M.Tech. Biotechnology

S.No.	Title	Credits
	SEMESTER ONE	
1	Biochemistry	3
2	Cell and Molecular Biology	3
3	Introduction to Engineering Principles	3
4	Microbiology	2
5	Plant and Animal Cell Technology	2
6	Basics of Mathematics and Statistics	2
7	Basics of Chemistry and Physics	2
8	Laboratory I: Biochemistry and Analytical Techniques	4
9	Laboratory II: Microbiology	4
	TOTAL	25
	SEMESTER TWO	
1	Genetic Engineering	3
2	Immunology	3
3	Bioprocess Engineering and Technology	3
4	Downstream Processing in Biotechnology	3
5	Bioreactor Operations	3
6	Computational Biology	3
7	Laboratory III: Molecular Biology and Genetic Engineering	4
8	Laboratory IV: Immunology	3
	TOTAL	25
	SEMESTER THREE	
1	Bioprocess Equipment Design and Economics	3
2	Bioentrepreneurship	3
3	Instrumentation and Control	2
4	Research Methodology and Scientific Communication Skills	2
5	Intellectual Property Rights, Biosafety and Bioethics	2
6	Project Proposal Preparation and Presentation	2
7	Laboratory V: Downstream Processing in Biotechnology	2
8	Dissertation	6
9	Elective	2
	TOTAL	24
	SEMESTER FOUR	
1	Dissertation	20
2	Elective	2
	TOTAL	22
	TOTAL CREDITS	96

Recommended Electives:

1. Bioreaction Engineering | 2. Computational Programming | 3. Environmental Biotechnology | 4. Enzyme Engineering and Technology | 5. Metabolic and Systems Biology | 6. Medical Devices | 7. Molecular Diagnostics | 8. Nanobiotechnology | 9. Production of Biotherapeutics | 10. OMICS Technologies

Semester One

Biochemistry

Credits

3

Course Objectives

The objectives of this course are to build upon undergraduate level knowledge of biochemical principles with specific emphasis on different metabolic pathways. The course shall make the students aware of various disease pathologies within the context of each topic.

Student Learning Outcomes

On completion of this course, students should be able to:

- Gain fundamental knowledge in biochemistry;
- Understand the molecular basis of various pathological conditions from the perspective of biochemical reactions.

Unit I

Protein structure

7 lectures

Chemical basis of life: Miller-Urey experiment, abiotic formation of amino acid oligomers, composition of living matter; Water – properties of water, essential role of water for life on earth pH, buffer, maintenance of blood pH and pH of gastric juice, pH optima of different enzymes (pepsin, trypsin and alkaline phosphatase), ionization and hydrophobicity, emergent properties of biomolecules in water, biomolecular hierarchy, macromolecules, molecular assemblies; Structure-function relationships: amino acids – structure and functional group properties, peptides and covalent structure of proteins, elucidation of primary and higher order structures, Ramachandran plot, evolution of protein structure, protein degradation and introduction to molecular pathways controlling protein degradation, structure-function relationships in model proteins like ribonuclease A, myoglobin, hemoglobin, chymotrypsin *etc.*; basic principles of protein purification; tools to characterize expressed proteins; Protein folding: Anfinsen's Dogma, Levinthal paradox, cooperativity in protein folding, free energy landscape of protein folding and pathways of protein folding, molten globule state, chaperons, diseases associated with protein folding, introduction to molecular dynamic simulation.

Unit II

Enzyme kinetics

6 lectures

Enzyme catalysis – general principles of catalysis; quantitation of enzyme activity and efficiency; enzyme characterization and Michaelis-Menten kinetics; relevance of enzymes in metabolic regulation, activation, inhibition and covalent modification; single substrate enzymes; concept of catalytic antibodies; catalytic strategies with specific examples of proteases, carbonic anhydrases, restriction enzymes and nucleoside monophosphate kinase; regulatory strategies with specific example of hemoglobin; isozymes; role of covalent modification in enzymatic activity; zymogens.

Unit III

Glycobiology

2 lectures

Sugars-mono, di, and polysaccharides with specific reference to glycogen, amylose and cellulose, glycosylation of other biomolecules-glycoproteins and glycolipids; lipids- structure and properties of important members of storage and membrane lipids; lipoproteins.

Unit IV

Structure and functions of DNA, RNA and Lipids

3 lectures

Self-assembly of lipids, micelle, biomembrane organization - sidedness and function; membrane bound proteins - structure, properties and function; transport phenomena; nucleosides, nucleotides, nucleic acids - structure, a historical perspective leading up to the proposition of DNA double helical structure; difference in RNA and DNA structure and their importance in evolution of DNA as the genetic material.

Unit V

Bio-energetics

8 lectures

Bioenergetics-basic principles; equilibria and concept of free energy; coupled interconnecting reactions in metabolism; oxidation of carbon fuels; recurring motifs in metabolism; Introduction to GPCR, Inositol/DAG//PKC and Ca++ signaling pathways; glycolysis and gluconeogenesis; reciprocal regulations and non-carbohydrate sources

of glucose; Citric acid cycle, entry to citric acid cycle, citric acid cycle as a source of biosynthetic precursors; Oxidative phosphorylation; importance of electron transfer in oxidative phosphorylation; F_1-F_0 ATP Synthase; shuttles across mitochondria; regulation of oxidative phosphorylation; Photosynthesis – chloroplasts and two photosystems; proton gradient across thylakoid membrane.

Unit VI

Role of vitamins & cofactors in metabolism

12 lectures

Calvin cycle and pentose phosphate pathway; glycogen metabolism, reciprocal control of glycogen synthesis and breakdown, roles of epinephrine and glucagon and insulin in glycogen metabolism; Fatty acid metabolism; protein turnover and amino acid catabolism; nucleotide biosynthesis; biosynthesis of membrane lipids and sterols with specific emphasis on cholesterol metabolism and mevalonate pathway; elucidation of metabolic pathways; logic and integration of central metabolism; entry/ exit of various biomolecules from central pathways; principles of metabolic regulation; steps for regulation; TOR (target of rapamycin) & autophagy regulation in relation to C & N metabolism, starvation responses and insulin signaling.

Recommended Textbooks and References:

1. Stryer, L. (2015). *Biochemistry*. (8th ed.) New York: Freeman.
2. Lehninger, A. L. (2012). *Principles of Biochemistry* (6th ed.). New York, NY: Worth.
3. Voet, D., & Voet, J. G. (2016). *Biochemistry* (5th ed.). Hoboken, NJ: J. Wiley & Sons.
4. Dobson, C. M. (2003). *Protein Folding and Misfolding*. Nature, 426(6968), 884-890. doi:10.1038/nature02261.
5. Richards, F. M. (1991). *The Protein Folding Problem*. Scientific American, 264(1), 54-63. doi:10.1038/scientificamerican0191-54.

Cell and Molecular Biology

Credits

3

Course Objectives

The objectives of this course are to sensitize the students to the fact that as we go down the scale of magnitude from cells to organelles to molecules, the understanding of various biological processes becomes deeper and inclusive.

Student Learning Outcomes

Student should be equipped to understand three fundamental aspects in biological phenomena: a) what to seek; b) how to seek; c) why to seek?

Unit I

Dynamic organization of cell

6 lectures

Universal features of cells; cell chemistry and biosynthesis: chemical organization of cells; internal organization of the cell - cell membranes: structure of cell membranes and concepts related to compartmentalization in eukaryotic cells; intracellular organelles: endoplasmic reticulum and Golgi apparatus, lysosomes and peroxisomes, ribosomes, cellular cytoskeleton, mitochondria, chloroplasts and cell energetics; nuclear compartment: nucleus, nucleolus and chromosomes.

Unit II

Chromatin structure and dynamics

12 lectures

Chromatin organization - histone and DNA interactome: structure and assembly of eukaryotic and prokaryotic DNA polymerases, DNA-replication, repair and recombination; chromatin control: gene transcription and silencing by chromatin-Writers,-Readers and –Erasers; Transcriptional control: Structure and assembly of eukaryotic and prokaryotic RNA Polymerases, promoters and enhancers, transcription factors as activators and repressors, trancriptional initiation, elongation and termination; post-transcriptional control: splicing and addition of cap and tail, mRNA flow through nuclear envelope into cytoplasm, breakdown of selective and specific mRNAs through

interference by small non-coding RNAs (miRNAs and siRNAs), protein translation machinery, ribosomes-composition and assembly; universal genetic codes, degeneracy of codons, Wobble hypothesis; Iso-accepting tRNA; mechanism of initiation, elongation and termination; co- and post-translational modifications, mitochondrial genetic code.

Unit III
Cellular signalling, transport and trafficking
3 lectures

Molecular mechanisms of membrane transport, nuclear transport, transport across mitochondria and chloroplasts; intracellular vesicular trafficking from endoplasmic reticulum through Golgi apparatus to lysosomes/cell exterior.

Unit IV
Cellular processes
8 lectures

Cell cycle and its regulation; cell division: mitosis, meiosis and cytokinesis; cell differentiation: stem cells, their differentiation into different cell types and organization into specialized tissues; cell-ECM and cell-cell interactions; cell receptors and trans-membrane signalling; cell motility and migration; cell death: different modes of cell death and their regulation.

Unit V
Manipulating and studying cells
3 lectures

Isolation of cells and basics of cell culture; observing cells under a microscope, different types of microscopy; analyzing and manipulating DNA, RNA and proteins.

Unit V
Genome instability and cell transformation
8 lectures

Mutations, proto-oncogenes, oncogenes and tumour suppressor genes, physical, chemical and biological mutagens; types of mutations; intra-genic and inter-genic suppression; transpositions- transposable genetic elements in prokaryotes and eukaryotes, role of transposons in genome; viral and cellular oncogenes; tumor suppressor genes; structure, function and mechanism of action; activation and suppression of tumor suppressor genes; oncogenes as transcriptional activators.

Recommended Textbooks and References:

1. Alberts, B., Johnson, A., Lewis, J., Raff, M., Roberts, K., & Walter, P. (2002). *Molecular Biology of the Cell*. New York: Garland Science.
2. Lodish, H. F. (2000). *Molecular Cell Biology*. New York: W.H. Freeman.
3. Krebs, J. E., Lewin, B., Kilpatrick, S. T., & Goldstein, E. S. (2014). *Lewin's Genes XI*. Burlington, MA: Jones & Bartlett Learning.
4. Cooper, G. M., & Hausman, R. E. (2009). *The Cell: a Molecular Approach*. Washington: ASM; Sunderland.
5. Hardin, J., Bertoni, G., Kleinsmith, L. J., & Becker, W. M. (2012). *Becker's World of the Cell*. Boston: Benjamin Cummings.
6. Watson, J. D. (1987). *Molecular Biology of the Gene* (7th ed.). Menlo Park, CA: Benjamin/Cummings.

Introduction to Engineering Principles

Credits
3

Course Objectives

The objectives of this course are to provide an introduction to the essentials of material and energy balances, properties of materials and transport phenomena.

Student Learning Outcomes

Students should be able to execute material and energy balances over a variety of biochemical systems and model systems which simultaneously involve momentum, heat and mass transport.

Unit I

Energy and material balances

6 lectures

Unit operations and unit processes: historical and recent developments in chemical engineering; Process variables and degrees of freedom; Differential and integral balances; Lumped and distributed balances; Balances in systems involving physical changes.

Unit II

Steady state energy and material balances

8 lectures

Balances in reacting systems; Balances in systems involving recycle, purge and bypass; Computer aided calculations; Generalization to unsteady state balances.

Unit III

Properties of substances

6 lectures

Single component and multicomponent systems; Single and multiphase systems.

Unit IV

Introduction to transport phenomena: momentum transfer

10 lectures

Viscosity; Molecular theory of Gases and Liquids; Shell balance: Falling film, Circular tube; Equations of Change for isothermal systems: Continuity, Motion, Energy, Substantial derivatives; Unidirectional flows: Pipe flow, Variable viscosity falling film, Couette viscometer, Rotating Sphere; Unsteady flows: Startup Plate flow, Parallel plates *etc.*

Unit V

Introduction to transport phenomena: heat and mass transfer

10 lectures

Thermal conductivity and mechanism of energy transport; Shell energy balances and temperature distributions in solids and laminar flow; Diffusivity and the mechanisms of mass transport; Concentration distributions in solids and laminar flow; Equations of change for multicomponent systems; Introduction to the concept of heat and mass transfer coefficients; Dimensional Analysis (Buckingham Pi theorem).

Recommended Textbooks and References:

1. R.M. Felder and R.W. Rousseau, (2015) *Elementary Principles of Chemical Processes*, 4th Edition, J. Wiley, New York.
2. D.M.Himmelblau, (2003), *Basic Principles and Calculations in Chemical Engineering*, 7th Edition, Prentice Hall of India. New Delhi.
3. B.I. Bhatt and S.M.Vora, (1996)., *Stoichiometry,* 3rd Edition, Tata McGraw Hill. New Delhi.
4. R. B. Bird *et al.*, (2006), *Transport Phenomena*, 2nd Edition, Wiley

Microbiology

Credits

2

Course Objectives

The objectives of this course are to introduce students to the field of microbiology with emphasis on microbial diversity, morphology , physiology and nutrition, methods for control of microbes and host- microbe interactions.

