

DEGREE COURSE IN PHARMACY ACADEMIC YEAR 2018/2019

Our Degree course in Pharmacy, held in the University of Rome Tor Vergata, is taught entirely in English with the purpose to provide the necessary knowledge in any and all aspects of drug and medicine use, whether the first discovery, the drug's development, or its supply to patients.

The course was founded by our School of Medicine and School of Science in partnership with the prestigious School of Pharmacy of the University of Nottingham and Alliance Boots, as a highly interdisciplinary school involving professors and experts from different sectors, from Chemistry to Medicine, Economics, Law as well as all subjects concerned in a complex traditional Pharmacy Course.

This relationship provides the opportunity, to our best students, to perform some stages in Nottingham University, as well as in other well organized European Universities through the Erasmus Mundus Project, emphasizing the internationalization and making this course highly competitive and innovative.

Besides the incredible educational goal, which relies on professionalism of our staff, the course requires a theoretical and practical training in order to allow to operate not only in the healthcare sector but also in the pharmaceutical industry and in the field of pharmaceutical research, as a very innovative aspect.

In addition to the traditional teaching which characterize any traditional Pharmacy Course, such as the basic subjects (statistics, general and inorganic chemistry, organic chemistry, biochemistry, pharmacology, pharmaceutical chemistry and toxicology), there are other specific matters that contribute to a pharmacological preparation and a medical and biological overview, such as the teachings of Biology (general biology, molecular biology, pharmaceutical biology, cell physiology, medicinal plant) and Medicine (human anatomy, immunology, microbiology, general pathology, internal medicine, dermato-pharmacology, clinical nutrition).

It is interesting to note that to fulfill some teaching courses is necessary to include some laboratory sessions to improve the appropriate knowledge and be able to deal with the increasing bank data in Advanced Pharmacology, Medicine and Biotechnology as a great challenge and upgrading of notions useful in the Italian and European markets, and in any international project diffused worldwide.

The didactic activity is also integrated with outstanding lectures and workshops held by qualified scientists belonging to different fields such as Pharmaceutical, Medical and Biological Sciences, all regarded as an instrument of discussion and debate to improve the students' background.

Another great innovation of this course is the introduction of the Scientific and Regulatory Assessment of New medicines, according to the new Pharmaceutical Legislation both at European and National level.

This step allows to reach a specific competence in the evaluation and assessment of a pharmaceutical dossier, which is compulsory to get the authorization by the European Medicines Agency (EMA) or national authorities to introduce the drug into the market.

All these competences and knowledge acquired by the students will be a key part declared in the Supplement Certificate, at the end of his curriculum studiorum, whose diploma is the utmost in this field.

For further information please visit the interne site at: <http://farmacia.uniroma2.it>

Premises and objectives

This single-cycle course is delivered in English only, and has a duration of 5 years, for a total of 300 university credits (hereinafter CFU) that the student must acquire to achieve the degree.

The degree program, together with the general information on the courses, in compliance with the regulations and the ministerial decrees in force, are an integral part the [Didactic Regulations](#).

According to the national and university regulations, students can get information on the degree course at the student administration office headed by the secretariat of the Biology Department. For any further clarification concerning the courses, students may refer to the secretariat of the degree course located on the second floor of the PP1 building, in the Mathematics, Physics and Natural Sciences Macro-area of the University of Rome 2 (“Tor Vergata”).

Structure of the course and university credits

The master’s degree course includes lessons, laboratory practice, seminars and conferences, also held at suitable public and private institutions both in Italy and abroad, which provide information, language and cultural relevance skills consistent with the topics of the course.

Each university credit (CFU) corresponds to a 25-hour student commitment, of which, normally, 8 hours of lectures.

The course is organized on an annual basis.

In compliance with the European directives, the skills acquired by the student, defined as specific, peculiar and characterizing, are then consolidated during vocational training periods spent in pharmacies open to the public or in-hospital ones as well as thanks to grants to study abroad according to international agreements or conventions established by universities. Among them, the School of Pharmacy in Nottingham or the Erasmus project give the possibility to take exams or to carry out experimental degree theses abroad. The course is complemented by lessons providing the knowledge of medical-surgical, dietetic, cosmetic, diagnostic and chemical-clinical products, keeping in mind also the employment opportunities offered in the Community.

This master’s degree course is divided into 29 courses (and activities chosen by the student, final exam and orientation training course) to which a number of CFUs is allocated, as determined by the Council of Degree Course in compliance with the provisions contained in the table of the compulsory courses.

In order to achieve the aforementioned educational objectives, the master’s degree course in Pharmacy provides that the total of 300 CFUs is distributed as follows:

- lectures (including numerical and/or laboratory practice) for a total of 243 CFUs;
- vocational internship for a total of 30 CFUs;
- final degree exam for a total of 15 CFUs;
- additional activities (chosen by the student) for a total of 12 CFUs.

Admissions

In order to be admitted to the Degree of Pharmacy it is necessary to take and pass a specific test. The test, written and oral, will be held on September 2019 (date to be confirmed), for further information please visit our internet site: <http://farmacia.uniroma2.it>

The admission requirements are based on qualifications and examination.

A total number of 100 places are available, divided as follows:

- a) 70 available to Italian citizens, EU citizens and non-EU citizens legally living in Italy, in agreement with art 26, of Law n 189/2002;
- b) 30 places are reserved to non_EU citizens resident abroad.

If the places reserved for non-EU citizens residing abroad are not fully utilized, those places will be available for applicants of the categories described in item a).

Any Italian citizens, EU citizens and non-EU citizens legally living in Italy, can participate to the admission test only if owners of a five years Diploma of Secondary School, issued by any Italian Institutes, or a qualification obtained abroad and valid for the admission to any Italian University.

The EU and non-EU citizens, legally living in Italy, in possession of a foreign certificate, will be admitted to the test after the evaluation of the certificate. In case they should be winners, their registration will be subject to the validity of the documents and qualification obtained abroad, see Circular MIUR prot. 1291 of 16/05/2008 and current laws.

Non EU students living abroad, will formalize the procedure for the enrolment through the University Foreign Student Office, Via Cracovia 50, 00133 Rome Ground floor, building D, room n.1. email: Rome, Studenti.stranieri@uniroma2.it

COURSE PROGRAM

I YEAR	SSD	CREDITS
Human Anatomy	BIO/06	10
General and Inorganic Chemistry	CHEM/03	6
Mathematics	MAT/05	6
Physics	FIS/01	5
Cellular and Development Biology and Zoology	BIO/06 BIO/05	10
Organic Chemistry	CHEM/06	8
 II YEAR		
Analytical Chemistry (Laboratory methods)	CHEM/03	8
Microbiology and Immunology	MED/07 MED/04	6
Molecular Biology	BIO/11	10
Drug Analysis I- Methodology I-Applications	CHEM/08	10
Pharmaceutical Biology And Pharmacology	BIO/14	7
Medical Statistics	MED/01	5
Biochemistry	BIO/10	11
Chemistry of Equilibria	CHEM/01	6
 III YEAR		
General Pathology	MED/04	8
Plant Biochemistry and Physiology	BIO/04	4
Medicinal Plants	BIO/01	4
Drug Analysis II	CHEM/08	12
Pharmaceutical and Toxicological Chemistry (I)	CHEM/08	14
General Pharmacology, Toxicology	BIO/14 MED/03	12
and Pharmacogenomics Physiology	BIO/09	7
 IV YEAR		
Internal Medicine and Dermatopharmacology	MED/35 MED/09	6
Pharmaceutical and Toxicological Chemistry (II)	CHEM/08	12
Pharmaceutical Tecnologies	CHEM/09	10
Special Pharmacology and Therapy	BIO/14	10
Neuropsychopharmacology	BIO/14	8
Chemiotherapy	BIO/14	8
 V YEAR		
Italian Pharmaceutical Legislation	CHEM/09	12
European Pharmaceutical Legislation and Commercial Law	CHEM/09 IUS/04	
Dietistic Sciences and Food Chemistry	MED/49 CHEM/10	8
Optional Courses		12
Final Exam		15
Training		30
Total		300

