan Mowat; Casey Weaver; et al. Janeway's Immunobiology. Garland Science 9th edition; Open Access book: https://www.ncbi.nlm.nih.gov/books/NBK10757/?term=janeway

## BIOSENSOR TECHNOLOGY

**Teacher: Francesco Ricci**

*Aims:* Knowledege of equilibria in solution. Ability to select and use biosensors

*Program:* Introduction and basic concepts: biosensors. Electrochemical Enzymatic Biosensors. Sensor and electrode preparation. Optical enzymatic biosensors. Signal processing and readout. DNA-based biosensors. Electrochemical DNA-based Biosensors. Sensor and electrode preparation. Immobilization of DNA probes. Optical DNA-based biosensors. Signal processing and readout. DNA-based nanomachines for sensing applications. DNA-based nanoswitches for diagnostic applications. Antibody-based biosensors. Basic and general concepts of ligand-receptor binding. Practical and commercial examples. External lecture. Project on literature examples. 9. Laboratory project on a case study.

**Suggested Textbooks:** J. Wang, "Analytical Electrochemistry" 3rd Edition, Wiley

## CLINICAL DATA QUALITY MANAGEMENT (two Modules)

*Aims:* The aim of the course is the learning of principal characteristics of a proper Quality System applied to clinical studies, so that it can guarantee the trustability of data as requested by the Good Clinical Practices.

**A) Clinical Monitoring**

**Teacher: Paolo Primiero**

General context and Regulations. Feasibility and Site Selection Visit. Approvals in Clinical Trials. Site Initiation Visit (SIV). Site Staff Training. Safety Information. Site Staff Training. Case Report Form (CRF). Site Staff

Training. Informed Consent. Site Staff Training. Trial Master File (ISF). Monitoring Ongoing/Interim Monitoring Visit (MOV/IMV). Close Out Visit (COV). Monitoring report. Monitoring Report Issues. Monitoring issues management. Risk Based Monitoring (RBM)

**B) Clinical Research quality management**

**Teacher: Annamaria Paparella**

General overview of main Quality requirements, with particular reference to ISO. Quality in Pharmaceutics; Risk Based Approach. Good x Practices (GxP); introducion to Good Clinical Practices (GCP). Quality at the Sponsor; Quality Assurance and Quality Control. Organization and Training of GCP personnel. Documentation System; selection of a Contract Research Organization (CRO). Data Quality; Data integrity. Handling of Quality events; management of Corrective and Preventive Actions (CAPA). Audit activities. Managing of inspections. Quality in handling of an Investigational Medicinal Product. Quality and Pharmacovigilance in clinical trials.

**Suggested textbooks** Materials provided by the teachers

**CLINICAL RESEARCH METHODOLOGY** (two Modules)

**Teachers: Stefano Vella and 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). A detailed analysis of the Good Clinical Practice (GCP) will be done, focusing on the aspects that have direct impact on the processes ruling the clinical protocol implementation. 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. The GCPs will be presented making clear reference to all the laws and regulations that are linked with their practical application.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 course will include 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.

**Textbooks**: Materials provided by the teachers

**CLINICAL RESEARCH DEVELOPMENT AND MANAGEMENT** (two Modules)

*Aims:* Knowledge of new drug development and concerning regulations

A) **Clinical Research** Development

**Teacher: Giuseppe Assogna**

Outline of Pharmacoeconomics.Price and Reimbursement (EU and Italian systems). From registration to drug availability: main steps and main stakeholders involved. Generics and Biosimilars. Italian law on scientific information (notes on Farmindustria code)

**B) Clinical Research Management**

**Teacher: Giovan Battista Leproux**

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

**Suggested textbooks**: Materials provided by the teachers

## DRUG DESIGN AND DEVELOPMENT

**Teacher: Tatiana Guzzo**

*Aims:* To gain knowledge on the different phases of the drug discovery and development process. To understand deeply the pharmacodynamics 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 Relationship, Pharmacophore, Bioisosterism, Chemical Modifications, Lead optimization Strategies). Computer Aided Drug Design (Ligand and Structure Based Approaches, Pharmacophore Screening, Database Virtual Screening, Docking, QSAR). Combichem Approaches in Drug Discovery (Combinatorial Synthesis, Parallel Synthesis Methodologies)

**Suggested textbooks**: G. Patrick An Introduction to Medicinal Chemistry 6th edition. materials provided by the teacher

## GENE EXPRESSION AND REGULATION

**Teacher: Daniela Barilà**

*Aims:* The aim of the course is to provide students with the tools for understanding and drawing experimental strategies for the study of problems related to the regulation of gene expression in eukaryotic cells useful for the development of biotechnological projects

*Program:* References and insights on molecular mechanism that ensure the control of gene expression: epigenetic control, transcriptional and post-transcriptional control. Role of microRNA and long non coding RNA. 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: cell cycle regulation, control of cell proliferation, genomic stability maintenance. 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.