Student Learning Outcomes

On completion of this course, students should be able to:

- Identify the major categories of microorganisms and understand their classification, diversity, and ubiquity;
- Describe the structural, physiological, and genetic similarities and differences of the major categories of microorganisms;
- Demonstrate how to control microbial growth;
- Evaluate the interactions between microbes, hosts and environment.

Unit I
Microbial characteristics
6 lectures

Introduction to microbiology and microbes, history & scope of microbiology, morphology, structure, growth and nutrition of bacteria, bacterial growth curve, bacterial culture methods; bacterial genetics: mutation and recombination in bacteria, plasmids, transformation, transduction and conjugation; antimicrobial resistance.

Unit II
Microbial diversity
5 lectures

Microbial taxonomy and evolution of diversity, classification of microorganisms, criteria for classification; classification of bacteria; Cyanobacteria, acetic acid bacteria, Pseudomonads, lactic and propionic acid bacteria, endospore forming bacteria, Mycobacteria and Mycoplasma; Archaea: Halophiles, Methanogens, Hyperthermophilic archaea, Thermoplasm; Eukaryotes: algae, fungi, slime molds and protozoa; extremophiles and unculturable microbes, introduction to metagenomics.

Unit III
Control of microorganisms
3 lectures

Sterilization, disinfection and antisepsis: physical and chemical methods for control of microorganisms, antibiotics, antiviral and antifungal drugs, biological control of microorganisms.

Unit IV
Virology
5 lectures

Virus and bacteriophages, general properties of viruses, viral structure, taxonomy of virus, viral replication, cultivation and identification of viruses; sub-viral particles – viroids and prions.

Unit V
Interaction of microbes with its environment
6 lectures

Host-pathogen interaction, ecological impacts of microbes; symbiosis (Nitrogen fixation and ruminant symbiosis); microbes and nutrient cycles; microbial communication system; biofilms, bacterial quorum sensing; microbial fuel cells.

Recommended Textbooks and References:

1. Joanne M. Willey, Linda Sherwood, Christopher J. Woolverton; (2011) *Prescott's Microbiology*, McGraw Hill.
2. Michael Joseph Pelczar, Eddie Chin Sun Chan, Noel R. Krieg; (1993) *Microbiology by Pelczar.* McGraw Hill.
3. Gerard J. Tortora, Berdell R. Funke, Christine L. Case; (2015); *Microbiology by Tortora.* Pearson Education.

Plant and Animal Cell Culture Technology

Credits
2

Course Objectives

The objectives of this course is to educate students about the fundamental concepts of animal and plant cell system, bioprocess technology using eukaryotic system and their related applications, thus, preparing them to meet challenges of new and emerging areas of biotechnology industry.

Student Learning Outcomes

Student should be able to gain strong understanding of plant and animal based cell cultures system. This will help them to take up animal/plant based biological research as well as placement in relevant biotech industry. They will be able to analyse bioprocess from an economics/ market point of view.

Unit I
Animal cell culture
15 lectures

Animal cell culture; media composition and growth conditions; Animal cell and tissue preservation; Anchorage and non-anchorage dependent cell culture; Primary and secondary culture; Animal cell growth characteristics and kinetics; Micro & macro-carrier culture; Hybridoma technology; Stem cell technology; Transgenic animals; Animal cloning; Mechanisms of drug resistance and cell death.

Unit II
Plant cell culture
15 lectures

Totipotency; Plant growth regulators; Regeneration and micropropagation of plants: clonal propagation, organogenesis, shoot-tip and meristem culture, haploid culture, triploid culture, protoplast culture; Somaclonal variation; Tissue culture and Cell suspension culture system: methodology, growth kinetics and nutrient optimization; Precursors and elicitors; Plant Transformation methods (emphasis on *Agrobacterium* mediated transformation); Hairy root culture; Plant products of industrial importance, Production of secondary metabolites.

Unit III
Secondary metabolite production
10 lectures

Principles, design and operation of bioreactors: specific design criteria for mammalian and plant systems; Strategies for fermentation with recombinant organisms; Isolation, characterization and production of secondary metabolites from different plant cell types; Bioprocess monitoring and control: current practices in the bioprocess industries, advanced methodologies; Overview of downstream processing: centrifugation, filtration and chromatographic techniques.

Recommended Textbooks and References:

1. Butterworth Heinemann Ltd., (1994) Biotol Series, *In vitro Cultivation of Plant cell*.
2. Bhojwani S.S. and Razdan M.K. (1996) *Plant Tissue Culture: Theory and Practice*, a Revised Edition, Elsevier Science
3. T. A. Brown, (2001) *Gene Cloning and DNA Analysis: an Introduction*, Blackwell Science.
4. M. L Shuler and F. Kargi. (2002), *Bioprocess Engineering*, Prentice Hall Inc.
5. A. Slater, N. Scott and M. Fowler (2003), *Plant Biotechnology: the Genetic Manipulation of Plants*, Oxford University Press.
6. M. M. Ranga (2007), *Animal Biotechnology*, 3rd Revised Edition, Agrobios.
7. Freshney. (2016) Culture of Animal Cells.
8. Meyer, Handschel, Wiesmann (2009). *Fundamentals of Tissue Engineering and Regenerative Medicine*.
9. Selected Papers from Scientific Journals, particularly Nature & Science.

Basics of Mathematics and Statistics

Credits
2

Course Objectives

The objective of this course is to give conceptual exposure of essential contents of mathematics and statistics to students.

Student Learning Outcomes

On completion of this course, students should be able to:

- Gain broad understanding in mathematics and statistics;
- Recognize importance and value of mathematical and statistical thinking, training, and approach to problem solving, on a diverse variety of disciplines.

Unit I
Algebra
6 lectures

Linear equations, functions: slopes-intercepts, forms of two-variable linear equations; constructing linear models in biological systems; quadratic equations (solving, graphing, features of, interpreting quadratic models *etc.*), introduction to polynomials, graphs of binomials and polynomials; Symmetry of polynomial functions, basics of trigonometric functions, Pythagorean theory, graphing and constructing sinusoidal functions, imaginary numbers, complex numbers, adding-subtracting-multiplying complex numbers, basics of vectors, introduction to matrices.

Unit II
Calculus
4 lectures

Differential calculus (limits, derivatives), integral calculus (integrals, sequences and series *etc.*)

Unit III

Mathematical models in biology

3 lectures

Population dynamics; oscillations, circadian rhythms, developmental patterns, symmetry in biological systems, fractal geometries, size-limits & scaling in biology, modeling chemical reaction networks and metabolic networks.

Unit IV

Statistics

5 lectures

Probability: counting, conditional probability, discrete and continuous random variables; Error propagation; Populations and samples, expectation, parametric tests of statistical significance, nonparametric hypothesis tests, linear regression, correlation & causality, analysis of variance, factorial experiment design.

Recommended Textbooks and References:

1. Stroud, K. A., & Booth, D. J. (2009). *Foundation Mathematics*. New York, NY: Palgrave Macmillan.
2. Aitken, M., Broadhursts, B., & Haldky, S. (2009) *Mathematics for Biological Scientists*. Garland Science.
3. Billingsley, P. (1986). *Probability and Measure*. New York: Wiley.
4. Rosner, B. (2000). *Fundamentals of Biostatistics*. Boston, MA: Duxbury Press.
5. Daniel, W. W. (1987). *Biostatistics, a Foundation for Analysis in the Health Sciences*. New York: Wiley.

Basics of Chemistry and Physics

Credits

Course Objectives

The objectives of this course are to cover all essentials required to appreciate physico-chemical principles underlying biological processes.

Student Learning Outcomes

Students should be able to have a firm foundation in fundamentals and application of current chemical and physical scientific theories.

Unit I

Basic physics for biologists

12 lectures: 10 hrs teaching + 2 hrs tutorials

Physical quantities and their dynamics: definitions and dimensions; vectors & scalars, displacement, velocity, acceleration, kinematic formulas, angular momentum, torque *etc.* force, power, work, energy (kinetic & potential/electric charge separation, electromagnetic spectrum, photons *etc.*); springs & Hookes laws; elastic and inelastic collisions; Newton's law of motions (centripetal and centrifugal forces *etc.*); simple harmonic motions, mechanical waves, Doppler effect, wave interference, amplitude, period, frequency & wavelength; diffusion, dissipation, random walks, and directed motions in biological systems; low Reynolds number - world of Biology, buoyant forces, Bernoulli's equation, viscosity, turbulence, surface tension, adhesion; laws of thermodynamics: Maxwell Boltzmann distribution, conduction, convection and radiation, internal energy, entropy, temperature and free energy, Maxwell's demon (entropic forces at work in biology, chemical assemblies, self-assembled systems, role of ATP); Coulomb's law, conductors and insulators, electric potential energy of charges, nerve impulses, voltage gated channels, ionic conductance; Ohms law (basic electrical quantities: current, voltage & power), electrolyte conductivity, capacitors and capacitance, dielectrics; various machines in biology *i.e.* enzymes, allostery and molecular motors (molecules to cells and organisms).

Unit II

Basic chemistry for biologists

Basic constituents of matter - elements, atoms, isotopes, atomic weights, atomic numbers, basics of mass spectrometry, molecules, Avogadro number, molarity, gas constant, molecular weights, structural and molecular formulae, ions and polyatomic

12 lectures: 10 hrs teaching + 2 hrs tutorials

ions; chemical reactions, reaction stoichiometry, rates of reaction, rate constants, order of reactions, Arrhenious equation, Maxwell Boltzmann distributions, rate-determining steps, catalysis, free-energy, entropy and enthalpy changes during reactions; kinetic versus thermodynamic controls of a reaction, reaction equilibrium (equilibrium constant); light and matter interactions (optical spectroscopy, fluorescence, bioluminescence, paramagnetism and diamagnetism, photoelectron spectroscopy; chemical bonds (ionic, covalent, Van der Walls forces); electronegativity, polarity; VSEPR theory and molecular geometry, dipole moment, orbital hybridizations; states of matter - vapor pressure, phase diagrams, surface tension, boiling and melting points, solubility, capillary action, suspensions, colloids and solutions; acids, bases and pH - Arrhenious theory, pH, ionic product of water, weak acids and bases, conjugate acid-base pairs, buffers and buffering action etc; chemical thermodynamics - internal energy, heat and temperature, enthalpy (bond enthalpy and reaction enthalpy), entropy, Gibbs free energy of ATP driven reactions, spontaneity versus driven reactions in biology; redox reactions and electrochemistry - oxidation-reduction reactions, standard cell potentials, Nernst equation, resting membrane potentials, electron transport chains (ETC) in biology, coupling of oxidative phosphorylations to ETC; theories of ATP production and dissipation across biological membranes; bond rotations and molecular conformations - Newman projections, conformational analysis of alkanes, alkenes and alkynes; functional groups, optically asymmetric carbon centers, amino acids, proteins, rotational freedoms in polypeptide backbone (Ramachandran plot).

Recommended Textbooks and References:

1. Baaquie, B. E. (2000). *Laws of Physics: a Primer.* Singapore: National University of Singapore.
2. Matthews, C. P., & Shearer, J. S. (1897). *Problems and Questions in Physics*. New York: Macmillan Company.
3. Halliday, D., Resnick, R., & Walker, J. (1993). *Fundamentals of Physics*. New York: Wiley.
4. Ebbing, D. D., & Wrighton, M. S. (1990). G*eneral Chemistry*. Boston: Houghton Mifflin.
5. Averill, B., & Eldredge, P. (2007). *Chemistry: Principles, Patterns, and Applications*. San Francisco: Benjamin Cummings.
6. Mahan, B. H. (1965). *University Chemistry.* Reading, MA: Addison-Wesley Pub.
7. Cantor, C. R., & Schimmel, P. R. (2004). *Biophysical Chemistry*. San Francisco: W.H. Freeman.

Laboratory I: Biochemistry & Analytical Techniques

Credits

4

Course Objectives

The objective of this laboratory course is to introduce students to experiments in biochemistry. The course is designed to teach utility of experimental methods in biochemistry in a problem oriented manner.

Student Learning Outcomes

Students should be able to:

- Elaborate concepts of biochemistry with simple experiments;
- Understand principle and working of basic laboratory instruments.

Syllabus

1. Estimation of sugars – Reducing and non-reducing sugars.
2. Titration of Amino Acids and separation of aliphatic, aromatic and polar amino acids by thin layer chromatography.

3. Purification and characterization of an enzyme from a recombinant source (such as Alkaline Phosphatase or Lactate Dehydrogenase or any enzyme of institution's choice).
    a. Preparation of cell-free lysates
    b. Ammonium Sulfate precipitation
    c. Ion-exchange Chromatography
    d. Gel Filtration
    e. Affinity Chromatography
    f. Generating a Purification Table (protein concentration, amount of total protein)
    g. Computing specific activity of the enzyme preparation at each stage of purification
    h. Assessing purity of samples from each step of purification by SDS-PAGE Gel Electrophoresis
    i. Enzyme Kinetic Parameters: Km, Vmax and Kcat.
    j. Dialysis of the purified protein solution against 60% glycerol as a demonstration of storage method
4. Identification of an unknown sample as DNA, RNA or protein using available laboratory tools.
5. Biophysical methods (Circular Dichroism Spectroscopy, Fluorescence Spectroscopy).
6. Determination of mass of small molecules and fragmentation patterns by Mass Spectrometry.

Laboratory II: Microbiology

Credits

Course Objectives

The objective of this laboratory course is to provide practical skills in basic microbiological techniques.