PROGRAMS

HUMAN ANATOMY 10 CREDITS

Prof. Barchi Marco

Prof. Giuseppe Sciamanna

FIRST PART: HISTOLOGY AND LOCOMOTOR SYSTEM (Prof. Marco Barchi). HISTOLOGY: Histology and its methods of study. EPITHELIAL TISSUES, CONNECTIVE TISSUES, NERVOUS TISSUE, BLOOD, MUSCLE TISSUES. General organization of the axial and appendicular skeleton, joints structure and classification. Major muscles of the shoulder girdle and of the trunk, respiratory muscles.--SECOND PART: NEURO-CARDIO-SPLANCHNOLOGY (Prof. Pellegrino Rossi) Neuroanatomy, Cardiovascular System and Splanchnology.

Knowledge of the essential morphological characteristics of the the Nervous System, of the Cardiovascular Apparatus and of the visceral organs, including digestive, urinary, reproductive, respiratory and endocrine systems.

Suggested textbooks

1) Martini Timmons: Human Anatomy
or 2) Tortora: Human Anatomy
or 3) Gray's Basic Anatomy
and (integration for Histology) 4) Anthony L. Mescer: Junqueira's Basic Histology.

GENERAL AND INORGANIC CHEMISTRY 6 CREDITS

Prof. Claudia Crestini

Units and Conversion factors, Dalton's Theory Structure of the atom. Ionic compounds. Covalent compounds. The mole. Balancing chemical equations. Stoichiometrical calculations. Laws of the gases. Energy, law of energy conservation. State functions. Enthalpy. Calorimetry. Hess's Law. Quantum theory and atomic structure. Electron configuration and chemical periodicity. Ionic bonding model. Covalent bonding model. VSEPR theory and molecular shape. orbital hybridization. Types of covalent bond. Physical states and phase changes. Intermolecular forces. Liquid state. Properties of solutions. Colligative properties. Equilibrium state and equilibrium constant. Le Chatelier's principle. Acids and bases. Hydrolysis of salts. Buffers. Titrations. Solubility equilibria. Second law of thermodynamics. Entropy free Energy and work. Balancing of redox reactions. Voltaic cells, Electrolytic cells.

Suggested textbooks

Silberberg. Principles of General Chemistry Mc Graw Hill

MATHEMATICS 6 CREDITS

Prof. Daniele Bertaccini

Numbers. Inverse formulas, change of scales and order of magnitudes in formulas; equivalence relations; errors in measures and calculations. Functions of one real variable: basic concepts, graphs, elementary functions (polynomials, roots, rational functions, trigonometric, exponentials and logarithms); Sequences; series, binomial coefficients; Limits; Geometric sums; Continuous functions; Differentiation: derivatives, monotonicity and concavity, extrema, sketching graphs; Taylor formula and polynomial approximation of functions. Riemann Integration; Definite integration: the fundamental theorem of calculus; Techniques.

Introduction to the software for approximating and plotting functions, approximation of definite integrals, linear and nonlinear systems. Introduction to the simulation of Phenomena in Medicine and drug preparation.

Suggested textbooks

Calculus for biology and medicine (2nd ed.), C. Neuhauser, Prentice Hall (2nd international edition). Ed. Pearson educational international, 2003.

Lecture notes

PHYSICS 5 CREDITS

Dr. Massimiliano Lucci

Introduction to physics:

SI System of units, Error Analysis: Statistical errors, Systematic errors, Error Propagation. weighted mean. Vectors and Scalars. Dot Products, Vector Cross Product.

Kinematics and Dynamics of point-like objects: Methods of Motion, Displacement, Velocity,

Acceleration, Graphical Analysis of Motion: Slope, Area. Projectile Motion Newton's First & Second Law, Free body diagrams, Friction, Newton's Third Law, Newton's Law of Gravitation, Newton's First Law and Physical Therapy, example of Cervical Traction. Circular Motion, Impulse and Momentum, Law of Conservation of Momentum, Elastic Collision, Inelastic Collision. Work, energy, Potentials, Power. Elastic Potential Energy & Springs, Simple Harmonic Motion, Hooke's Law, Conservation of Energy,

Fluid Mechanics – Hydrostatics, States of Matter, Density, Fluid, Pressure, Pascal's Principle, Archimedes's Principle, Fluid Dynamics, Bernoulli's Principle,

Thermodynamics: Calorimetry, Heat, Internal Energy, Isolated, Closed and Open Systems, Internal vs. "External" Energy, Absolute Zero & the Kelvin Scale, Heat Transfer Processes, Laws of Thermodynamics: Zeroth Law, First Law, Second Law, entropy, Boyle's Law and the Ideal Gas Scale, The Ideal Gas Law. Thermal Expansion for gas, liquid, solid.

Electricity and magnetism: Electric Fields and Forces, Charge, Conductors and Insulators, Induction and Grounding, Electrical Energy, Potential and Capacitance, Dielectric, Electric Circuits, Ohm's Law, example - Iontophoresis, Magnetic Fields and Forces, Lorentz Force, Right Hand Rule, ElectroMagnetic Induction, Faraday's Law, Transformers, Microphones, Lenz's Law

Waves and Sound: Standing Waves, Closed Pipes, Open Pipes, Harmonics, Example – Note, Ultrasound in diagnostics and therapy, propagation parameters, pulse-eco principle, velocity of sound, intensity and attenuation, reflection, acoustic impedance, transmission, refraction, Example – Ecography, Doppler effect.

Suggested textbooks

Serway, Jewett: "Physics for scientists and engineers" Halliday,
Joseph W. Kane Morton M. Sternheim "Life Science Physics"
John Wiley & Sons. "Fisica Biomedica" EMSI.

CELLULAR AND DEVELOPMENT BIOLOGY AND ZOOLOGY 10 CREDITS

Prof. Mauro Piacentini (3 credits)

Dr. Cesare Gargioli (7 credits)

The Program in Cell Biology offers to undergraduate students in Pharmacy the basic knowledge on cellular biology, genetic and molecular approaches to address structure-function relationships associated with cell growth, differentiation; chromatin structure; transcriptional control of gene expression; DNA replication; RNA structure. In particular the structure and function of the main organelles is analyzed. In addition an introduction to Reproductive Biology aimed to understand the scientific principles that govern reproduction in humans is also addressed during the course. The students will learn the requirements for reproduction, including the production of sufficient numbers of viable gametes, fertilisation, implantation in the uterus, formation of a placenta.

Suggested textbooks

The Cell: A Molecular Approach. Cooper G M and Hausman RE

Dr. Cesare Gargioli (7 credits)

Human genetic program offers to undergraduate students in Pharmacy the Genetic basic knowledge, as well as chromatin and RNA structure, transcriptional control of gene expression and DNA replication. Moreover, particular attention will be given to human genetic e then to its implication in the clinical field.