**Suggested textbooks**: Students will evaluate their textbooks with the teacher

## MICROBIAL TECHNOLOGY

**Teacher: To be assigned**

*Aims:* A deep insight on the microbe/man interaction dynamics, the importance of the human associated microbiota and its possible outcomes. Students should understand the bacterial virulence strategies and the current state and perspectives of fighting them. They should acquire the basic skills to handle the main microorganisms used for microbial biotechnologies.

*Program:* Microbe/man interactions and their possible outcomes. Bacterial pathogens: pathogenic power and virulence. Virulence evolution, strategies and mechanisms. The Human-associated microbiota: community structure and diversity. Influence of age, diet and genetic background on the microbiota/host interactions; possible outcomes of microbiome expression and microbiota alterations. Fighting pathogens: antibiotics, bacterial resistance strategies and related problems. Facing “superbugs” with the phage therapy. Microorganisms and biotechnology: basics, history, research fields. Choosing the optimal host Codon, adaptation index and PLS modeling. Industrial employing of microorganisms. Microbes for biotechnologies: taxonomy, features, cultivation, genetic manipulation and heterologous expression in Bacteria (*Escherichia coli; Bacillus, Lactic Acid bacilli –LABs*-and *Streptomyces*) and -Yeasts (*Saccharomyces, Hansenula, Pichia, Kluyveromyces*)

## NANOBIOTECHNOLOGY

**Teacher: Lina Ghibelli**

*Aims:* The course aims at providing the basic notions of nanotechnology, within the Materials Science ambit, and deeply review the biotechnological applications of the various types of nanomaterials. The goal of the course is to reach a deep comprehension of nanomaterials and their biotechnological applications

*Program:* Nanomaterials: generalities and biotechnological explotation; Basic notions on nanomaterials; Properties of nanomaterials of biomedical interest. Interaction of nanomaterials with biological systems. Biocorona and its significance. Agglomeration, aggregation, contaminants and ion leaching. Routes of nanoparticle entry and epithelial barrier crossing. Basic techniques in nanoparticle biotechnological applicatons. Biomedical applications of Carbon based materials: benefits and hazard. Intrinsically active nanomaterials: the oxides. Biomedical exploitation of intrinsically bioactive nanomaterials. Nanomaterials as antioxidant: Overview of intracellular ROS flow and antioxidant defences. Nanomaterials as anticancer agents: Overview of DNA damage, DNA repair and DNA damage response. Nanomaterials as anticancer agents: Overview of normal and cancer microenvironment. Nanomaterials as UV-protecting agents: Overview of UV biological effects. Cerium oxide nanoparticles as antioxidant agents. Cerium oxide nanoparticles as UV protecting agents. Cerium oxide nanoparticles as radio-sensitizing agents. Nanomaterials in anticancer therapy: photo-activation and up-conversion. Nanotoxicology. Potential adverse effects of nanomaterials on health. Nanomaterials as Drug delivery agents. Nanomaterials in regenerative medicine. Other applications of nanoparticles in biotechnology

**Suggested textbooks**: Materials provided by the teachers

## PHARMACEUTICAL APPLICATIONS OF PLANT METABOLITES

**Teacher: Patrizia Aducci**

*Aims:* The course aims to provide students with knowledge of natural substances and the properties of medicinal plants and their applications to medicine and nutrition. The study of different classes of natural bioactive molecules and the legislation regulating their applications will give to the students the means to carry out research on this area starting from the methods for the isolation to the clinical application of natural drug

*Program:*

Distribution and characterization of bioactive natural products in plants. Medicinal plants and officinal herbs: definition, classification and regulation. Methods for preparation and analysis of herbal active components: Elixir,Spirit,Tincture and methods for their quality control. Role of secondary metabolites in plant defense against pathogens and herbivores. Biosynthesis of phenols. Biosynthesis of terpenes , from mono to tetraterpenes. Nitrogen-containing compounds. Alkaloids, cyanogenic glucosides, glucosinolates. Essential oils :methods for preparation and their applications . Plants containing metabolites of each group will be described as well as their applications in pharmacology and nutrition.