Student Learning Outcomes

On completion of this laboratory course, students should be able to:

- Isolate, characterize and identify common bacterial organisms;
- Determine bacterial load of different samples;
- Perform antimicrobial sensitivity test;
- Preserve bacterial cultures.

Syllabus
Basic techniques

1. Sterilization, disinfection and safety in microbiological laboratory, good laboratory practices
2. Preparation of media for cultivation of bacteria, liquid and agar.

Syllabus
Culture techniques

1. Spread plate method
2. Pour plate method
3. Streaking
4. Bacterial growth curve
5. Bacterial plate count method
6. Maintenance of stock cultures: slants, stabs and glycerol stock cultures.

Syllabus
Staining techniques

1. Preparation of bacterial smear and Gram's staining
2. Acid fast staining
3. Endospore staining
4. Capsule staining
5. Negative staining
6. Flagellar staining.

Syllabus

Microscopy-related techniques

1. Bright field light microscopy
2. Hanging drop slide preparation
3. Motility of bacteria
4. Dark field light microscopy
5. Phase contrast microscopy
6. Fluorescence microscopy.

Syllabus

Biochemical and antibiotic tests

1. MR test
2. VP test
3. Sucrose fermentation
4. Lactose fermentation
5. Indole test
6. Antimicrobial sensitivity test and demonstration of drug resistance
7. Zone of clearance, zone of inhibition.

Syllabus

Environmental factors

1. Effect of pH and temperature on microbial growth
2. Determination of phenol co-efficient of antimicrobial agents
3. Determination of Minimum Inhibitory Concentration (MIC)
4. Isolation and identification of bacteria from soil/water samples.

Recommended Textbooks and References:

1. Cappuccino, J. G., & Welsh, C. (2016). *Microbiology: a Laboratory Manual.* Benjamin -Cummings Publishing Company.
2. LM Prescott, JP Harley, DA Klein, (2002), *Laboratory Exercises in Microbiology*.

Semester Two

Genetic Engineering

Credits

3

Course Objectives

The objectives of this course are to teach various approaches to conducting genetic engineering and their applications in biological research as well as in biotechnology industries. Genetic engineering is a technology that has been developed based on our fundamental understanding of principles of molecular biology and this is reflected in contents of this course.

Student Learning Outcomes

Given the impact of genetic engineering in modern society, the students should be endowed with strong theoretical knowledge of this technology. In conjunction with practicals in molecular biology and genetic engineering, students should be able to take up biological research as well as placement in relevant biotech industry.

Unit I

Introduction and tools for genetic engineering

6 lectures

Impact of genetic engineering in modern society; general requirements for performing a genetic engineering experiment; restriction endonucleases and methylases; DNA ligase, Klenow enzyme, T4 DNA polymerase, polynucleotide kinase, alkaline phosphatase; cohesive and blunt end ligation; linkers; adaptors; homopolymeric tailing; labelling of DNA: nick translation, random priming, radioactive and non-radioactive probes; hybridization techniques: northern, southern, south-western and far-western and colony hybridization, fluorescence *in situ* hybridization.

Unit II

Different types of vectors

7 lectures

Plasmids; Bacteriophages; M13 mp vectors; PUC19 and Bluescript vectors, phagemids; Lambda vectors; Insertion and Replacement vectors; Cosmids; Artificial chromosome vectors (YACs; BACs); Principles for maximizing gene expression: expression vectors, pMal, GST, pET-based vectors; Protein purification: His-tag; GST-tag; MBP-tag *etc.*

Intein-based vectors; Inclusion bodies; methodologies to reduce formation of inclusion bodies; mammalian expression and replicating vectors; Baculovirus and *Pichia* vectors system, plant based vectors, Ti and Ri plasmids as vectors, yeast vectors, shuttle vectors.

Unit III

Different types of PCR techniques

7 lectures

Principles of PCR: primer design; fidelity of thermostable enzymes; DNA polymerases; types of PCR – multiplex, nested; reverse-transcription PCR, real time PCR, touchdown PCR, hot start PCR, colony PCR, asymmetric PCR, cloning of PCR products; TA cloning vectors; proof reading enzymes; PCR based site specific mutagenesis; PCR in molecular diagnostics; viral and bacterial detection; sequencing methods; enzymatic DNA sequencing; chemical sequencing of DNA; automated DNA sequencing; RNA sequencing; chemical synthesis of oligonucleotides; mutation detection: SSCP, DGGE, RFLP.

Unit IV

cDNA analysis

7 lectures

Insertion of foreign DNA into host cells; transformation, electroporation, transfection; construction of libraries; isolation of mRNA and total RNA; reverse transcriptase and cDNA synthesis; cDNA and genomic libraries; construction of microarrays – genomic arrays, cDNA arrays and oligo arrays; study of protein-DNA interactions: electrophoretic mobility shift assay; DNaseI footprinting; methyl interference assay, chromatin immunoprecipitation; protein-protein interactions using yeast two-hybrid system; phage display.

Unit V

Gene silencing and genome editing technologies

13 lectures

Gene silencing techniques; introduction to siRNA; siRNA technology; Micro RNA; construction of siRNA vectors; principle and application of gene silencing; gene knockouts and gene therapy; creation of transgenic plants; debate over GM crops; introduction to methods of genetic manipulation in different model systems *e.g.* fruit flies (*Drosophila*), worms (*C. elegans*), frogs (*Xenopus*), fish (zebra fish) and chick; Transgenics - gene replacement; gene targeting; creation of transgenic and knock-out mice; disease model; introduction to genome editing by CRISPR-CAS with specific emphasis on Chinese and American clinical trials.

Recommended Textbooks and References:

1. Brown, T. A. (2006). *Genomes* (3rd ed.). New York: Garland Science Pub
2. S. Primrose, R. Twyman, B. Old, and G. Bertola (2006), *Principles of Gene Manipulation and Genomics*, Blackwell Publishing Limited; 7th Edition
3. Green, M. R., & Sambrook, J. (2012). *Molecular Cloning: a Laboratory Manual.* Cold Spring Harbor, NY: Cold Spring Harbor Laboratory Press.
4. Selected Papers from Scientific Journals, particularly Nature & Science.
5. Technical Literature from Stratagene, Promega, Novagen, New England Biolab *etc.*

Immunology

Credits

3

Course Objectives

The objectives of this course are to learn about structural features of components of immune system as well as their function. The major emphasis of this course will be on development of immune system and mechanisms by which our body elicits immune response. This will be imperative for students as it will help them to predict about nature of immune response that develops against bacterial, viral or parasitic infection, and prove it by designing new experiments.

Student Learning Outcomes

On completion of this course, students should be able to:

- Evaluate usefulness of immunology in different pharmaceutical companies;
- Identify proper research lab working in area of their own interests;
- Apply their knowledge and design immunological experiments to demonstrate innate, humoral or cytotoxic T lymphocyte responses and figure out kind of immune responses in the setting of infection (viral or bacterial).

Unit I

Immunology: fundamental concepts and anatomy of the immune system

5 lectures

Components of innate and acquired immunity; phagocytosis; complement and inflammatory responses; pathogen recognition receptors (PRR) and pathogen associated molecular pattern (PAMP); innate immune response; mucosal immunity; antigens: immunogens, haptens; Major Histocompatibility Complex: MHC genes, MHC and immune responsiveness and disease susceptibility.

Unit II

Immune responses generated by B and T lymphocytes

8 lectures

Immunoglobulins - basic structure, classes & subclasses of immunoglobulins, antigenic determinants; multigene organization of immunoglobulin genes; B-cell receptor; Immunoglobulin superfamily; principles of cell signaling; basis of self & non-self discrimination; kinetics of immune response, memory; B cell maturation, activation and differentiation; generation of antibody diversity; T-cell maturation, activation and differentiation and T-cell receptors; functional T Cell subsets; cell-mediated immune responses, ADCC; cytokines: properties, receptors and therapeutic uses; antigen processing and presentation- endogenous antigens, exogenous antigens, non-peptide bacterial antigens and super-antigens; cell-cell co-operation, Hapten-carrier system.

Unit III

Antigen-antibody interactions

6 lectures

Precipitation, agglutination and complement mediated immune reactions; advanced immunological techniques: RIA, ELISA, Western blotting, ELISPOT assay, immunofluorescence microscopy, flow cytometry and immunoelectron microscopy; surface plasmon resonance, biosensor assays for assessing ligand –receptor interaction; CMI techniques: lymphoproliferation assay, mixed lymphocyte reaction, cell cytotoxicity assays, apoptosis, microarrays, transgenic mice, gene knock outs.

Unit IV

Vaccinology

8 lectures

Active and passive immunization; live, killed, attenuated, subunit vaccines; vaccine technology: role and properties of adjuvants, recombinant DNA and protein based vaccines, plant-based vaccines, reverse vaccinology; peptide vaccines, conjugate vaccines; antibody genes and antibody engineering:chimeric, generation of monoclonal antibodies, hybrid monoclonal antibodies; catalytic antibodies and generation of immunoglobulin gene libraries, idiotypic vaccines and marker vaccines, viral-like particles (VLPs), dendritic cell based vaccines, vaccine against cancer, T cell based vaccine, edible vaccine and therapeutic vaccine.

Unit V

Clinical immunology

8 lectures

Immunity to infection: bacteria, viral, fungal and parasitic infections (with examples from each group); hypersensitivity: Type I-IV; autoimmunity; types of autoimmune diseases; mechanism and role of CD4+ T cells; MHC and TCR in autoimmunity; treatment of autoimmune diseases; transplantation: immunological basis of graft rejection; clinical transplantation and immunosuppressive therapy; tumor immunology: tumor antigens; immune response to tumors and tumor evasion of the immune system, cancer immunotherapy; immunodeficiency: primary immunodeficiencies, acquired or secondary immunodeficiencies, autoimmune disorder, anaphylactic shock, immunosenescence, immune exhaustion in chronic viral infection, immune tolerance, NK cells in chronic viral infection and malignancy.

Unit VI

Immunogenetics

5 lectures

Major histocompatibility complex genes and their role in autoimmune and infectious diseases, HLA typing, human major histocompatibility complex (MHC), Complement genes of the human major histocompatibility complex: implication for linkage disequilibrium and disease associations, genetic studies of rheumatoid arthritis, systemic lupus erythematosus and multiple sclerosis, genetics of human immunoglobulin, immunogenetics of spontaneous control of HIV, KIR complex.

Recommended Textbooks and References:

1. Kindt, T. J., Goldsby, R. A., Osborne, B. A., & Kuby, J. (2006). *Kuby Immunology*. New York: W.H. Freeman.
2. Brostoff, J., Seaddin, J. K., Male, D., & Roitt, I. M. (2002). *Clinical Immunology*. London: Gower Medical Pub.
3. Murphy, K., Travers, P., Walport, M., & Janeway, C. (2012). *Janeway's Immunobiology*. New York: Garland Science.
4. Paul, W. E. (1993). *Fundamental Immunology*. New York: Raven Press.
5. Goding, J. W. (1986). *Monoclonal Antibodies: Principles and Practice: Production and Application of Monoclonal Antibodies in Cell Biology, Biochemistry, and Immunology.* London: Academic Press.
6. Parham, P. (2005). *The Immune System*. New York: Garland Science.

Bioprocess Engineering & Technology

Credits

3

Course Objectives

The objectives of this course are to educate students about the fundamental concepts of bioprocess technology and its related applications, thus preparing them to meet the challenges of the new and emerging areas of biotechnology industry.

Student Learning Outcomes

Students should be able to:

- Appreciate relevance of microorganisms from industrial context;
- Carry out stoichiometric calculations and specify models of their growth;
- Give an account of design and operations of various fermenters;
- Present unit operations together with the fundamental principles for basic methods in production technique for bio-based products;
- Calculate yield and production rates in a biological production process, and also interpret data;
- Calculate the need for oxygen and oxygen transfer in a bioproduction process;
- Critically analyze any bioprocess from an economics/market point of view;
- Give an account of important microbial/enzymatic industrial processes in food and fuel industry.

Unit I

Basic principles of biochemical engineering

4 lectures

Isolation, screening and maintenance of industrially important microbes; microbial growth and death kinetics (an example from each group, particularly with reference to industrially useful microorganisms); strain improvement for increased yield and other desirable characteristics.

Unit II

Stoichiometry and models of microbial growth

6 lectures

Elemental balance equations; metabolic coupling – ATP and NAD+; yield coefficients; unstructured models of microbial growth; structured models of microbial growth, MATLAB basics for modelling and solving the equations.

Unit III

Bioreactor design and analysis

8 lectures

Batch and continuous fermenters; modifying batch and continuous reactors: chemostat with recycle, multistage chemostat systems, fed-batch operations; conventional fermentation *vs* biotransformations; immobilized cell systems; large scale animal and plant cell cultivation; fermentation economics; upstream processing: media formulation and optimization; sterilization; aeration, agitation and heat transfer in bioprocess; scale up and scale down; measurement and control of bioprocess parameters.

Unit IV

Downstream processing and process economics

4 lectures

Separation of insoluble products - filtration, centrifugation, sedimentation, flocculation; Cell disruption; separation of soluble products: liquid-liquid extraction, precipitation, chromatographic techniques, reverse osmosis, ultra and micro filtration, electrophoresis; final purification: drying; crystallization; storage and packaging.