Suggested textbooks

R Lewis. "Human Genetics ". McGRAW-HILL

ORGANIC CHEMISTRY 8 CREDITS

Prof. Gianfranco Ercolani

Review of the concepts of chemical bonding, hybridization, resonance, and molecular structure. Acidity and basicity of organic compounds. Functional groups and principles of IUPAC nomenclature. Stereochemistry of organic compounds. Nomenclature, properties, and reactions of alkanes, cycloalkanes, alkenes, alkynes, aromatic compounds, alkyl halides, alcohols, thiols, ethers, sulfides, aldehydes, ketones, carboxylic acids and derivatives, amines, and heterocyclic compounds. Introduction to the structure and properties of bioorganic compounds: amino acids, peptides and proteins (primary structure), carbohydrates, triacylglycerols, phospholipids, nucleosides, nucleotides, and nucleic acids (primary structure).

Suggested textbooks

1) John McMurry "Organic Chemistry with Biological Applications" 2nd International Edition –

Brookscole, 2010. ISBN: 0495391476

2) Susan McMurry "Study Guide and Student Solutions Manual for McMurry's Organic Chemistry with Biological Applications 2e" BrooksCole, 2010. ISBN: 049539145X

ANALYTICAL CHEMISTRY 8 CREDITS

Prof. Giuseppe Palleschi

Acid base titrations Determination of the unknown concentration of acetic acid. Precipitation titration with Mohr method: Detection of unknown concentration of chloride with silver nitrate. Complexometry titrations Detection of Calcium ions in the water. Redox titration: Detection of hydrogen peroxide with potassium permanganate.

Suggested textbooks

Gary Christian: analytical chemistry Piccin or any book of analytical chemistry at university level.

MICROBIOLOGY AND IMMUNOLOGY 6 CREDITS

Prof. Francesca Ceccherini Silberstein (5 credits)

Prof. Florance Malisan (1 credit)

General and special virology: Nature, origin and morphology of viruses. Oncogenic RNA and DNA viruses. Virus-cell interaction. Vaccines. Antiviral therapy and resistance. Adenovirus. Herpesvirus. Poxvirus. Papovavirus. Parvovirus. Picornavirus. Hepatitis viruses. Retrovirus. Orthomyxovirus. Paramyxovirus. Rhabdovirus. Togavirus and other viruses transmitted by insects. Filoviruses. Rubella virus. Reovirus and rotavirus. Prions.

General and special bacteriology: The bacterial cell. Metabolism and bacterial growth. Host-parasite relationship. Immune sera and vaccines. Principles of microbiological diagnostics. Antibacterial drugs and resistance. Staphylococci. Streptococci. Pneumococci. Enterococci. Bacilli and clostridia. Enterobacteriaceae. Pseudomonas. Vibrios. Helicobacter. Neisseria. Mycobacteria. Treponema Pallidum. Mycoplasma. Rickettsiae. Chlamydia.

General and special parasitology: Protozoan parasites of man. Cestodes, trematodes and nematodes of human relevance. Arthropod pests and vectors of major human parasitic diseases.

General and special mycology: The mycetes: structure, dimorphism and replication. Mechanisms of pathogenicity. Mycosis by opportunistic fungi. Mycosis superficial, skin, subcutaneous and systemic. Description of Innate and Adaptive Immunity - Antibodies- B cells- Cytokines- Major Histocompatibility Complex (MHC)- Antigen presentation, dendritic cells- T cell development, thymic selection- T cell subsets- T cell activation - Cell mediated immunity - Humoral immunity -An overview of immunopathology including allergy, immunodeficiency, tolerance, autoimmunity, and tumor Immunity.

Suggested textbooks

Patrick R. Murray, Ken S. Rosenthal, Michael A. Pfaller "Medical Microbiology"

Basic Immunology, Abul K. Abbas, Andrew H. Lichtman, and Shiv Pillai, 5th Edition, Elsevier.

MOLECULAR BIOLOGY 10 CREDITS

Module I (5 credits)

Dr. Maria Cristina Piro

DNA stores biological information.

Nucleotides: structure and properties. The double helix. Semiconservative replication. Chemistry of DNA. Supercoiling.

DNA packaging. Chromatin components and structure. Histone-DNA interactions. Histone post-translational modifications. Gene expression and methylation.

DNA replication.

Bacterial genome is a single replicon while eukaryotic chromosomes contains many. Origin of replication. DNA polymerases. Proteins participating to DNA replication. The two DNA strands are replicated in a coordinated manner. Systems that repair DNA. Mutability and DNA repair. Homologous recombination. Transposition.

Translation.

Genetic code. tRNA and mRNA roles. Ribosomes: structure and function. tRNA activation. Codon-anticodon recognition. Initiation, elongation and termination of protein synthesis.

Suggested textbooks

Watson- Molecular Biology Of The Gene 6 or 7th Edition

Module II (5 credits)

Prof. Eleonora Candi

RNAs - mRNA: structure and function. Eukaryotic mRNAs structure. Eukaryotic mRNAs splicing and processing. Transfer RNA: structure and function. Ribosomal RNA: structure and function.

MicroRNAs. LncRNAs.

Transcription and its regulation - Bacterial RNA polymerases. Sigma factors and the control of bacterial transcription. Transcription units. Bacterial transcription: initiation, synthesis and termination. Eukaryotic RNA polymerases. RNA polymerase II promoters. Transcription factors cooperating with RNAPol II in transcription initiation. The process of mRNA transcription initiation. Transcription factors: DNA sequences recognition, structures and function. General mechanisms for activation or repression of transcription. Chromatin structure and transcription. Histone methylation and acetylation regulate transcription.

Genome - Sequence components. Repetitive and non-repetitive DNA. Genes: shapes, sizes and structures. Polycistronic bacterial genes. Gene families.

Gene isolation - Restriction enzymes. Plasmids. DNA sequences. Vectors for cloning DNA. DNA cloning.

DNA technology - Nucleic acids hybridising. Methods for studying mRNA expression. Polymerase chain reaction. DNA/RNA sequencing. Cloned genes can be expressed in prokaryotic and eukaryotic systems.

Suggested textbooks

1) Text book: Molecular Biology of the Gene, Watson, Baker, Bell, Gann, Levine, Losick. Pearson International Edition.

2) Scientific seminars on different molecular biology topics organized every year in which the students are invited.

DRUG ANALYSIS 10 CREDITS

METHODOLOGY

Prof. Laura Micheli (5 credits)

The program of this course is performed in parallel with the course of Equilibria of Chemistry, which supports the theory part of what is dealt with in class.

- Safety standards, classes and hazard symbols of noxious substances and first aid.
- Basic techniques and operations: solubilization, dilution, filtration, centrifugation, extraction. Description of the laboratory equipment and basic laboratory practice
- Theoretical aspects of the processes of solubilization, extraction and precipitation.
- Preliminary testing. Dry tests: flame tests, preliminary essays.
- Systematic analysis of cations analytical groups.
- Systematic analysis of anions analytical groups.
- analysis of Ions of pharmaceutical interest:
- Analytical reactions of
- Analysis of the anions

Suggested textbooks

D. Harris – Analytical Chemistry - W. H. Freeman and Company

APPLICATIONS

Dr. Alessandro Terrinone (5 credits)

Errors in Chemical Analyses.