**Suggested textbooks**: Materials provided by the teachers

## PHARMACOLOGY AND PHARMACEUTICAL CHEMISTRY (two Modules)

*Aims:* The course aims to provide learning on the fundamental aspects of general pharmacology and in particular the pharmacokinetics (ADME) and pharmacodynamics. In addition, students must acquire the molecular basis of drug action and the factors that influence the pharmacological effects and adverse drug reactions. The course also has the task of providing the molecular basis of toxicology, as well as the phases of clinical development and the regulations of clinical trials.

### *A) Pharmacology*

***Teacher: Robert Nisticò***

*Program:* Principles of pharmacokinetics: routes of administration and absorption of drugs. Distribution, biotransformation and excretion of drugs. Drug interactions.

Principles of pharmacodynamics: drug-receptor interaction, agonists and antagonists, allosteric modulators. Classification of receptors, adaptive responses to drugs. Mechanisms underlying signal transduction pathways. Voltage-dependent and voltage-independent ion channels.
Intercellular transmission: glutamate, GABA, acetylcholine, catecholamines, serotonin, nitric oxide, cannabinoids, opioid peptides. Basic principles of normal and pathological synaptic plasticity.
Principles of cellular and molecular toxicology. Drug addiction.
**Suggested textbooks**: Goodman and Gilman: The pharmacological basis of therapeutics, XII ed. McGraw-Hill; Bertram Katzung, Anthony Trevor: Basic & Clinical Pharmacology, XIII ed. McGraw-Hill; Casarett & Doull's Toxicology: The Basic Science of Poisons, VIII ed. McGraw-Hill

*B)* ***Pharmaceutical Chemistry***

***Teacher: Orazio Nicolotti***

*Program:* Drugs and drug targets: an overview. Protein,enzymes, receptors and nucleic acids: structure and function. Enzymes and receptors as drug targets. Pharmacokinetics and related topics. Drug discovery: finding a lead. Drug design: optimizing target interactions. Drug design: optimizing access to the target. Getting the drug to market. Computers in medicinal chemistry. Quantitative structure–activity relationships (QSAR). Case studies: Statins as anti-cholesterol agents; ACE inhibitors; Artemisinin and related antimalarial drugs; De novo design of a thymidylate kinase inhibitor; Antidepressant agents.
**Suggested textbooks**: Patrick: An introduction to medicinal chemistry

## PLANT BIOMASS AND PHYTOTECHNOLOGIES

**Teacher: Cinzia Forni**

*Aims:* Improvement of the knowledge concerning plant biotechnology, focusing on the utilization of plant biomass. The achievement of the results will be verified through individual presentation of scientific literature during the course, as well as final oral exam.
*Program:* Plant microporpagation. Plant cell and tissue cultures. Cultures of calli, meristems and organs. Somatic embryos. Somaclonal variation. In situ and ex situ germplasm preservation. Cryopreservation. Plant cells as a tool for the production of useful compounds. From lab bench to industrial scale. Bioreactors. Plant molecular farming. Bioplastics and bio-based materials. Phytotechnologies and phytoremediation
**Suggested textbook:** materials provided by the teacher

## REGULATORY ACTIVITIES

**Teacher:** to be assigned

## STRUCTURAL AND INDUSTRIAL BIOCHEMISTRY (two Modules)

*Aims:* The program has the general objective of illustrating some of the main applications of biochemistry in the industrial, medical and food sectors and to provide the student with the cultural tools to understand how to produce and modify the proteins used in many of these processes. To this end, the knowledge of the structures of protein macromolecules, of the interactions important for their stabilization and of their structural and functional features will be deepened. A further objective is to provide the student with a critical scientific method that can be applied independently in dealing with new scientific problems in structural biology and applied biochemistry.

***A) Industrial Biochemistry***

***Teacher: Andrea Battistoni***

*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.

**Suggested textbook:** materials provided by the teacher

***B) Structural Biochemistry***

***Teacher: Alessandro Desideri***

*Program:* Characteristics of amino acid side chains, their reactivity and frequency in proteins. The weak interactions. Protein maturation, the process of "folding", "unfolding" and "misfolding". The problem of folding in vivo, the control mechanisms.Protein Stability. Examples of Molecular recognition.

**Suggested textbook:** Creighton. Proteins: Structures and Molecular Properties. W.H.Freeman & Co Ltd and materials provided by the teacher