Unit V

Applications of enzyme technology in food processing

4 lectures

Mechanism of enzyme function and reactions in process techniques; enzymatic bioconversions *e.g.* starch and sugar conversion processes; high-fructose corn syrup; interesterified fat; hydrolyzed protein *etc.* and their downstream processing; baking by amylases, deoxygenation and desugaring by glucose oxidase, beer mashing and chill proofing; cheese making by proteases and various other enzyme catalytic actions in food processing.

Unit VI

Applications of microbial technology in food processing and biorefineries

4 lectures

Fermented foods and beverages; food ingredients and additives prepared by fermentation and their purification; fermentation as a method of preparing and preserving foods; microbes and their use in pickling, producing colours and flavours, alcoholic beverages and other products; process wastes-whey, molasses, starch substrates and other food wastes for bioconversion to useful products; bacteriocins from lactic acid bacteria: production and applications in food preservation; biofuels and biorefinery; production of antibiotics in a reactor; single cell protein; probiotics and prebiotics.

Unit VII

Applications of biotechnology in production of biologicals

12 lectures

Industrial production of penicillin via fungal route, insulin from recombinant E. coli; Production of metabolites such as shikonin using plant cell culture, astaxanthin from algae, and biotransformation routes for novel/specialty chemicals; Production of HBsAg using yeast cultures, erythropoietin using CHO cells, monoclonal antibodies such as Humira using mammalian cells.

Recommended Textbooks and References:

1. Shuler, M. L., & Kargi, F. (2002). *Bioprocess Engineering: Basic Concepts*. Upper Saddle River, NJ: Prentice Hall.
2. Stanbury, P. F., & Whitaker, A. (1997). *Principles of Fermentation Technology*. Oxford: Pergamon Press.
3. Pauline Doran (1995) *Bioprocess Engineering Principles*. Elsevier Science & Technology Books
4. Mansi EMTEL, Bryce CFA. *Fermentation Microbiology and Biotechnology*, 2nd Edition, Taylor & Francis Ltd, UK, 2007
5. Harrison, R.G., Todd, P., Rudge, S.R., and Petrides, D.P. (2015). *Bioseparations Science and Engineering*. 2nd Edition. Oxford University Press.)

Downstream Processing in Biotechnology

Credits

3

Course Objectives

The objective of this course is to provide an overview of various aspects of recovery and processing of biological products.

Student Learning Outcomes

Students should be able to identify and design relevant unit operations for recovery of a biological product.

Unit I **Biomass removal** 3 lectures	Characteristics of biological materials: pretreatment methods; Separation of cell mass: centrifugation, sedimentation, flocculation and filtration; Continuous operation.
Unit II **Cell disruption** 4 lectures	Mechanical approaches: sonication, bead mills, homogenizers; non-mechanical approaches: freeze/thaw, osmotic shock, chemical lysis, enzymatic lysis; measurement of cell disruption.
Unit III **Membrane processes** 3 lectures	Filtration theory; Micro and ultrafiltration; Reverse osmosis; dialysis; electrodialysis, diafiltration; pervaporation; perstraction; Multistage and continuous operation.
Unit IV **Adsorption and chromatography** 5 lectures	Adsorption equilibrium, Van Deemter equation; Chromatography: size, charge, polarity, shape, hydrophobic interactions; Biological affinity; Process configurations (packed bed, expanded bed, simulated moving beds).
Unit V **Extraction processes** 5 lectures	Solvent extraction: phase equilibrium and distribution, counter-current operation, dissociative extraction, multiple stage analysis; Reciprocating-plate and centrifugal extractors; Reverse micellar extraction; Aqueous two phase, Supercritical fluid extraction; Aqueous two-phase extraction.
Unit VI **Concentration steps** 8 lectures	Precipitation: effect of size and charge, solvent effects, ionic strength effects, precipitate growth and aging models. Crystallization: nucleation and growth aspects; Drying: solvent removal aspects, dryers (vacuum, freeze, spray); Scale up aspects.
Unit VII **Product characterization** 4 lectures	Biophysical characterization, chemical characterization, modern spectroscopy, QbD, stability Bioassays: Cell based assay, receptor mediated assay, *in vivo* evaluation, immunogenicity.
Unit VIII **Process design** 8 lectures	Process synthesis: Identification and ordering of unit operations relevant for a case study. Analysis: comparison of different process synthesis steps. Case studies such as production and recovery of therapeutics, metabolites and antibodies.

Recommended Textbooks and References:

1. Harrison, R.G., Todd, P., Rudge, S.R., and Petrides, D.P. (2015). *Bioseparations Science and Engineering*. 2nd Edition. Oxford University Press.
2. Ladisch, M. (2000). *Bioseparations Engineering: Principles, Practice, and Economics*. Wiley.
3. Doran P. (2013). *Bioprocess Engineering Principles*. 2nd Edition. Oxford. Academic Press.
4. P.A. Belter, E.L. Cussler and Wei-Shou Hu., (1988), *Bioseparations-Downstream Processing for Biotechnology,* Wiley-Interscience Publication.

Bioreactor Operations

Course Objectives

The course is an overview on biological reactions, elements of bioreactor design, and fundamentals of mass and energy balances in biological reactions. It gives an idea on various types of important

Student Learning Outcomes

Student should be able to gain strong understanding on design and applications of various bioreactors. They will be able to analyse bioprocess from an economics/ market point of view.

Credits
3

bioreactors for microbial, animal and plant cell processes. It covers mechanical design considerations for various kinds of bioreactors.

Unit I
Introduction to bioreactor design
3 lectures

Introduction; General design information; Material and energy balance calculations; Process Flow.

Unit II
Scale up and scale down processes
12 lectures

Scale up and scale down issues: Effect of scale on oxygenation, mixing, sterilization, pH, temperature, inoculum development, nutrient availability and supply; Bioreactor scale-up based on constant power consumption per volume, mixing time, impeller tip speed (shear), mass transfer coefficients. Scale-up of downstream processes: Adsorption (LUB method); Chromatography (constant resolution *etc.*); Filtration (constant resistance *etc.*); Centrifugation (equivalent times *etc.*); Extractors (geometry based rules). Scale-down related aspects.

Unit III
Bioreactor equipment
11 lectures

Selection of bioprocess equipment (upstream and downstream); Specifications of bioprocess equipment; Mechanical design of reactors, heat transfer and mass transfer equipment; Design considerations for maintaining sterility of process streams and process equipment; Piping and instrumentation; Materials of construction for bioprocess plants.

Unit IV
Basic bioreactor operations
8 lectures

Spectrum of basic bioreactor operations: immobilized cell system, animal cells, plant cell cultures and waste management; Enzyme immobilization techniques; Bioconversion using immobilized enzyme preparation; Bioconversion in batch, Fed-batch and continuous bioreactors; Mass transfer in immobilized cell/enzyme reactor.

Unit V
Bioreactor facility design
6 lectures

Facility design aspects; Utility supply aspects; Equipment cleaning aspects; Culture cell banks; cGMP guidelines; Validation; Safety; Process economics; Case studies.

Recommended Textbooks and References:

1. Roger Harrison *et al.*, (2003), *Bioseparations Science and Engineering*, Oxford University Press.
2. Michael Shuler and Fikret Kargi, (2002), *Bioprocess Engineering: Basic Concepts,* 2nd Edition, Prentice Hall, Englewood Cliffs, NJ.
3. Michael R. Ladisch, (2001), *Bioseparations Engineering: Principles, Practice and Economics*, 1st Edition, Wiley.
4. M. V. Joshi and V.V.Mahajani., (2000). *Process Equipment Design*, 3rd Edition, Macmillan India Ltd
5. Robert H. Perry and Don W. Green (eds.), (1997), *Perry's Chemical Engineers' Handbook,* 7th Edition, McGraw Hill Book Co.
6. Max S. Peters and Klaus, D. Timmerhaus, (1991). *Plant Design and Economics for Chemical Engineers*, 4th Edition, McGrawHill Book Co.
7. J. Bailey and D.Ollis, (1986), *Biochemical Engineering Fundamentals*; McGraw Hill.
8. Relevant articles from Bioprocess Journals.

Computational Biology

Credits

3

Course Objectives

The objective of this course is to provide students with theory and practical experience of essentials to aid for genomic, proteomic and metabolomics courses and drug design program.

Student Learning Outcomes

On completion of this course, the students are expected to:

- Develop an understanding of the basic theory of these computational tools;
- Develop required database extraction, integration, coding for computational tools and methods necessary for all Omics;
- Create hypothesis for investigating specific contemporary biological questions, provide help to experiment with or develop appropriate tools;
- Critically analyze and interpret results of their study with respect to whole systems.

Unit I

Introduction to computational biology basics and biological databases

4 lectures

Computers in biology and medicine; Overview of biological databases, nucleic acid & protein databases, primary, secondary, functional, composite, structural classification database, Sequence formats & storage, Access databases, Extract and create sub databases, limitations of existing databases.

Unit II

Pairwise and multiple sequence alignments

5 lectures

Local alignment, Global alignment, Scoring matrices - PAM, BLOSUM, Gaps and penalties, Dot plots. Dynamic programming approach: Needleman and Wunsch Algorithm, Smith and Waterman Algorithm, Hidden Markov Model: Viterbi Algorithm. Heuristic approach: BLAST, FASTA. Building Profiles, Profile based functional identification.

Unit III

Genome analysis

6 lectures

Polymorphisms in DNA sequence, Introduction to Next Generation Sequencing technologies, Whole Genome Assembly and challenges, Sequencing and analysis of large genomes, Gene prediction, Functional annotation, Comparative genomics, Probabilistic functional gene networks, Human genome project, Genomics and crop improvement. Study available GWAS, ENCODE, HUGO projects, extract and build sub databases; Visualization tools including Artemis and Vista for genome comparison; Functional genomics case studies.

Unit IV

Structure visualization

3 lectures

Retrieving and drawing structures, Macromolecule viewing platforms, Structure validation and correction, Structure optimization, Analysis of ligand-protein interactions; Tools such as PyMol or VMD.

Unit V

Molecular modelling

6 lectures

Significance and need, force field methods, energy, buried and exposed residues; side chains and neighbours; fixed regions; hydrogen bonds; mapping properties onto surfaces; RMS fit of conformers and protein chains, assigning secondary structures; sequence alignment: methods, evaluation, scoring; protein curation: backbone construction and side chain addition; different types of protein chain modelling: *ab initio*, homology, hybrid, loop; Template recognition and alignments; Modelling parameters and considerations; Model analysis and validation; Model optimization; Substructure manipulations, annealing, protein folding and model generation; loop generating methods; loop analysis; Analysis of active sites using different methods in studying protein–protein Interactions.

Unit VI

Structure-based drug development

6 lectures

Molecular docking: Types and principles, Semi-flexible docking, Flexible docking; Ligand and protein preparation, Macromolecule and ligand optimization, Ligand conformations, Clustering, Analysis of docking results and validation with known information. Extra-precision docking platforms, Use of Small-molecule libraries, Natural compound libraries for virtual high throughput screenings.

Unit VII

Ligand-based drug development

6 lectures

Quantitative structure activity relationships; Introduction to chemical descriptors like 2D, 3D and Group-based; Radar plots and contribution plots and Activity predictions, Pharmacophore modeling, Pharmacophore-based screenings of compound library, analysis and experimental validation.

Recommended Textbooks and References:

1. Mount, D. W. (2001). *Bioinformatics: Sequence and Genome Analysis*. Cold Spring Harbor, NY: Cold Spring Harbor Laboratory Press.
2. Bourne, P. E., & Gu, J. (2009). *Structural Bioinformatics*. Hoboken, NJ: Wiley-Liss.
3. Lesk, A. M. (2004). *Introduction to Protein Science: Architecture, Function, and Genomics*. Oxford: Oxford University Press.
4. Campbell, M & Heyer, L. J. (2006), *Discovering Genomics, Proteomics and Bioinformatics*, Pearson Education.
5. Oprea, T. (2005). *Chemoinformatics in Drug Discovery*, Volume 23. Wiley Online Library.
6. Gasteiger, J. & Engel,T. (2003), *Chemoinformatics: a Textbook*, Wiley Online Library.

Laboratory III: Techniques in Molecular Biology and Genetic Engineering

Credits

Course Objectives

The objectives of this course are to provide students with the experimental knowledge of molecular biology and genetic engineering.

Student Learning Outcomes

Students should be able to gain hands-on experience on gene cloning, protein expression and purification. This experience would enable them to begin a career in industry.

Syllabus

1. Concept of lac-operon:
   a. lactose induction of β-galactosidase.
   b. Glucose Repression.
   c. Diauxic growth curve of *E. coli.*
2. UV mutagenesis to isolate amino acid auxotroph.
3. Phage titre with λ phage/M13.
4. Genetic Transfer-Conjugation, gene mapping.
5. Plasmid DNA isolation and DNA quantitation.
6. Restriction Enzyme digestion of plasmid DNA.
7. Agarose gel electrophoresis.
8. Polymerase Chain reaction.
9. DNA Ligation.

10. Preparation of competent cells.
11. Transformation of *E.coli* with standard plasmids, Calculation of transformation efficiency.
12. Confirmation of the insert, Miniprep of recombinant plasmid DNA, Restriction mapping.
13. Expression of recombinant protein, concept of soluble proteins and inclusion body formation in *E.coli*, SDS-PAGE analysis
14. Purification of His-Tagged protein on Ni-NTA columns
    a. Random Primer labeling
    b. Southern hybridization.