Systematic Errors

Random Errors in Chemical Analysis, The Nature of Random Errors

Statistical Treatment of Random Errors

Standard Deviation of Calculated Results

Statistical Data Treatment and Evaluation

Confidence Intervals

Statistical Aids to Hypothesis Testing

Analysis of Variance

Detection of Gross Errors

Sampling, Standardization and Calibration

Analytical Samples and Methods, Sampling, Automated Sample Handling

Standardization and Calibration

Spectrochemical Methods:

Introduction to Spectrochemical Methods

Instruments for Optical Spectrometry

Molecular Absorption Spectrometry, Ultraviolet and Visible Molecular Absorption

Spectroscopy. Infrared Absorption Spectroscopy

Molecular Fluorescence Spectroscopy, Theory of Molecular Fluorescence, Effect of Concentration on Fluorescence Intensity, Fluorescence Instrumentation, Applications of Fluorescence Methods

Atomic Spectroscopy, Origins of Atomic Spectra, Production of Atoms and Ions, Atomic Emission Spectrometry, Atomic Absorption Spectrometry Mass Spectrometry, Principles of Mass

Spectrometry, Mass Spectrometers, Atomic Mass Spectrometry, Molecular Mass Spectrometry Separations:

Introduction to Analytical Separations, chromatographic separations

Gas Chromatography, Instruments for Gas-Liquid Chromatography,

Gas Chromatographic Columns and Stationary Phases, Applications of Gas-Liquid Chromatography, Use of GC/MS to Identify a Drug Metabolite in Blood.

High-Performance Liquid Chromatography, Instrumentation.

Partition Chromatography, Adsorption Chromatography, Ion Chromatography

Size-Exclusion Chromatography.

Comparison of High-Performance Liquid Chromatography and Gas Chromatography

Suggested textbooks

David G Watson: Pharmaceutical Analysis, second Edition, Elsevier

Skoog, West: Fondamenti di chimica analitica, EDISES

Douglas A. Skoog, Fundamentals of Analytical Chemistry 9e, Cengage Learning

PHARMACEUTICAL BIOLOGY AND PHARMACOLOGY 7 CREDITS

Dr. Beatrice Macchi

General principles on drug discovery. Rational drug design and druggable targets, drug discovery and development.

How drugs act: general principles: Evaluation of drug-receptor interaction: Agonist, partial agonist, antagonist, allosteric potentiation, allosteric inhibition, inverse agonist

Biopharmaceuticals and drug targets: Therapeutic monoclonal antibodies, RNA target: The proteasome pathway, Cell cycle checkpoints, Apoptosis: principle of apoptotic mechanisms: Drugs promoting and inhibiting apoptosis, Mitochondria, Metabolism, Interferon, Epigenetic-enzymes, Telomere structures and telomerase:

DNA: nuclear receptors; DNA repair enzymes, Genome Editing: The CRISPR/Cas system. Drug Targets in Neurodegeneration, Autophagy and mTOR system.

Suggested readings

J. L. Medina-Franco, M. A. Giulianotti, G.S. Welmaker, R. A. Houghten. Shifting from the single to the multitarget paradigm in drug discovery. *Drug Discovery Today*. 2013. 18: 495-501.

-Beck A, Wurch T, Bailly C, Corvaia N. Strategies and challenges for the next generation of therapeutic antibodies. *Nat Rev Immunol*. 2010 May;10(5):345-52.

-Rask-Andersen M, Almén MS, Schiöth HB. Trends in the exploitation of novel drug targets. *Nat Rev Drug Discov*. 2011 Aug 1;10(8):579-90.

-Gashaw I, Ellinghaus P, Sommer A, Asadullah K. What makes a good drug target? *Drug Discov Today*. 2012 Feb;17 Suppl:S24-30.

-Watts JK, Corey DR. Silencing disease genes in the laboratory and the clinic. *J Pathol*. 2012 Jan;226(2):365-79.

De Strooper B, Iwatsubo T, Wolfe MS. Presenilin and γ -secretase: Structure, Function and Role in Alzheimer disease. *Cold Spring Harb Perspect Med* 2012 Jan 2(1):a006304

Suggested textbooks

Rang and Dale's Pharmacology Ottava edizione (2016), HP Rang, MM Dale, Ritter JM, Flower RJ, Henderson G. Elsevier

The Cell: A Molecular Approach, Sesta Edizione (2013) Geoffrey M. Cooper and Robert E. Hausman, ASM Press and Sinauer Associates, Inc.

MEDICAL STATISTICS 5 CREDITS

Dr. Simona Iacobelli

Statistics: objects and methods. Collective phenomena, variability, quantification. Statistics in research. Statistics and medicine: Evidence-Based Medicine / Nursing / Prevention.

Elements of descriptive statistics. Basic concepts and terminology; classification of variables and their coding. Summary of the frequency distributions by tables, charts, and summary indexes for position / centrality and variability (arithmetic mean - simple and weighted - median and other quantiles, mode; ranges of variation, standard deviation, variance and coefficient of variation). The statistical indices in relation to the shape of the distribution (symmetry, skewness, multimodality).

Elements of probability theory. Events and basic calculation rules; conditional probability and the concept of independence; Bayes formula. Applications in the problems and in particular in diagnostic tests (sensitivity concepts, specificity, predictive values of the test). Some probability distributions and their use in problems: Binomial, Poisson, Normal.

Elements of frequentist statistical inference. General concepts and the principle of repeated sampling; Distribution of the sample average. Point estimation: main properties of the estimators. Estimation by confidence intervals. Intuitive principles and basic elements of hypothesis testing; type I and type II errors and related parameters, method of rejection regions, calculation, meaning and interpretation of the p-value. Relationship between significance testing and confidence interval.

Applications: CI and T-test on the mean and on the proportion.

Elements of the study of relationships. General concepts (significance vs. relevance, causality and confounding). Applications to the case of independent samples. Cross-tables and Chi-Square test. Measurement of effect: comparison of probabilities between two groups via Risk Ratio and Odds Ratio. T-test for comparison between two means. Correlation coefficient and the regression line. Notions about alternative methods (non-parametric tests/ tests for small samples). Introduction to multivariable regression models.

Some notions regarding the analysis of the occurrence of events in time: rates and Rate Ratio; Survival curves and main tools for survival analysis (Kaplan-Meier method, Log-Rank test, Cox regression). Some notions on the methodology of clinical trials: usefulness of randomization and blinding; main types of designs for comparisons; hypothesis testing in clinical trials. Laboratory measurement: basic statistics on measurement error.

Suggested textbooks

- "An introduction to medical statistics", Bland M, ed. Oxford Medical Publications (or Italian version "Statistica medica", ed. Apogeo)
- "Medical statistics at a glance", Petrie A, Sabin C, Ed.: Wiley-Blackwell

BIOCHEMISTRY 11 CREDITS

Prof. Maria Rosa Ciriolo (6 Credits)

Overview of Intermediary Metabolism. Bioenergetics: The Role of ATP. Nutrition: Digestion and Absorption of Proteins, Lipids and Carbohydrates. Carbohydrates metabolism: assimilation, degradation – Glycolysis reactions and regulation. Galactose, Mannose and Fructose metabolism. Pyruvate destiny. Glycogen metabolism: synthesis, degradation and metabolic regulation, pathologies associated. The Pentose Phosphate Pathway: reactions, physiological implications, regulation, pathologies associated (Favism). Lipid metabolism: assimilation, transport, lipoproteins. Glycerol degradation. Oxidation (alpha, beta and omega) of even and odd fatty acids, saturated and unsaturated, propionyl moiety, metabolic regulation. Ketone bodies. Pyruvate dehydrogenase complex, mechanism, acetyl-CoA production, metabolic regulation. The tricarboxylic acid cycle, reactions and metabolic regulation. Mitochondrial electron transport chain complexes, redox potential, ubiquinone cycle. Oxidative phosphorylation: chemiosmotic theory, F₀F₁ ATP synthase structure and function, energetic yield. Malate/aspartate shuttle, Glycerol 3-phosphate shuttle. Biological Nitrogen fixation. The destiny of amino group of aminoacids: structure and function of transaminases. Glucose/alanine cycle. Urea cycle: reactions and metabolic regulation. Gluconeogenesis. Cori's cycle. Glycoproteins biosynthesis. Fatty acids biosynthesis, elongation, unsaturation and regulation. Triacylglycerols and phospholipids synthesis. Ceramides synthesis. Sphingolipids synthesis. Biosynthesis of Arachidonic acid and other lipids of interest. Leukotrienes synthesis. Biosynthesis of cholesterol and its derivatives. Purines and Pyrimidines synthesis and degradation, synthesis of deoxyribonucleotides and of thymidine. Uric acid production. Pathologies associated with altered purine metabolism and anticancer therapeutic strategies.

Suggested textbooks

Lehninger Principles of Biochemistry
of David L. Nelson and Michael M. Cox

Prof. Gerry Melino (5 credits)

Foundations of Biochemistry. Water. Weak interactions in aqueous systems. Ionization of water, weak acids, weak bases. Buffers. Water as reactant.

Aminoacids: structure and physical-chemical properties.

Peptides and proteins. Peptides charge. Methods to analyze, separate and characterize proteins. Primary structure of proteins. Three dimensional structure of proteins. Protein secondary structures. Protein tertiary structure: motifs, folds and domains. Protein denaturation, folding and disease.

Hemoglobin and Myoglobin: structures, functions, oxygen binding properties and curves.

Enzymes: structure, classification, mechanism of action. Mechanisms of catalysis. Enzyme's kinetics: Michaelis and Menten equation and constant. Enzyme inhibition, reversible, irreversible, competitive, uncompetitive, mixed. Enzyme regulation: non covalent/allosteric, covalent reversible, covalent irreversible.

Water soluble vitamins: structure and function.

Carbohydrates, structures and functions: Monosaccharides and disaccharides. Polysaccharides. Glicoconjugates : Proteoglycans, Glycoproteins and Glycolipids.

Lipids. Storage lipids. Structural lipids in membranes. Sterols. Eicosanoids. Lipid soluble vitamins: structure and functions. Biological membranes and transport. Structure and function of biological membranes

Biosignaling: G protein-coupled receptors and second messengers. Receptor tyrosine kinases, the insulin signaling. Guanylyl cyclases. Regulation of transcription by steroid hormones.

Introduction to bioenergetic and metabolism.

Suggested textbooks

Lehninger Principles of Biochemistry 5th, 6th or 7th Edition
by David L. Nelson (Author), Michael M. Cox (Author)

CHEMISTRY OF EQUILIBRIA 6 CREDITS

Prof. G. Palleschi

Concentrations of the solutions % W/W, W/V, V/V ppm ppb, % in mg/dL.

Equilibria involving acid and bases concept of pH. monoprotic, diprotic and polyprotic acid equilibria. Buffer solutions and hydrolysis. Solubility and solubility product equilibria.

Dependence of the solubility from the pH. Complexation equilibria. Formation constant EDTA equilibria. Redox equilibria Cells and batteries Nernst equation.

Suggested textbooks

Gary Christian: analytical chemistry Piccin or any book of analytical chemistry at university level.

GENERAL PATHOLOGY 8 CREDITS

Prof. Vittorio Colizzi (5 credits)

Prof. Roberto Bei (3 credits)

Cell injury. Cellular stress. Cellular adaptations. Necrosis. Apoptosis.

General features of inflammation: Acute inflammation: historical highlights, vascular changes; cellular events: leukocyte extravasation and phagocytosis. Adhesion molecules involved in the inflammatory response. Chemotaxis. Defects in leukocyte functions. Chemical mediators of inflammation. Outcomes of acute inflammation.

Neoplasia: Definitions. Biology of tumor growth: benign and malignant neoplasms. Molecular basis of cancer. Carcinogenic agents: chemical carcinogenesis. Microbial carcinogenesis: oncogenic DNA viruses, oncogenic RNA viruses.

Liver physiopathology: general features of hepatic diseases. Hepatic failure. Cirrhosis. Portal hypertension. Bilirubin and bile formation. Causes and classification of jaundice. Hereditary hyperbilirubinemias. Cholestasis. Viral hepatitis. Ascites.

Suggested textbooks

Robbins & Cotran, Pathologic Basis of Disease.

Rubin's Pathology: Clinicopathologic Foundations of Medicine.

PLANT BIOCHEMISTRY AND PHYSIOLOGY 4 CREDITS

Prof. Patrizia Aducci

Role of plants in food, environment, drugs, alternative energy resources. Pharmaceuticals and nutraceuticals derived from plants

Organization of the Plant Cell:

Cell Wall, Membranes and Organelles.

Water and Solute Transport:

Water absorption and transport . Passive and Active transport of Solutes. Membrane Transport Processes. Membrane Transport Proteins: Channels, Carriers, ATPases. Translocation of Photosynthates in the Phloem: Phloem loading; The Pressure-Flow Model.

Biochemistry and metabolism

Photosynthesis: the Light Reactions:

Introduction; Organization of the Photosynthetic Apparatus; Mechanism of Electron Transport; Proton Transport and ATP Synthesis; Photoinhibition and Photoprotection.

Photosynthesis: the Carbon Reactions:

The Calvin Cycle: Reactions and Regulation; The C₂ Oxidative Photosynthetic Carbon Cycle; Adaptations of Photosynthesis: The C₄ Carbon Cycle; Crassulacean Acid Metabolism (CAM). Biosynthesis of Starch and Sucrose.

(it is necessary to know and write the reactions and the chemical structures of molecules in the cycles)

Plant Hormones:

Regulatory role and general properties of plant hormones.

Structure, activities and mode of action of Auxin

Suggested textbooks

Taiz, Zeiger, Moller, Murphy

Plant Physiology and Development Fifth Edition 2010

Sinclair Associates Inc Publishers, Sunderland Massachusetts, USA

MEDICINAL PLANTS 4 CREDITS

Prof. Antonella Canini (1 credit)

Dr. Angelo Gismondi (3 credits)

Plant cell, plant tissues (structure and function), plant metabolism, secondary metabolites (structure, classification and function), extraction and analytical methods of plant compounds, Angiosperms (classification, flower, fruit), plant bioactive molecules: source, geographical distribution of the origin plants, effects on animal and humans (Apocynaceae, Papaveraceae, Menispermaceae, Cannabaceae, Salicaceae, Solanaceae, Asteraceae, Rubiaceae, Sterculiaceae, Erythroxylaceae, Malvaceae, Scrophulariaceae, Rutaceae, Leguminosae, Zingiberaceae, Orchidaceae, Liliaceae, Aloeaceae, Iridaceae, Lamiaceae, Theaceae, Araliaceae, Hypericaceae, Valerianaceae, Apiaceae, Loganiaceae, Cactaceae, Dioscoreaceae, Gimnosperme, Fungi).

Suggested textbooks

Chemistry, Biosynthesis And Bioactivity Of Natural Compounds. Iii Edition. Piccin. Paul M. Dewick

DRUG ANALYSIS II 12 CREDITS

Module I

Dr. Gaetano Barbato (6 credits)

1. Elementary Analysis (HCN analysis, Calcination, minimum formula) 2. Signal digitalization 3. IR spectroscopy, spectra analysis 4. Mass Spectrometry, spectra analysis 5. NMR spectroscopy, spectra analysis 6. Analysis strategy of unknown compounds by the combined use of points 1-5. Laboratories: Analysis of 8-10 compounds pharmacologically active with the studied spectroscopies.