Laboratory IV: Immunology

Credits

Course Objectives

The objectives of this laboratory course are to develop an understanding about practical aspects of components of immune system as well as their function. Basic as well as advanced methods will be taught to detect different antigen and antibody interactions, isolation of different lymphocyte cells *etc.* and how they can be used in respective research work.

Student Learning Outcomes

On completion of this course, students should be able to:

- Evaluate the usefulness of immunology in different pharmaceutical companies;
- Identify proper research lab working in the area of their own interests;
- Apply their knowledge and design immunological experiments to demonstrate innate, humoral or cytotoxic T lymphocyte responses and figure out the kind of immune responses in the setting of infection (viral or bacterial) by looking at cytokine profile.

Syllabus

1. Handling of animals like rabbits, mice.
2. Preparation of antigens, immunization and methods of blood collection, serum separation and storage.
3. Antibody titre by ELISA method.
4. Double diffusion, Immunoelectrophoresis and Radial Immuno diffusion.
5. Complement fixation test.
6. Isolation and purification of IgG from serum or IgY from chicken egg.
7. SDS-PAGE, Immunoblotting, Dot blot assays.
8. Blood smear identification of leucocytes by Giemsa stain.
9. Culture of Hela/J774 cells and phagocytosis.
10. Separation of mononuclear cells by Ficoll-Hypaque.
11. Differential leucocyte count under a microscope.
12. Cryopreservation of cells.

Semester Three

Bioprocess Equipment Design and Economics

Credits

3

Course Objectives

This is an introductory course to aspects of equipment design and process economics and follows coursework on reactor design and downstream processing.

Student Learning Outcomes

Students should be able to become proficient in applying basic design principles towards implementing bioprocess manufacturing systems.

Unit I
Introduction
4 lectures

Mechanical design of process equipment: pressure vessels, process piping design; Materials and Fabrication Selection.

Unit II
Economics
10 lectures

Design Strategy and Optimum Equipment Design: Economic Design criteria; Cost and Asset Accounting; Cost Estimation; Interest and Investment Costs; Taxes and Insurance; Depreciation; Profitability, Alternative Investments and Replacement.

Unit III
Case studies
14 lectures

Case Study in Process Equipment Design and Costing of Equipment in each of the following categories: Material Transfer, Handling and Treatment Equipment.

Unit IV
Heat transfer equipment
7 lectures

Shell and tube heat exchangers (Kern and Bell-Delaware design methods), Plate heat exchangers, Evaporators.

Unit V
Mass transfer equipment
7 lectures

Absorption/ Stripping columns (packed/tray), Multicomponent distillation column (Fenske-Underwood-Gilliland correlations).

Unit VI
Reaction equipment
7 lectures

Choice of reactors, non-isothermal reactors, reactor configuration, interstage heating/ cooling, multi-tubular reactors, catalyst deactivation.

Recommended Textbooks and References:

1. M.S. Peters and K.D. Timmerhaus, (1991), *Plant Design and Economics for Chemical Engineers*, McGraw Hill.
2. D.F. Rudd and C.C. Watson, (1969), *Strategy of Process Engineering*, John Wiley.
3. F.C. Jelen and J.H. Black., (1992), *Cost and Optimization Engineering.* 3rd ed, McGraw Hill.
4. Harrison, R.G., Todd, P., Rudge, S.R., and Petrides, D.P. (2015). *Bioseparations Science and Engineering*. 2nd Edition. Oxford University Press.
5. M.V. Joshi, (1976), *Process Equipment Design*, McMillan India, New Delhi.
6. R.K. Sinnot, (1989), *An Introduction to Chemical Engineering Design*,

Pergamon Press, Oxford.
7. R. Smith, (1995), *Chemical Process Design*, McGraw Hill.

Bioentrepreneurship

Credits

2

Course Objectives

Research and business belong together and both are needed. In a rapidly developing life science industry, there is an urgent need for people who combine business knowledge with the understanding of science & technology. Bio-entrepreneurship, an interdisciplinary course, revolves around the central theme of how to manage and develop life science companies and projects. The objectives of this course are to teach students about concepts of entrepreneurship including identifying a winning business opportunity, gathering funding and launching a business, growing and nurturing the organization and harvesting the rewards.

Student Learning Outcomes

Students should be able to gain entrepreneurial skills, understand the various operations involved in venture creation, identify scope for entrepreneurship in biosciences and utilize the schemes promoted through knowledge centres and various agencies. The knowledge pertaining to management should also help students to be able to build up a strong network within the industry.

Unit I

Innovation and entrepreneurship in bio-business

8 lectures

Introduction and scope in Bio-entrepreneurship, Types of bio-industries and competitive dynamics between the sub-industries of the bio-sector (*e.g.* pharmaceuticals vs. Industrial biotech), Strategy and operations of bio-sector firms: Factors shaping opportunities for innovation and entrepreneurship in bio-sectors, and the business implications of those opportunities, Alternatives faced by emerging bio-firms and the relevant tools for strategic decision, Entrepreneurship development programs of public and private agencies (MSME, DBT, BIRAC, Make In India), strategic dimensions of patenting & commercialization strategies.

Unit II

Bio markets: business strategy and marketing

8 lectures

Negotiating the road from lab to the market (strategies and processes of negotiation with financers, government and regulatory authorities), Pricing strategy, Challenges in marketing in bio business (market conditions & segments; developing distribution channels, the nature, analysis and management of customer needs), Basic contract principles, different types of agreement and contract terms typically found in joint venture and development agreements, Dispute resolution skills.

Unit III

Finance and accounting

8 lectures

Business plan preparation including statutory and legal requirements, Business feasibility study, financial management issues of procurement of capital and management of costs, Collaborations & partnership, Information technology.

Unit IV

Technology management

8 lectures

Technology – assessment, development & upgradation, Managing technology transfer, Quality control & transfer of foreign technologies, Knowledge centers and Technology transfer agencies, Understanding of regulatory compliances and procedures (CDSCO, NBA, GCP, GLA, GMP).

Recommended Textbooks and References:

1. Adams, D. J., & Sparrow, J. C. (2008). *Enterprise for Life Scientists: Developing Innovation and Entrepreneurship in the Biosciences*. Bloxham: Scion.

2. Shimasaki, C. D. (2014). *Biotechnology Entrepreneurship: Starting, Managing, and Leading Biotech Companies*. Amsterdam: Elsevier. Academic Press is an imprint of Elsevier.
3. Onetti, A., & Zucchella, A. (n.d.). *Business Modeling for Life Science and Biotech Companies: Creating Value and Competitive Advantage with the Milestone Bridge*. Routledge.
4. Jordan, J. F. (2014). *Innovation, Commercialization, and Start-Ups in Life Sciences*. London: CRC Press.
5. Desai, V. (2009). *The Dynamics of Entrepreneurial Development and Management*. New Delhi: Himalaya Pub. House.

Instrumentation and Control

Credits

3

Course Objectives

This is an introductory course to aspects of process control and instrumentation.

Student Learning Outcomes

Students should be able to become proficient in applying the fundamental concepts of process control towards the modeling and control of practical processes.

Unit I
Introduction
4 lectures

Essentials of mathematical models and modeling considerations.

Unit II
Dynamic processes
10 lectures

Linearization of non-linear systems; Laplace transforms; Transfer functions and input-output models; Analysis of first, second, and higher-order systems.

Unit III
Feedback control
10 lectures

Dynamics of feedback-controlled processes; Stability analysis; Controller design; Frequency response analysis and its application.

Unit IV
Advanced control schemes
7 lectures

Dead time or inverse response systems; Systems with multiple loops; Feedforward and ratio control.

Unit V
Instrumentation
7 lectures

Devices for measurement of flow, temperature, pH, pressure and liquid level.

Recommended Textbooks and References:

1. D.E. Seborg, T.F. Edgar, D. A. Mellichamp. (2004), *Process Dynamics and Control*, 2nd ed, John Wiley and Sons.
2. B.W. Bequette, (2003), *Process Control: Modeling, Design and Simulation*, Prentice Hall, New Delhi.
3. W.L. Luyben, (1990). *Process Modeling Simulation and Control for Chemical Engineers*, 2nd ed., McGraw Hill.
4. G. Stephanopoulos, (1984), *Chemical Process Control: an Introduction to Theory and Practice*, Prentice Hall, New Delhi.

5. Smith, C.A. and Corripio, A.B. (1997). *Principles and Practice of Automatic Process Control*, Wiley, New York.
6. Johnson, C.D. (2006). *Process Control Instrumentation Technology*, Prentice-Hall, New Delhi

Research Methodology and Scientific Communication Skills

Credits

3

Course Objectives

The objectives of this course are to give background on history of science, emphasizing methodologies used to do research, use framework of these methodologies for understanding effective lab practices and scientific communication and appreciate scientific ethics.

Student Learning Outcomes

Students should be able to:

- Understand history and methodologies of scientific research, applying these to recent published papers;
- Understand and practice scientific reading, writing and presentations;
- Appreciate scientific ethics through case studies.

Unit I

History of science and science methodologies

8 lectures

Empirical science; scientific method; manipulative experiments and controls; deductive and inductive reasoning; descriptive science; reductionist *vs* holistic biology.

Unit II

Preparation for research

2 lectures

Choosing a mentor, lab and research question; maintaining a lab notebook.

Unit III

Process of communication

5 lectures

Concept of effective communication- setting clear goals for communication; determining outcomes and results; initiating communication; avoiding breakdowns while communicating; creating value in conversation; barriers to effective communication; non-verbal communication-interpreting non-verbal cues; importance of body language, power of effective listening; recognizing cultural differences; Presentation skills - formal presentation skills; preparing and presenting using over-head projector, PowerPoint; defending interrogation; scientific poster preparation & presentation; participating in group discussions; Computing skills for scientific research - web browsing for information search; search engines and their mechanism of searching; hidden Web and its importance in scientific research; internet as a medium of interaction between scientists; effective email strategy using the right tone and conciseness.

Unit IV

Scientific communication

9 lectures

Technical writing skills - types of reports; layout of a formal report; scientific writing skills - importance of communicating science; problems while writing a scientific document; plagiarism, software for plagiarism; scientific publication writing: elements of a scientific paper including abstract, introduction, materials & methods, results, discussion, references; drafting titles and framing abstracts; publishing scientific papers - peer review process and problems, recent developments such as open access and non-blind review; plagiarism; characteristics of effective technical communication; scientific presentations; ethical issues; scientific misconduct.

Recommended Textbooks and References:

1. Valiela, I. (2001). *Doing Science: Design, Analysis, and Communication of Scientific Research.* Oxford: Oxford University Press.
2. *On Being a Scientist: a Guide to Responsible Conduct in Research*. (2009). Washington, D.C.: National Academies Press.
3. Gopen, G. D., & Smith, J. A. *The Science of Scientific Writing*. American Scientist, 78(Nov-Dec 1990), 550-558.
4. Mohan, K., & Singh, N. P. (2010). *Speaking English Effectively.* Delhi: Macmillan India.
5. Movie: Naturally Obsessed, The Making of a Scientist.

Intellectual Property Rights, Biosafety and Bioethics

Credits

3

Course Objectives

The objectives of this course are:

- To provide basic knowledge on intellectual property rights and their implications in biological research and product development;
- To become familiar with India's IPR Policy;
- To learn biosafety and risk assessment of products derived from biotechnology and regulation of such products;
- To become familiar with ethical issues in biological research.

Student Learning Outcomes

On completion of this course, students should be able to:

- Understand the rationale for and against IPR and especially patents;
- Understand why India has adopted an IPR Policy and be familiar with broad outline of patent regulations;
- Understand different types of intellectual property rights in general and protection of products derived from biotechnology research and issues related to application and obtaining patents;
- Gain knowledge of biosafety and risk assessment of products derived from recombinant DNA research and environmental release of genetically modified organisms, national and international regulations;
- Understand ethical aspects related to biological, biomedical, health care and biotechnology research.

Unit I

Introduction to IPR

5 lectures

Introduction to intellectual property; types of IP: patents, trademarks, copyright & related rights, industrial design, traditional knowledge, geographical indications, protection of new GMOs; International framework for the protection of IP; IP as a factor in R&D; IPs of relevance to biotechnology and few case studies; introduction to history of GATT, WTO, WIPO and TRIPS; plant variety protection and farmers rights act; concept of 'prior art': invention in context of "prior art"; patent databases - country-wise patent searches (USPTO, EPO, India); analysis and report formation.

Unit II

Patenting

5 lectures

Basics of patents: types of patents; Indian Patent Act 1970; recent amendments; WIPO Treaties; Budapest Treaty; Patent Cooperation Treaty (PCT) and implications; procedure for filing a PCT application; role of a Country Patent Office; filing of a patent application; precautions before patenting-disclosure/non-disclosure - patent application- forms and guidelines including those of National Bio-diversity Authority (NBA) and other regulatory bodies, fee structure, time frames; types of patent applications: provisional and complete specifications; PCT and conventional patent applications; international patenting-requirement, procedures and costs; financial assistance for patenting-introduction to existing schemes; publication of patents-gazette of India, status in Europe and US; patent infringement- meaning, scope, litigation, case studies and examples;

commercialization of patented innovations; licensing – outright sale, licensing, royalty; patenting by research students and scientists-university/organizational rules in India and abroad, collaborative research - backward and forward IP; benefit/credit sharing among parties/community, commercial (financial) and non-commercial incentives.