Suggested textbooks

The spectrometric identification of organic compounds. Silverstein, Webster, Kiemle. 7th edition (2005) or more recent, Wiley & sons. ISBN-10: 0471393622

Books for reference, not to buy, but where to find different and complementary explanations of what seen at lesson. You can find these books at the University library under the codes indicated.

Fundamentals of molecular spectroscopy. C.N. Banwell, McGraw Hill. [F33-0002]* (Chap. #1-3,5,6,7)**

Biophysical chemistry. Vol. II. Cantor & Schimmell. Freeman & Co. [574-19-CAN]* (Chap. #7,8,9)**

Instrumental Methods of Analysis. Willard Hobart H. 7nth edition. Wadsworth Publishing Co.[543-08-WIL]* (Chap #5-7, 11, 15, 16)**

Module II

Dr. Heiko Lange (6 credits)

The teaching module will consist of lessons in which the theory behind the various techniques used for isolating and characterising organic active ingredients is covered, and a practical part, in which the theoretically discussed separation techniques and wet-chemical analyses are performed in the lab:

Topics covered in detail: Survey of functional groups in drug-like small molecules, organoleptic analyses/scientific description of chemical samples, analysis strategies, separation techniques, determination of physical properties of a sample, qualitative wet chemical analysis methods targeting elements and specific functional groups, analyses and interpretation of scientific data sets, 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). Antibacterial agents. Antiviral agents. Anticancer agents. 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

summaries of course program and laboratory experiences

PHARMACEUTICAL AND TOXICOLOGICAL CHEMISTRY (I) 14 CREDITS

PROF. ORAZIO NICOLOTTI

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). Antibacterial agents. Antiviral agents. Anticancer agents. 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 (6th edition)
Slides shown at lessons

GENERAL PHARMACOLOGY, TOXICOLOGY AND PHARMACOGENOMICS

12 CREDITS

Prof. Robert Nistico (10 credits)

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. Synaptic plasticity.

Principles of toxicology. Drug addiction.

Suggested textbooks

Goodman and Gilman: Le basi farmacologiche della terapia, XII ed. Zanichelli
Bertram Katzung, Farmacologia generale e clinica, XII ed. Piccin-Nuova Libreria
Casarett & Doull: Elementi di tossicologia, VII ed. CEA

PHARMACOGENOMICS

Prof. Paola Borgiani (2 credits)

Definitions of Key Terms and Basic genetics Principles.

The genetic inter-individual variability and the concepts of polymorphism and mutation. Principal types of genetic polymorphisms. Haplotypes.

Methodological Approaches to study inter-individual genetic variability

The role of genetic variability in the response to drugs, both in terms of efficacy and toxicity

Different types of genetic testing and their correct use in clinical practice.

The definitions of pharmacogenetics/pharmacogenomics (PGt, PGx)

Pharmacogenetics testing and clinical utility: various illustrative examples in details of application of Pharmacogenomics in safety and efficacy of drugs in different fields:

-Oncology (Irinotecan, 5FU, Tamoxifen, Cetuximab, Herbitux)

-Cardiovascular diseases (Warfarin, Statins, Clopidogrel)

-Infectious diseases (Hiv: Abacavir, Nevirapine, HCV: Peg Interferon)

- Therapy of pain and anesthesia

Applications of PGx in Drug Discovery and Clinical Trials. From Genotyping to Drug Label-Challenges Pharmacogenomics; The Regulatory Environment .

Suggested textbooks

PDF Files By Professor and advised scientific papers on the argument

PHYSIOLOGY 7 CREDITS

Prof. Cristina Zona

Cytoplasmic membrane structure and functions. Action potential and its propagation. Electrical and chemical synapses. Neurotransmitters and their receptors. Neuromuscular junction. Molecular basis of skeletal muscle contraction. Cardiac muscle and smooth muscle. Pacemaker activity of the heart. Systole and diastole. The ECG. Relationships between pressure, flow and resistance. The medullary cardiovascular center. The blood. Gas exchange and transport. Control of ventilation. The Urinary system. The glomerular filtration, the tubular reabsorption and secretion. RAA system. The Nervous System. Cerebral cortex, basal nuclei, thalamus and hypothalamus, cerebellum, brain stem and spinal cord. Sensory perception and motor control. Sympathetic and parasympathetic systems. Regulation of digestive function. The endocrine system. The hormones and the hypothalamus.

Suggested textbooks

Human Physiology: from cells to systems, Author: Lauralee Sherwood, Publisher: Brooks Cole
Human Physiology: An Integrated Approach , D.U. Silverthorn

INTERNAL MEDICINE AND DERMATOPHARMACOLOGY 6 CREDITS

Prof. Manfredi Tesauro (3 credits)

Endothelial function, Atherosclerosis, Heart failure, Coronary syndrome, Hypertension, Diabetes Insulin resistance, Metabolic syndrome, Respiratory diseases, Liver cirrhosis, Inflammatory bowel diseases, Renal disorders ,Thyroid disorders, Osteoporosis.

Suggested textbooks

Notes from the lessons

Prof. Steven Paul Nisticò (3 credits)

Skin anatomy and function, Inflammatory and Oncological aspects, Cosmetology, dermatopharmacology, galenic preparations

Suggested textbooks

Lecture Slides

Rook Textbook of Dermatology

PHARMACEUTICAL AND TOXICOLOGICAL CHEMISTRY 2 12 CREDITS

Dr. Lorenzo Botta

General Section: Introduction, Receptor, Pharmacophore.

Special Section: Sedative–Hypnotics, Antiepilepsy drugs, Local anesthetics, Calcium channel blockers, Antiarrhythmics, Narcotic analgesics, Anti-inflammatories, Steroidal anti-inflammatory drugs, Cardiotonics, Drugs against angina, Adrenergic drugs, Cholinergics, Drugs acting on the renin-angiotensin system, Diuretics, Antihistamine drugs, Drugs for treatment of peptic ulcer, Neuroleptics, Antidepressants, Anti-Parkinson's drugs, CNS stimulants, Anti-obesity drugs, Antimigraine drugs, Antilipemics drugs

Suggested textbooks

Foye (Principles of Medicinal Chemistry - Piccin)

Wilson (Medicinal pharmaceutical Organic Chemistry - Delgado)

Patrick (Introduction to pharmaceutical chemistry)

Wermuth (The applications of Pharmaceutical Chemistry)

Burger (Medicinal Chemistry 5 volumes)

Goodman & Gilman (Pharmacology)

PHARMACEUTICAL TECHNOLOGIES 10 CREDITS

Module I

Prof. Franco Alhaique (5 credits)

Introduction to biopharmaceutics Blood levels and therapeutic effects. Routes of administration. Mechanisms of drug dissolution and absorption. Compartment models and pharmacokinetic parameters. Apparent distribution volume. Drug-protein interaction. Drug stability. Sterilization. Bacterial endotoxins. Limulus test. Glass for pharmaceutical uses. Isotonic and iso-osmotic solutions and calculations. Alcohol in pharmaceutical forms. Lyophilization. Interfacial phenomena. Surface tension. Surfactants. Wetting. Micelles. Disperse systems: emulsions and suspensions. Basic principles of rheology. Classification of dosage forms. An overview on the various dosage forms and their control.

Innovative dosage forms. Modified release dosage forms. Drug targeting. Lab works (Galenic preparation laboratory): preparation and control of the most usual pharmaceutical dosage forms. Labelling and price of the preparations.

Suggested textbooks

"Pharmaceutics: The science of Dosage Form Design", Edited by M.E.Aulton, Churchill Livingstone, N.Y.

"Principi di tecnologia farmaceutica" (Second Edition) P.Colombo, F. Alhaique, C. Caramella, B. Conti, A. Gazzaniga, E.Vidale, Casa Editrice Ambrosiana

"Physical Pharmacy", A.Martin Ed., Williams & Wilkins, Baltimore

Farmacopea Italiana (ultima edizione e supplementi)

Module II

Dr. Gabriella De Martino (5 credits)

Operazioni tecnologiche di base:

Filtrazione

Sterilizzazione

Distillazione

Stabilità, stabilizzazione e conservazione dei medicinali

Altre forme farmaceutiche:

Preparazioni oftalmiche, Preparazioni auricolari, Preparazioni nasali, Preparazioni inalatorie,

Preparazioni rettali e vaginali,

Preparati da droghe vegetali,

Preparazioni omeopatiche,

Radiofarmaci,

Medicinali veterinari

Basic technologic operations: Filtration, Sterilization, Distillation

Drug stability

Pharmaceutical forms:
Eye preparations
Ear preparation
Nasal preparation
Inhalatory preparation
Rectal and vaginal preparation
Plant drugs
Homeopathic drugs
Radiopharmaceuticals
Veterinary drugs

Suggested textbooks

Lab works (Galenic preparation laboratory): preparation and control of the most usual pharmaceutical dosage forms. Labelling and price of preparation

SPECIAL PHARMACOLOGY AND THERAPY 10 CREDITS

PROF. TBA

Cardiovascular Pharmacology: Inotropic Drugs, Diuretics, Vasodilators, Antihypertensive drugs, Antiarrhythmic drugs, Antiplatelet drugs, Thrombolytic drugs, Drugs in the treatment of dyslipidemia. Antiinflammatory drugs: NSAIDs, Cortisonics, Drugs used for pain relief, DMARDs. Drugs used in Respiratory Diseases: Broncodilators and antiasthma, Mucolytics. Drugs of intestinal tract: Inhibitors of gastric K⁺ pump and of H₂ receptor, Drugs regulating intestinal tone. Drugs used in treating Diabetes Mellitus. Antigout drugs and Xantine oxidase inhibitors

Suggested textbooks

Manual of Pharmacology and Therapeutics, Goodman&Gilman's

NEUROPSYCHOPHARMACOLOGY 8 CREDITS

Prof. Robert Nisticò

Basic mechanisms of synaptic transmission. Adrenergic and cholinergic agents. Treatment of Parkinson's disease, Alzheimer's disease and multiple sclerosis. Treatment of affective and anxiety disorders. Pharmacotherapy of psychotic illness and mania. Antiepileptic agents. General and local anesthetics. Antimigraine agents and drugs of abuse.

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

CHEMOTHERAPY 8 CREDITS

Prof. Grazia Graziani

Anti-microbial chemotherapy: general principles of anti-microbial chemotherapy and resistance mechanisms; antibacterial agents; antimycobacterial agents; antifungal agents; antiviral drugs; antiprotozoal drugs; antimalarial agents; antihelminthic drugs.

Anti-cancer chemotherapy: general principles of anti-cancer chemotherapy and resistance mechanisms; cytotoxic agents; differentiating agents; targeted therapies; hormonal agents.

Suggested textbooks

Goodman and Gilman The Pharmacological Basis of Therapeutics, dodicesima edizione, Laurence L Brunton, Bruce A. Chabner, Björn C. Knollmann, McGraw Hill.

Goodman and Gilman Manual of Pharmacology and Therapeutics, Seconda Edizione, Randa Hilal-Dandan and Laurence L Brunton, McGraw Hill.

LINKS: www.ncbi.nlm.nih.gov/pubmed; ecdc.europa.eu/en/activities/surveillance/EARS-Net/publications/Pages/documents.aspx; <http://app.esac.ua.ac.be/public/>;
<http://www.who.int/topics/en/>

ITALIAN AND EUROPEAN PHARMACEUTICAL LEGISLATION AND COMMERCIAL LAW 12 CREDITS

Dr. Emanuele Cesta (5 credits)

1. Marketing Authorization (MA) of a pharmaceutical product: clinical trials, granting (national, MR, DC or centralized procedure), reimbursement class (A, H, C, Cnn) and prescription regime, suspension/revocation, expiration.
2. Pharmacovigilance (adverse reactions, purpose, roles, forms)
3. Quality defects and precautionary measures for health protection; manufacturing and distribution dysfunctions, shortages and unavailability of medicines, import, reports and controls.
4. Pharmaceutical crime (counterfeiting, illegal drugs, on line purchase, illegal import)

Suggested textbooks

Handouts and PPT presentations provided by the teacher .

EUROPEAN PHARMACEUTICAL LEGISLATION

Dr. Armando Magrelli (5 credits)

The pharmaceutical legislative framework is made up by Directives and Regulations as the basis for a general guideline for the EU community with the scope of setting up “harmonized standards” throughout the European Union and at the same time maintain an appropriate level of protection for public health.

The course wants to deeply analyse the rules that governing the Pharmaceutical Field, starting to the patent protection of new inventions, and ending with the introduction of the medicinal products on the market.

Suggested textbooks

Sally Shorthose ed., Bird & Bird LLP, Guide to EU Pharmaceutical Regulatory Law, Wolters Kluwer, 2013.

COMMERCIAL LAW

Prof. Gianluca Perone (2 credits)

Unfair business-to-consumer commercial practises in the internal market and the pharmaceutical sector; Advertising of medicinal products for human use; Patent medicines and legal protection. In particular Community patent in the Decision 2011/62/EU; Industrial inventions; pharmaceutical inventions;

The legal protection of biotechnological inventions; Patents and vegetable crop diversity

Suggested textbooks

DIETISTIC SCIENCES AND FOOD CHEMISTRY 8 CREDITS

Prof. Antonino De Lorenzo (3 credits)

Assessment of nutritional status and energy requirements. Principles of diet therapy.

Nutrition and non communicable diseases. Principles of nutritional genomics.

1) Assessment of nutritional status and body composition

1.1 Family and individual history;

1.2 Anthropometric measurements; anthropometric measures:

- Measurement of weight (kg), height (cm) for calculating the $BMI = \frac{\text{body weight (Kg)}}{\text{height (m)}^2}$;

1.3 Determination of water compartments with methodical BIA (bioelectrical impedance): Resistance, reactance, impedance and phase angle at 50 kHz frequency were measured using a BIA phase sensitive system

1.4 Assessment of body composition:

1.4.1 Measurement tricipitale folds, iliac and subscapular (Plicometry)

1.4.2 Evaluation of body composition by DXA (dual energy X-ray absorbimetry) (i-DXA, GE Medical Systems, Milwaukee, WI, USA): determination of levels of total body lean mass (TBLean), total body fat mass (TBFat) and total body bone mass (TBBone):

Appendicular Scheletar Muscle Mass Index determination;

1.3 Nutritional survey of dietary habits (Food Frequency Questionnair, Simplified Nutritional Appetite Questionnaire, i.e. SNAQ questionnaire);

1.4 Determination of energy expenditure (indirect calorimetry): respiratory quotients, basal metabolism, energy expenditure;

1.5 Assessment of psychological profile and eating behaviour

2) Nutrigenetic and Nutrigenomic:

2.1 Role of genetic polymorphisms in the cross-talk between adipose tissue, muscle tissue and bone to evaluate the risk of obesity, sarcopenia, osteoporosis, metabolic syndrome, cardiovascular diseases.