Unit III
Biosafety
5 lectures

Biosafety and Biosecurity - introduction; historical background; introduction to biological safety cabinets; primary containment for biohazards; biosafety levels; GRAS organisms, biosafety levels of specific microorganisms; recommended biosafety levels for infectious agents and infected animals; definition of GMOs & LMOs; principles of safety assessment of transgenic plants – sequential steps in risk assessment; concepts of familiarity and substantial equivalence; risk – environmental risk assessment and food and feed safety assessment; problem formulation – protection goals, compilation of relevant information, risk characterization and development of analysis plan; risk assessment of transgenic crops vs cisgenic plants or products derived from RNAi, genome editing tools.

Unit IV
National and international regulations
5 lectures

International regulations – Cartagena protocol, OECD consensus documents and Codex Alimentarius; Indian regulations – EPA act and rules, guidance documents, regulatory framework – RCGM, GEAC, IBSC and other regulatory bodies; Draft bill of Biotechnology Regulatory authority of India - containments – biosafety levels and category of rDNA experiments; field trails – biosafety research trials – standard operating procedures - guidelines of state governments; GM labeling – Food Safety and Standards Authority of India (FSSAI).

Unit V
Bioethics
5 lectures

Introduction, ethical conflicts in biological sciences - interference with nature, bioethics in health care - patient confidentiality, informed consent, euthanasia, artificial reproductive technologies, prenatal diagnosis, genetic screening, gene therapy, transplantation. Bioethics in research – cloning and stem cell research, Human and animal experimentation, animal rights/welfare, Agricultural biotechnology - Genetically engineered food, environmental risk, labeling and public opinion. Sharing benefits and protecting future generations - Protection of environment and biodiversity – biopiracy.

Recommended Textbooks and References:

1. Ganguli, P. (2001). *Intellectual Property Rights: Unleashing the Knowledge Economy.* New Delhi: Tata McGraw-Hill Pub.
2. *National IPR Policy*, Department of Industrial Policy & Promotion, Ministry of Commerce, GoI
3. *Complete Reference to Intellectual Property Rights Laws*. (2007). Snow White Publication Oct.
4. Kuhse, H. (2010). *Bioethics: an Anthology*. Malden, MA: Blackwell.
5. Office of the Controller General of Patents, Design & Trademarks; Department of Industrial Policy & Promotion; Ministry of Commerce & Industry; Government of India. http://www.ipindia.nic.in/
6. Karen F. Greif and Jon F. Merz, *Current Controversies in the Biological Sciences -Case Studies of Policy Challenges from New Technologies*, MIT Press
7. World Trade Organisation. http://www.wto.org
8. World Intellectual Property Organisation. http://www.wipo.int
9. International Union for the Protection of New Varieties of Plants. http://www.upov.int
10. National Portal of India. http://www.archive.india.gov.in
11. National Biodiversity Authority. http://www.nbaindia.org
12. Recombinant DNA Safety Guidelines, 1990 Department of Biotechnology, Ministry of Science and Technology, Govt. of India. Retrieved from http://www.envfor.nic.in/divisions/csurv/geac/annex-5.pdf
13. Wolt, J. D., Keese, P., Raybould, A., Fitzpatrick, J. W., Burachik, M., Gray, A., Wu, F. (2009). *Problem Formulation in theEnvironmental Risk Assessment for Genetically*

Modified Plants. Transgenic Research, 19(3), 425-436. doi:10.1007/s11248-009-9321-9
14. Craig, W., Tepfer, M., Degrassi, G., & Ripandelli, D. (2008). *An Overview of General Features of Risk Assessments of Genetically Modified Crops*. Euphytica, 164(3), 853-880. doi:10.1007/s10681-007-9643-8
15. Guidelines for Safety Assessment of Foods Derived from Genetically Engineered Plants. 2008.
16. Guidelines and Standard Operating procedures for Confined Field Trials of Regulated Genetically Engineered Plants. 2008. Retrieved from http://www.igmoris.nic.in/ guidelines1.asp
17. Alonso, G. M. (2013). *Safety Assessment of Food and Feed Derived from GM Crops: Using Problem Formulation to Ensure "Fit for Purpose" Risk Assessments*. Retrieved from http://biosafety.icgeb.org/inhousepublicationscollectionbiosafetyreviews.

Project Proposal Preparation & Presentation

Credits

2

Course Objectives

The purpose of this course is to help students organize ideas, material and objectives for their dissertation and to begin development of communication skills and to prepare the students to present their topic of research and explain its importance to their fellow classmates and teachers.

Student Learning Outcomes

Students should be able to demonstrate the following abilities:

- Formulate a scientific question;
- Present scientific approach to solve the problem;
- Interpret, discuss and communicate scientific results in written form;
- Gain experience in writing a scientific proposal;
- Learn how to present and explain their research findings to the audience effectively.

Syllabus

Project Proposal Preparation

Selection of research lab and research topic: Students should first select a lab wherein they would like to pursue their dissertation. The supervisor or senior researchers should be able to help the students to read papers in the areas of interest of the lab and help them select a topic for their project. The topic of the research should be hypothesis driven.
Review of literature: Students should engage in systematic and critical review of appropriate and relevant information sources and appropriately apply qualitative and/or quantitative evaluation processes to original data; keeping in mind ethical standards of conduct in the collection and evaluation of data and other resources.
Writing Research Proposal: With the help of the senior researchers, students should be able to discuss the research questions, goals, approach, methodology, data collection, *etc.* Students should be able to construct a logical outline for the project including analysis steps and expected outcomes and prepare a complete proposal in scientific proposal format for dissertation.

Syllabus

Poster Presentation

Students will have to present the topic of their project proposal after few months of their selection of the topic. They should be able to explain the novelty and importance of their research topic.

Syllabus

Oral Presentation

At the end of their project, presentation will have to be given by the students to explain work done by them in detail. Along with summarizing their findings they should also be able to discuss the future expected outcome of their work.

Laboratory V: Downstream Processing in Biotechnology

Credits

2

Course Objectives

The objectives of this course are to provide students with hands on knowledge of primary unit operations involved in downstream processing.

Student Learning Outcomes

Students should be able to gain hands-on experience on approaches to cell disruption, centrifugation, filtration, and precipitation.

Syllabus

1. Conventional filtration
2. Centrifugation in batch and continuous centrifuges
3. Cell disruption
4. Protein precipitation and its recovery
5. Ion-exchange chromatography
6. Membrane based filtration-ultra filtration in cross flow modules and micro filtration
7. Adsorption in batch and continuous mode.

Recommended Textbooks and References:

1. Desai, M. (2000) *Downstream Processing of Proteins: Methods and Protocols*, Humana Press.

Semester Four

Dissertation

Credits

26

(Semester III: 6 Credits; Semester IV: 20 Credits)

Course Objectives

The objectives of this course are to prepare the students to adapt to the research environment and understand how projects are executed in a research laboratory. It will also enable students to learn practical aspects of research and train students in the art of analysis and thesis writing.

Student Learning Outcomes

Students should be able to learn how to select and defend a topic of their research, how to effectively plan, execute, evaluate and discuss their experiments. Students should be able to demonstrate considerable improvement in the following areas:

- In-depth knowledge of the chosen area of research.
- Capability to critically and systematically integrate knowledge to identify issues that must be addressed within framework of specific thesis.
- Competence in research design and planning.
- Capability to create, analyse and critically evaluate different technical solutions.
- Ability to conduct research independently.
- Ability to perform analytical

techniques/experimental methods.

- Project management skills.
- Report writing skills.
- Problem solving skills.
- Communication and interpersonal skills.

Syllabus

Planning & performing experiments

Based on the project proposal submitted in earlier semester, students should be able to plan, and engage in, an independent and sustained critical investigation and evaluate a chosen research topic relevant to biological sciences and society. They should be able to systematically identify relevant theory and concepts, relate these to appropriate methodologies and evidence, apply appropriate techniques and draw appropriate conclusions. Senior researchers should be able to train the students such that they can work independently and are able to understand the aim of each experiment performed by them. They should also be able to understand the possible outcomes of each experiment.

Syllabus

Thesis writing

At the end of their project, thesis has to be written giving all the details such as aim, methodology, results, discussion and future work related to their project. Students may aim to get their research findings published in a peer-reviewed journal. If the research findings have application-oriented outcomes, the students may file patent application.

Recommended Electives

Bioreaction Engineering

Credits

2

Course Objectives

This course aims to introduce bioreaction engineering principles to students.

Student Learning Outcomes

On completion of this course, students should be able to understand:

- Growth kinetics of cell cultures;
- Basic stoichiometry of bioreactions;
- Thermodynamic aspects of bioreactions;
- Metabolic flux analysis;
- Bioreactor design.

Unit I

Growth kinetics of cell cultures

5 lectures

Kinetics of cell growth and product formation, mass and energy balances in biological systems, structured growth models; Compartmental models; Cybernetic models.

Unit II

Biocatalysts

5 lectures

Immobilized biocatalysts: external mass transfer; Internal diffusion; Reaction within catalysts; Kinetic analysis of batch processes.

Unit III

Bioreactor design

5 lectures

Reactor design (batch, continuous, fed-batch, plug flow, packed bed, airlift, immobilized enzyme/cell *etc.*); Optimal bioreactor operation using simple reaction kinetics.

Unit IV

Bioreactor process

5 lectures

Dynamic simulation of bioreactor processes (batch, fed-batch, continuous *etc.*); Reactors in series.

Unit V
Stoichiometry of bioreactions
5 lectures

Pathway analysis: Stoichiometric analysis; Thermodynamics-derived constraints; Flux balancing techniques; Metabolic control analysis.

Recommended Textbooks and References:

1. J. Nielsen,J. Villadsen, G. Liden, *Bioreaction Engineering Principles*, 2nd Edition, Kluwer Academic. 2003.
2. Irving J. Dunn, Elmar Heinzle, John Ingham, Jiri E. Prenosil, *Biological Reaction Engineering: Dynamic Modelling Fundamentals with Simulation Examples*, 2nd Edition, Wiley-VCH. 2003.

Computational Programming

Credits

Course Objectives

The objectives of this course are to teach students about essentials of computer programming using modern languages such as java, C++, python, and PERL.

Student Learning Outcomes

Students should be able to become proficient in applying fundamental concepts of programming in solving problems in science and engineering. This proficiency is critical towards developing research-grade tools in domains such as bioinformatics.

Unit I
Introduction
4 lectures

Higher level programming concepts, assembly level programming concepts, libraries, compilers, STDIN, STDOUT; Integrated programming environments.

Unit II
Variables
5 lectures

Number representations, Variables, data types, declarations, Operators (assignment).

Unit III
Loops & subroutines
5 lectures

Control structures and conditional statements; Do, while, until constructs. Functions, Arrays. Recursive functions.

Unit IV
Object-oriented programming
5 lectures

Structures and Objects; Object-oriented programming and Classes.

Unit V
Applications
7 lectures

Sample problems in science, engineering and text processing.

Recommended Textbooks and References:

1. Ranade, A. (2014) *An Introduction to Programming through C++*, McGraw Hill Education.
2. Lutz, M. (2011) *Programming Python*. O'Reilly media.
3. Schwartz, R.L., Foy, B.D., Phoenix, T. (2011) *Learning Perl*, O'Reilly media.
4. Stroustrup, B. (2013) *The C++ Programming Language,* Addison-Wesley Professional Publishers.

Environmental Biotechnology

Credits

2

Course Objectives

This course aims to introduce fundamentals of Environmental Biotechnology. The course will introduce students major groups of microorganisms-tools in biotechnology and their most important environmental applications. The environmental applications of biotechnology will be presented in detail and will be supported by examples from national and international literature.

Student Learning Outcomes

On completion of the course, students should be able to understand use of basic microbiological, molecular and analytical methods, which are extensively used in environmental biotechnology.

Unit I

Introduction to environment

6 lectures

Introduction to environment; pollution and its control; pollution indicators; waste management: domestic, industrial, solid and hazardous wastes; strain improvement; Biodiversity and its conservation; Role of microorganisms in geochemical cycles; microbial energy metabolism, microbial growth kinetics and elementary chemostat theory, relevant microbiological processes, microbial ecology.

Unit II

Bioremediation

6 lectures

Bioremediation: Fundamentals, methods and strategies of application (biostimulation, bioaugmentation) – examples, bioremediation of metals (Cr, As, Se, Hg), radionuclides (U, Te), organic pollutants (PAHs, PCBs, Pesticides, TNT *etc.*), technological aspects of bioremediation (*in situ*, *ex situ)*.

Unit III

Role of microorganisms in bioremediation

6 lectures

Application of bacteria and fungi in bioremediation: White rot fungi *vs* specialized degrading bacteria: examples, uses and advantages *vs* disadvantages; Phytoremediation: Fundamentals and description of major methods of application (phytoaccumulation, phytovolatilization, rhizofiltration, phytostabilization).

Unit IV

Applications of environmental biotechnology in agriculture

11 lectures

Bioinsecticides: *Bacillus thuringiensis*, Baculoviruses, uses, genetic modifications and aspects of safety in their use; Biofungicides: Description of mode of actions and mechanisms (*e.g. Trichoderma, Pseudomonas fluorescens*); Biofertilizers: Symbiotic systems between plants – microorganisms (nitrogen fixing symbiosis, mycorrhiza fungi symbiosis), Plant growth promoting rhizobacteria (PGPR) – uses, practical aspects and problems in application.