2.2 Assessment of gene expression of gene related to obesity, sarcopenia, osteoporosis, cardiovascular diseases, inflammation and oxidative stress.

3) definition of phenotypes:

3.1 Normal weight lean

3.2 Normal weight obese, with or without metabolic syndrome

3.3 Obese, with or without metabolic syndrome

4) Dietary treatment for a personalized medicine

5) Clinical case and practice

Suggested textbooks

Didactic material will be provided to the student.

FOOD CHEMISTRY

Prof. Laura di Rienzo (5 credits)

Program of the course

Foods: main composition in terms of proteins, fats and carbohydrates. Food energy as calories.

Food safety and food security: Nutrient and Hazard analysis and critical control point.

Microbial, chemical and physical hazard. Chemical preservatives. Dimethoate and Glyphosate. Foods and their conservation. The mechanism of alteration. Water activity: the role of water in food conservation. pH and Temperature control.

The peroxidation process.

The bioactive compound of the Mediterranean Diet. The Mediterranean Adequacy Index.

The Nutritional Quality Indexes.

The composition of olive oil. Fats, butter, oil and hydrogenated fats.

The composition of wine, and effects on human health.

The composition of tomato, and effects on human health.

The composition of nut (hazelnut and chestnut), and effects on human health.

The composition of chilly pepper, and effects on human health.

The composition of cocoa, and effects on human health.

Western Diet and dependence; sugar, salt and fat.

Role of antioxidant in organic compound, and effects on human health.

Microbiota and role of probiotics.

Fibers in foods. Starch and cellulose. Amilose and amilopectin. Structure and hydration properties.

The browning of foods and the Maillard reaction: Enzymatic browning. Browning by caramelization. The Maillard reaction. The Amadori products. The reaction mechanism.

Nutritional consequences of the Maillard reaction. The melanoidins.

Aromatic amines from roasted meat and their mutagenicity.

Ames test. Acrolein production in deep frying. Acrylamide in potatoes.

Additives: gelificants, thickeners and emulsifiers. Natural or synthetic sweeteners. The supercritical viscosity (ketchup). Emulsions and foams and their evolution upon time.

Suggested textbooks

Didactic material will be provided to the student.

OPTIONAL COURSES

THE AUTHORIZATION OF MEDICINAL PRODUCTS IN THE EU

5 CREDITS

Prof.

1. Part 1 EU Directives and Regulations on Medicinal products

General Aspects of the EU legislation – covering Named patient basis/compassionate use/ public health authorisations, industrial manufacturing, national marketing authorisations, decentralised and mutual recognition, referral procedures, arbitration at the European Medicines Agency, CHMP.

2. Part 2 EU Directives and Regulations on Medicinal products

Pharmacovigilance regulations and obligations

3. Part 3 EU Directives and Regulations on Medicinal products

Risk Management Plans and Advertising of Medicinal products issues and case examples

4. The EU regulatory Framework on Biosimilars

General aspects on Biosimilars/Quality-clinical programs and regulatory updates.

5. How to assess a medicinal product including an OTC.

6. General aspects on what assessors do when evaluating risk/benefit of medicines and OTC

7. Part 1 the well established use licensing of medicinal products

Extrapolation of literature data to support a marketing authorisation

8. Does the Regulator face ethical issues

Updates on the clinical trial regulation and a case example of ECMO.

9. Part I pre-clinical data required to support a medicine's safety - Ion channel of excitable membranes

General aspects of receptors and electrophysiology

10. Part 2 – pre-clinical data required to support a medicine’s safety - Applying basic concepts to understand clinical relevance

11. Part 3 - pre-clinical data required to support a medicine’s safety – ICHS7A & ICHS7B explained

General discussion on how industry assesses cardiac safety of medicines in development.

12. Part 4 - pre-clinical data required to support a medicine’s safety – juvenile toxicology studies

13. Part 5 - pre-clinical data required to support a medicine’s safety – Non-Clinical Investigation of the Dependence Potential of Medicinal Products

14. Part 6 - data required to support a medicine’s safety – Biotech products

15. Part 7- data required to support a medicine’s safety – anticancer/DSMBs/Extrapolation of Animal data.

16. Licensing of Generics - Understanding Bioequivalence studies and the analytical method part 1

17. Licensing of Generics - Understanding Bioequivalence studies and the analytical method part 2

GENDER MEDICINE 3 CREDITS

Prof. Walter Malorni

The study of gender-specific medicine in health and disease

1. Gender-specific medicine: a new perspective in the field of biomedicine

General aspects of the role of sex and gender in health and disease

2. Why medicine must take into account gender disparity: disequities

Disequities in care and cure

3. Biological issues I: preclinical studies and pathogenetic issues

4. Biological issues I: preclinical studies and pathogenetic issues

On the cellular and molecular mechanisms of gender and sex disparity

5. Epidemiological and biological issues I: immunity

Immune system and gender differences: a milestone of gender medicine

6. Epidemiological and biological issues II: cancer

Various forms of cancers display gender differences in the incidence and response to therapy

7. Epidemiological and biological issues III: infectious diseases

Differences in the infections, mainly viral infections, will be treated

8. Epidemiological and biological issues IV: degenerative and chronic diseases

Metabolic diseases, such as diabetes, and neurodegenerative diseases, including dementia, will be treated

9. Literacy and communication strategies with particular attention to gender medicine

CLINICAL MONITORING 2 CREDITS

Prof. Paolo Primiero

Feasibility and Site Selection: site ID, Pre Study Visit, site facility tour, essential Study documents/Trial Master File (TMF), start up activities, Investigator's meeting.

Site Initiation: site staff training, GCP refresh, informed consent process revision, Study procedures and correct use of the supplies/equipment, check of Study materials.

Interim Monitoring/Site Management: source data verification (SDV), ALCOA definition, patient file and Case Report Form (CRF), Study tools.

Site Closure.

Study Management. Clinical Monitoring Team. Clinical Monitor Communication with the Site Staff and Study Staff. Monitoring Strategies. Risk Based Quality Management.

[Suggested textbooks](#)

Powerpoint presentations
Lecture notes provided by Professor

CRO (CONTRACT RESEARCH ORGANIZATION) DEVELOPMENTS AND MANAGEMENT 1 CREDIT

Prof. Luigi Godi

The Italian CRO Decree will be introduced as well as how the clinical research responsibilities will be shared between CRO and Sponsor.

Main concepts of Business Development, marketing, and quoting will be presented to the Students offering them some Team exercises too.

Main concepts of Human Resources in the CRO will be introduced too: routine training, performance review and carrier development in the CRO will be also faced.

Suggested textbooks

The slides sets used during the frontal lessons will be available for the Students.

Moreover, to improve knowledge on different topics, please see in:

www.farindustria.it

www.clinicaltrials.gov

www.clinicaltrialsregister.eu

www.aicro.it

www.oss-sper-clin.agenziafarmaco.it

CLINICAL TRIALS 1 CREDIT

Prof. Carlo Tomino

Making a Clinical Trial: Protocol structure, role and responsibility of the involved actors

Clinical Trials: general procedures and laws in force

The Drug Competent authority in Italy: structure and tasks

Job opportunity for chemists within regulatory field

Suggested textbooks

Slides and literature will be provided to the students.