Unit V

Biofuels

11 lectures

Environmental Biotechnology and biofuels: biogas; bioethanol; biodiesel; biohydrogen; Description of the industrial processes involved, microorganisms and biotechnological interventions for optimization of production; Microbiologically enhanced oil recovery (MEOR); Bioleaching of metals; Production of bioplastics; Production of biosurfactants: bioemulsifiers; Paper production: use of xylanases and white rot fungi.

Recommended Textbooks and References:

1. G. M. Evans and J. C. Furlong (2003), *Environmental Biotechnology: Theory and Applications*, Wiley Publishers.
2. B. Ritmann and P. L. McCarty, (2000), *Environmental Biotechnology: Principle & Applications*, 2nd Ed., McGraw Hill Science.
3. Scragg A., (1999) *Environmental Biotechnology*. Pearson Education Limited.
4. J. S. Devinny, M. A. Deshusses and T. S. Webster, 1998, *Biofiltration for Air Pollution Control*, CRC Press.
5. H. J. Rehm and G. Reed, (1993), *Biotechnology – a Multi-Volume Comprehensive Treatise*, Vol. 11, 2nd Ed., VCH Publishers Inc.
6. H. S. Peavy, D. R. Rowe and G. Tchobanoglous, (1985), *Environmental Engineering*, McGraw-Hill Inc.

Enzyme Engineering & Technology

Credits

2

Course Objectives

The objectives of this course are to teach principles of enzyme engineering and enzyme technology.

Student Learning Outcomes

On completion of this course, students should be able to:

- Understand essential principles of enzyme engineering and technology;
- Become aware of applications in biotechnology processes.

Unit I

Enzymes, coenzymes and cofactors

3 lectures

Enzymes: Classification, mode of action, activation, specificity, Source of enzymes; production, isolation and purification of enzymes; Characterization in terms of pH, temperature, ionic strength, substrate and product tolerance, effects of metal ions; Coenzymes and cofactors: Coenzymes, classification of vitamins, role and mechanism of action of some important coenzyme (NAD+/NADP+, FAD, lipoic acid, tetrahydrofolate, B12-coenzyme), role of cofactors with specific examples.

Unit II

Enzyme kinetics

8 lectures

Enzyme as biological catalysts; Enzyme action, active site, functional group, enzyme substrate complex, cofactors, Michaelis-Menten equation, Km and Vmax, enzyme inhibition; order of reaction, methods of plotting enzyme kinetics data; Enzyme turnover number. competitive, non-competitive, uncompetitive, irreversible; order of reaction, methods of plotting enzyme kinetics data; determination of Kcat, Km, Vmax, Ki, Half life, activation and deactivation energy etc, Cross-linked enzyme aggregates, Cross linked enzymes, enzyme crystals, their use and preparation; Solution of numerical problems; Energy yielding and energy-requiring reactions; Calculation of equilibrium constants; Activation energy *etc.*; Multisubstrate enzymes and kinetics mechanisms; Enzyme induction, repression, covalent modification, Isoenzymes, allosteric effects.

Unit III

Enzyme engineering

5 lectures

Introduction, Random and rational approach of protein engineering; Directed evolution and its application in Biocatalysis; various approaches of creating variant enzyme molecules; Future of Biocatalysis; Ideal biocatalyst.

Unit IV

Applications of enzyme technology

4 lectures

Immobilized enzyme technology: Different techniques of immobilization of enzymes and whole cells; Advantages and disadvantages of immobilization; Kinetics of immobilized enzymes, design and operation of immobilized enzymes reactors; Type of reactors, classification, retention of enzymes in a reactor, kinetics of enzyme reactors; Reactor performance with inhibition, operation of enzyme reactors; case studies; starch conversion; APA production, biotransformations using soluble as well as immobilized enzymes; Calculation of diffusional resistances and Thiele's modulus, multi-step immobilized enzyme systems; Solution of numerical problems; Application and future of immobilized enzyme technology; Enzyme in organic solvents and ionic liquids: Various organic solvents and ionic liquids used in biocatalysis; Potential in organic solvents and ionic liquids; Applications of enzymes in analysis.

Recommended Textbooks and References:

1. Stryer, L. (2002). *Biochemistry*. Freeman. New York.
2. Lehninger, A. L. (2004). *Principles of Biochemistry* (4th ed.). Worth. New York, NY
3. Voet, D., & Voet, J. G. (2004). *Biochemistry* (4th ed.). Wiley & Sons. Hoboken, NJ: J
4. Rehm, H. & J. Reed, G., (1986). *Enzyme Technology.* Volume 7a. John Wiley & Sons.
5. Irwin H. Segel, (1976). *Biochemical Calculations: How to Solve Mathematical Problems in General Biochemistry*, 2nd revised Ed. John Wiley & Sons.
6. Biotol, (1992). *Bioreactor Design & Product Yield*. Butterworth-Heinemann
7. Wang, D. I. C. (1979). *Fermentation and Enzyme Technology.* Wiley. New York.

Metabolic and Systems Biology

Credits

2

Course Objectives

This course work will provide essential knowledge to make career in bioprocess industries and in field of computational systems biology.

Student Learning Outcomes

At the end of this course, students should be able to:

- Understand the current advances in systems biology;
- Gain insights into the field of metabolic engineering.

Unit I

Introduction to systems biology

6 lectures

Systems level understanding of biological systems. Networks and graph theory: Basic properties of Network: Degree, average degree and degree distribution. Adjacency matrix, weighted and unweighted networks, Bipartite network, Paths and distances, Random Networks: Erdos-Renyi model, Small-world effect, clustering coefficient, Scale-free networks: Power laws, Hubs, ultra-small property, degree exponent, Barabasi-Albert Model; Degree correlations: assortativity and disassortativity.

Unit II

Metabolic flux analysis

5 lectures

Introduction to Flux balance analysis, Construction of stoichiometric matrices, Constraint based models. Network basics, examples of mathematical reconstruction of transcriptional networks and signal transduction networks; Tools for metabolic flux analysis - Monitoring and measuring the metabolome, Methods for the experimental determination of metabolic fluxes by isotope labeling metabolic fluxes using various separation-analytical techniques; GC-MS for metabolic flux analysis, genome wide technologies: DNA /phenotypic microarrays and proteomics; Basics of MATLAB.

Unit III

Kinetic modelling

6 lectures

Kinetic modelling of biochemical reactions, describing dynamics with ODEs, rate equations, deriving a rate equation, incorporating regulation of enzyme activity by effectors, E-cell platform and erythrocyte modelling, case studies in E. coli, S. cerevisiae metabolic network reconstruction methods, optimization of metabolic network, Identification of targets for metabolic engineering; software and databases for genome scale modelling; Use of computational techniques to solve ODEs.

Unit IV

Networks in biological systems

4 lectures

Network motifs, Feed forward loop network motif. Gene circuits, robustness of models, Chemotaxis model, Integration of data from multiple sources: Building genome scale models.

Unit V

Tools and case studies

5 lectures

Tools and databases for modelling: Pathway databases KEGG, EMP, Metacyc, Enzyme kinetics database BRENDA, Gene expression databases, Biomodels database, Basics of Systems Biology Markup Language (SBML), SBML editors. Transcriptomics: Microarray technology, expression profiles, data analysis; SAGE; Proteomics: 2D gel electrophoresis; Mass Spectrometry; Protein arrays; Metabolomics: 13C NMR based metabolic flux analysis.

Recommended Textbooks and References:

1. Edda Klipp, Wolfram Liebermeister, Christoph Wierling, (2009). *Systems Biology, a Textbook*, Wiley-BlackWell Publications.
2. Uri Alon, (2007). *An Introduction to Systems Biology: Design Principles of Biological Circuits*, Chapman and Hall / CRC.
3. EddaKlipp, Ralf Herwig, Axel Kowald, Christoph Wierling, Hans Lehrach, 2005. *Systems Biology in Practice: Concepts, Implementation and Application*, Wiley – VCH

4. Hiroaki Kitano, *Foundations of Systems Biology*, MIT Press.
5. Stephanopoulos, G.N. (1998), *Metabolic Engineering: Principles and Methodologies*. Academic Press / Elsevier.
6. Jonathan Pevsner, (2003), *Bioinformatics and Functional Genomics*, 1st Edition, Wiley-Liss.

Medical Devices

Credits

2

Course Objectives

The objective of the course is to familiarize students with emerging trends in medical devices for early detection, selection of appropriate treatment, monitoring treatment effectiveness and disease surveillance.

Student Learning Outcomes

On successfully completing this course, students are expected to be able to:

- Extend principles of engineering to the development of medical devices and design of sensors;
- Appreciate basic configuration and distinction among biosensor systems.

Unit I
Sensors
5 lectures

Rationale of electronic biosensors; Essence of three types of electronic biosensors (*i.e.*, potentiometric, amperometric, and cantilever-based sensors); Three essential metrics that define modern electronic sensors; detection time, sensitivity, and selectivity; Physics of detection time that allows one to organize every available sensor in a systematic way; Fundamental limits of detection of various classes of sensors; Opportunities and challenges of integrating sensors in a system platform.

Unit II
Transducers
5 lectures

Principles and applications of Calorimetric, Piezoelectric, semiconductor, impedimetric, based transducers; Biochemical Transducers: Electrode theory: electrode-tissue interface, metal-electrolyte interface, electrode-skin interface, electrode impedance, electrical conductivity of electrode jellies and creams.

Unit III
Optical sensors
5 lectures

Photo detectors, optical fiber sensors, indicator mediated transducers; General principles of optical sensing, optical fiber temperature sensors; Pulse sensor: photoelectric pulse transducer, strain gauge pulse transducer.

Unit IV
Bio recognition systems
5 lectures

Enzymes; Oligonucleotides Nucleic Acids; Lipids (Langmuir-Blodgett bilayers, Phospholipids, Liposomes); Membrane receptors and transporters; Immunoreceptors; Chemoreceptors.

Unit V
Electrodes and immobilization
5 lectures

Microelectrodes, body surface electrodes, needle electrodes, pH electrode, specific ion electrodes/ Ion exchange membrane electrodes, enzyme electrodes; Reference electrodes: hydrogen electrodes, silver-silver chloride electrodes, Calomel electrodes; Enzyme immobilization; Peptide immobilization; Antibody immobilization; Oligonucleotides and Nucleic Acid immobilization; Cell immobilization; Mono-enzyme electrodes; Bi-enzyme electrodes: enzyme sequence electrodes and enzyme competition electrodes.

Unit VI
Fundamentals and applications of microfluidics
5 lectures

Capillary flow and electro kinetics; Micro pump, Micro mixers, Micro reactors, Micro droplets, Micro particle separators; Micro fabrication techniques (different types of lithography methods); Application of micro-fluidics (*e.g.* Lab- in –Chip).

Unit VII
Applications
5 lectures

Biomarkers: Disease and pathogen specific information, availability by sample type (blood, serum, urine, sputum, saliva, stool, mucus); Specificity, sensitivity, shelf life,

portability; Clinical chemistry; Test-strips for glucose monitoring; Urea determination; Implantable Sensors for long-term monitoring; Drug development and detection; Environmental monitoring; Examples of various diseases (Cancer, HIV/AIDS, Tuberculosis, Malaria, Lymphatic Filariasis, Schistosomiasis, Dengue, Chikungunya).

Recommended Textbooks and References:

1. Alice Cunningham, (1998), *Introduction to Bio Analytical Sensors*, John Wiley & Sons.
2. Jiri Janata, (2009), *Principles of Chemical Sensors*, 2nd Ed., Plenum Press.
3. F. Schellr, F. Schubert, J. Fedrowitz, (1997), *Frontiers in Biosensors*, Birkhauser.
4. F. Ligler, C. Rowe Taitt, (2002), *Optical Biosensors. Present & Future*. Elsevier.
5. Brian Eggins, (2002), *Chemical Sensors and Biosensors*, John Willey & Sons.
6. Graham Ramsay, (1998), *Commercial Biosensors*, John Wiley& Sons.
7. Ursula Spichiger-Keller, (1998), *Chemical Sensors and Biosensors for Medical and Biological Applications*, Wiley-VCH.
8. Berthier Jean, and Silberzan Pascal, (2010), *Microfluidics for Biotechnology*, 2nd Ed. Artech House.
9. Frank A Gomez, (2008), *Biological Applications of Microfluidics*, Wiley.
10. Gareth Jenkins, Colin D. Mansfield, (2013), *Microfluidic Diagnostics: Methods and Protocols*, Springer.
11. J G. Webster, (1998), *Encyclopedia of Medical Devices and Instrumentation*. Vol I, II, III, IV, Wiley-Blackwell.

Molecular Diagnostics

Credits

2

Course Objectives

The objectives of this course are to sensitize students about recent advances in molecular biology and various facets of molecular medicine which has potential to profoundly alter many aspects of modern medicine including pre- or post-natal analysis of genetic diseases and identification of individuals predisposed to disease ranging from common cold to cancer.

Student Learning Outcomes

Students should be able to understand various facets of molecular procedures and basics of genomics, proteomics and metabolomics that could be employed in early diagnosis and prognosis of human diseases.

Unit I

Genome biology in health and disease

4 lectures

DNA, RNA and Protein: An overview; chromosomal structure & mutations; DNA polymorphism: human identity; clinical variability and genetically determined adverse reactions to drugs.

Unit II

Genome: resolution, detection and analysis

5 lectures

PCR: Real-time; ARMS; Multiplex; ISH; FISH; ISA; RFLP; DHPLC; DGGE; CSCE; SSCP; Nucleic acid sequencing: new generations of automated sequencers; Microarray chips; EST; SAGE; microarray data normalization & analysis; molecular markers: 16S rRNA typing; Diagnostic proteomics: SELDI-TOF MS; Bioinformatics data acquisition & analysis.

Unit III

Diagnostic metabolomics

2 lectures

Metabolite profile for biomarker detection in the body fluids/tissues under various metabolic disorders by making use of LCMS & NMR technological platforms.

Unit IV
Detection and identity of microbial diseases
4 lectures

Direct detection & identification of pathogenic-organisms that are slow growing or currently lacking a system of *in vitro* cultivation as well as genotypic markers of microbial resistance to specific antibiotics.

Unit V
Detection of inherited diseases
4 lectures

Exemplified by two inherited diseases for which molecular diagnosis has provided a dramatic improvement of quality of medical care: - Fragile X Syndrome: Paradigm of the new mutational mechanism of the unstable triplet repeats, von-Hippel Lindau disease: recent acquisition in the growing number of familial cancer syndromes.

Unit VI
Molecular oncology
5 lectures

Detection of recognized genetic aberrations in clinical samples from cancer patients; types of cancer-causing alterations revealed by next-generation sequencing of clinical isolates; predictive biomarkers for personalized onco-therapy of human diseases such as chronic myeloid leukemia, colon, breast, lung cancer and melanoma as well as matching targeted therapies with patients and preventing toxicity of standard systemic therapies.

Unit VII
Quality assurance and control
1 lecture

Quality oversight; regulations and approved testing.

Recommended Textbooks and References:

1. Campbell, A. M., & Heyer, L. J. (2006). *Discovering Genomics, Proteomics, and Bioinformatics*. San Francisco: Benjamin Cummings.
2. Brooker, R. J. (2009). *Genetics: Analysis & Principles*. New York, NY: McGraw-Hill.
3. Glick, B. R., Pasternak, J. J., & Patten, C. L. (2010). *Molecular Biotechnology: Principles and Applications of Recombinant DNA*. Washington, DC: ASM Press.
4. Coleman, W. B., & Tsongalis, G. J. (1997). *Molecular Diagnostics: for the Clinical Laboratorian*. Totowa, NJ: Humana Press.

Nanobiotechnology

Credits
2

Course Objectives

The course aims at providing general and broad introduction to multi-disciplinary field of nanotechnology. It will familiarize students with combination of top-down approach of microelectronics and micro-mechanics with bottom-up approach of chemistry/biochemistry; a development that is creating new and exciting cross-disciplinary research fields and technologies. The course will also give an insight into complete systems where nanotechnology can be used to improve everyday life.

Student Learning Outcomes

On successful completion of this course, students should be able to describe basic science behind the properties of materials at the nanometre scale, and the principles behind advanced experimental and computational techniques for studying nanomaterials.

Unit I
Introduction to nanobiotechnology
5 lectures

Introduction to Nanobiotechnology; Concepts, historical perspective; Different formats of nanomaterials and applications with example for specific cases; Cellular Nanostructures; Nanopores; Biomolecular motors; Bio-inspired Nanostructures, Synthesis and characterization of different nanomaterials.

Unit II
Nano - films
5 lectures

Thin films; Colloidal nanostructures; Self Assembly, Nanovesicles; Nanospheres; Nanocapsules and their characterisation.

Unit III
Nano - particles
6 lectures

Nanoparticles for drug delivery, concepts, optimization of nanoparticle properties for suitability of administration through various routes of delivery, advantages, strategies for cellular internalization and long circulation, strategies for enhanced permeation through various anatomical barriers.

Unit IV
Applications of nano - particles
5 lectures

Nanoparticles for diagnostics and imaging (theranostics); concepts of smart stimuli responsive nanoparticles, implications in cancer therapy, nanodevices for biosensor development.

Unit V
Nano - materials
6 lectures

Nanomaterials for catalysis, development and characterization of nanobiocatalysts, application of nanoscaffolds in sythesis, applications of nanobiocatalysis in the production of drugs and drug intermediates.

Unit VI
Nano - toxicity
5 lectures

Introduction to Safety of nanomaterials, Basics of nanotoxicity, Models and assays for Nanotoxicity assessment; Fate of nanomaterials in different stratas of environment; Ecotoxicity models and assays; Life cycle assessment, containment.

Recommended Textbooks and References:

1. GeroDecher, Joseph B. Schlenoff, (2003); *Multilayer Thin Films: Sequential Assembly of Nanocomposite Materials,* Wiley-VCH Verlag GmbH & Co. KGaA
2. David S. Goodsell, (2004); *Bionanotechnology: Lessons from Nature*, Wiley-Liss
3. Neelina H. Malsch, *Biomedical Nanotechnology,* CRC Press
4. Greg T. Hermanson, (2013); *Bioconjugate Techniques*, (3rd Edition); Elsevier
5. Recent review papers in the area of Nanomedicine.

Production of Biotherapeutics

Credits
2

Course Objectives

The objectives of this course are to equip students with essentials of biomanufacturing principles and good manufacturing practices for production of biotherapeutics.

Student Learning Outcomes

Students should develop conceptual clarity and knowledge about systems for quality manufacturing of biotherapeutics (biopharmaceuticals, diagnostics and foods) manufactured for human use. The knowledge of GMP and GLP requirements is critical for students who opt for careers in biomanufacturing.

Unit I
Biomanufacturing principles
6 lectures

Overview and design of biomanufacturing, quality by design approach, technical considerations, phases and scale up: life cycle of manufacturing, raw material considerations, compliance and quality in biomanufacturing, lean biomanufacturing; Process analytical technology (PAT) during biomanufacturing: background and need tools for data acquisitions (software in fermenters, flow filtrations, chromatography, analysis and design process analyzers, process control tools and continuous improvement and knowledge management; Standard manufacturing operating procedures of biotechnology, including upstream and downstream processing of proteins, and quality control of protein production, and final fill and finish of product; Case studies to be included therapeutic proteins, monoclonal antibodies, human vaccines.

Unit II
Quality system
4 lectures

Introduction to quality system, main elements of a quality system; Essential of quality system; Practical implementation of a quality system; Structure of quality manual, correlation between GMP requirements (WHO) and ISO 9001:2000.

Unit III

Principles and practice of GMP

10 lectures

Personnel: Principles of human resource management, duties of senior management, organizational structures, qualification and profiles requirement, workplace and job descriptions, health monitoring and occupational health safety, training, functions owners subject to public law; Premises: Official requirements, material & personnel flow and layout, air cleanliness classes and grades, construction elements, barrier systems, isolators and safety cabinets, building services, heating ventilation air conditioning (HVAC), process gases, qualification of premises and HVAC systems, pharma monitoring of HVAC systems, particle monitoring.; Facilities and Equipment: Facility planning, materials, hygienic design in solids handling, system controllers and process control systems, technical documentation, calibration, maintenance, cleaning of facilities, containment (personnel protection) in solids handling; Pharmaceutical water: Water qualities, generation of pharmaceutical water, distribution and storage of pharmaceutical water, qualification of water supplies, operation of water supplies, pure steam systems; Qualification: Official requirements, preparation of the qualification, qualification documentation, design qualification (DQ), Installation qualification (IQ), operational qualification (OQ), Performance qualification (PQ), special cases of qualification; Process Validation: Official requirements, Validation - a key element of quality management, validation planning and procedure, validation documentation, process validation and product lifecycle ; Cleaning Validation: Official requirements, how to validate cleaning procedures, cleaning validation master plan, establishing the scope of validation, acceptance criteria and limit calculation, sampling procedures, analytical procedure, documentation, maintenance of the validated status, cleaning validation documentation; Production: Sanitation, personnel hygiene, production hygiene, sanitation programme, environmental monitoring, GMP in the production process, weigh-in, identification, in-process control prevention of cross-contamination, empty chapter, reworking, warehouse and logistics; Sterile Production and Packaging: Introduction, Air lock concepts, manufacture of terminally sterilised products, sterilisation processes, aseptic processing, freeze-drying, testing for sterility, testing for endotoxins, testing for leakage and for particles, microbiological monitoring, packaging materials, packaging process, qualification of a servo-controlled blister packaging line, blow-fill-seal technology (BFS technology); Documentation: Official requirements, GMP-compliant documentation, batch documentation, standard operating procedures (SOPs), site master file, electronic batch recording and batch release, CAPA, document management systems.

Unit IV

GMP in regulation

2 lectures

Information, national bodies and pharmaceutical associations; Pharmacopeia; EU directives and guidelines, USA: CFR and FDA guidelines, ICH-guidelines, PIC/S guidelines, GMP of other regions, WHO guidelines.

Recommended Textbooks and References:

1. *Introduction to Biomanufacturing*. By Northeast Biomanufacturing Center and collaboration, 2012.
2. *Introduction to Biomanufacturing*, by Mark Witcher. In Encyclopedia of Industrial Biotechnology.
3. *Good Manufacturing Practices for Pharmaceuticals (e-resource): a Plan for Total Quality Control*. Sidney Willig and James Stoker.
4. *Biotechnology Operations: Principles and Practices*; by John M. Centanni, Michael J. Roy; CRC press
5. *Learn Biomanufacturing*, 1st Edition; Author Nigel Smart; Woodhead Publishing
6. *GMP Manual*; Publisher Maas & Peither America, Inc. GMP Publishing.

OMICS Technologies

Credits

2

Course Objectives

The aim of this course is to give an overview of genomics, proteomics and metabolomics to the students. The students should be able to gain working knowledge of these technologies and appreciate their ability to impart a global understanding of biological systems and processes in health and disease.

Student Learning Outcomes

At the end of the course, students should be:

- Understand high throughput analysis;
- Gain knowledge of current cutting edge technologies;
- Know the application of various Omics technologies.

Unit I

Genomics and methods in genomics

5 lectures

Organization and structure of genomes in prokaryotes, eukaryotes, and organelles (chloroplast, mitochondrion); Genome mapping methods (genetic and physical); RAPD , RFLP, SNP analyses; Fluorescence *in-situ* Hybridization (FISH) techniques; Advances in gene finding and functional prediction; Chain termination and chemical degradation sequencing methods. Genome-wide association (GWA) analysis; Comparative Genomic Hybridization(CGH); Massively parallel Signature Sequencing (MPSS); Whole genome shot-gun sequencing and its applications; Introduction of Next Generation Sequencing (NGS).

Unit II

Transcriptomics and methods in transcriptomics

5 lectures

ne expression analysis by cDNA and oligonucleotide arrays; Micro array experimental analysis and data analysis; Bioinformatic analysis of large-scale microarray data for comparative transcriptomics.

Unit III

Proteomics and methods in proteomics

10 lectures

Over-view of strategies used for the identification and analysis of proteins; Protein extraction from biological samples (Mammalian Tissues, Yeast, Bacteria, and Plant Tissues); 2-DE of proteins for proteome analysis; Liquid chromatography separations in proteomics (Affinity, Ion Exchange, Reversed-phase, and size exclusion); Enzymatic cleavage of proteins. Analysis of complex protein mixtures using Nano-liquid chromatography (Nano-LC) coupled to Mass-spectrometry analysis. Over-view of strategies used for the identification and analysis of proteins; Protein extraction from biological samples (Mammalian Tissues, Yeast, Bacteria, and Plant Tissues); 2-DE of proteins for proteome analysis; Liquid chromatography separations in proteomics (Affinity, Ion Exchange, Reversed-phase, and size exclusion); Enzymatic cleavage of proteins. Analysis of complex protein mixtures using Nano-liquid chromatography (Nano-LC) coupled to Mass-spectrometry analysis. Common ionization methods for peptide/protein analysis; Introduction to Mass spectrometers; MALDI-TOF and LC-MS analyses; Comparative proteomics based on global in-vitro and in-vivo labelling of proteins/peptides followed by Mass-spectrometry. Analysis of post-translational modification (PTM) of proteins; Characterization of protein interactions using yeast two-hybrid system and Protein microarrays; Proteomics informatics and analysis of protein functions.

Unit IV

Metabolomics and methods in metabolomics

8 lectures

Introduction to metabolic engineering, comprehensive models of cellular reactions with stoichiometry and reaction rates; metabolic flux analysis of exactly/over/under determined systems; Shadow price, sensitivity analysis; Monitoring and measuring the metabolome, Methods for the experimental determination of metabolic fluxes by isotope labelling metabolic fluxes using various separation-analytical techniques; GC-MS for metabolic flux analysis.

Recommended Textbooks and References:

1. S.P. Hunt and F. J. Livesey, (2000) *Functional Genomics*.
2. Twyman R. M. (2004), *Principles of Proteomics*. Taylor & Francis.
3. Voit, E.O., 2000 *Computational Analysis of Biochemical Systems: a Practical Guide for Biochemists and Molecular Biologists*. Cambridge University Press.
4. Melanie J Filiatrault, *Progress in Prokaryotic Transcriptomics, Current Opinion in Microbiology*, Volume 14, Issue 5, October 2011, Pages 579-586.
5. Alex Sánchez-Pla, Ferran Reverter, M. Carme Ruíz de Villa, Manuel Comabella, *Transcriptomics: mRNA and Alternative Splicing*. Journal of Neuroimmunology, Volume 248, issues 1-2,15 July 2012, pp 23-31.