



# **SYLLABUS**

## **M.S. (Pharm.) Biotechnology**

**NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH  
GUWAHATI**

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# M.S. (Pharm.) Biotechnology

Course No.	Course Name	Credits
<b>Semester-I</b>		
BT-510	Cell Biology	2
BT-520	Microbiology: Basics, Genetics and Genomics	2
BT-530	Biochemistry	2
BT-540	Applied Bioengineering and Fermentation Technology	2
GE-510	Biostatistics	2
GE-520	Fundamentals of Intellectual Property (IP) and Technology Management	1
GE-511	Seminar	1
LG-510	General Laboratory Experience	3
<b>Elective</b>		2
<b>TOTAL CREDITS</b>		<b>17</b>
<b>Semester-II</b>		
BT-610	Molecular Biology	2
BT-620	Recombinant DNA Technology	2
BT-630	Basic and Applied Immunology	2
BT-640	Principles and Techniques for Diagnostics and Cell Based Screening	2
GE-611	Seminar	1
LS-610	General Lab Experience in the Area of Specialization	2
<b>Elective</b>		2
<b>TOTAL CREDITS</b>		<b>13</b>
<b>Semester-III</b>		
<b>Project (22 weeks)</b>		
TH-598	Synopsis	5
TH-599	Presentation	3
<b>TOTAL CREDITS</b>		<b>8</b>
<b>Semester-IV</b>		
TH-698	Thesis	9
TH-699	Defence of Thesis	3
<b>TOTAL CREDITS</b>		<b>12</b>
<b>GRAND TOTAL CREDITS (I to IV Semesters)</b>		<b>50</b>

# M.S. (Pharm.) Biotechnology

## Semester - I

### BT-510 :- Cell Biology

(2 Credits)

1. **Cell structure and organization:** Cells as a unit of life, prokaryotic and eukaryotic cells, biomembranes, structure and basic functions of various cell organelles i.e. nucleus, ribosomes, ER, golgi, lysosomes, peroxisomes, exosomes, cytoskeleton.
2. **Common methods to study cells and organelles in the laboratory:** Histology, staining, fluorescence, confocal microscopy, TEM and SEM, Fluorescent dyes and GFP tagged proteins in visualization, FACS, cell fractionation, cell culture, Cell transformation, Stable cell lines.
3. **Organization of tissues:** Cell-cell and cell-matrix interactions, cell adhesion molecules, components of the extracellular matrix, cellular junctions and role.
4. **Cell cycle and its regulation:** G1, G2, S and M Phase of the cell cycle, Cell cycle analysis and its applications, programmed cell death apoptosis versus necrosis, Role of telomeres in the cell cycle.
5. **Cell signaling:** Receptor concept, receptor signaling and expression, G protein-coupled receptors, orphan receptors, extracellular signals and cell functions, hormones, second messengers and hormone actions, growth factor.
6. **Transport across membranes:** Osmosis, active and passive transport. Protein transporters, antiporters, symporters, Protein pump, ion channels, Ca<sup>++</sup> regulated events, Vesicular trafficking.
7. **Cellular movement and Molecular motors:** Types of movement, extravasation, role of cytoskeletal proteins in movement, The actin-myosin cytoskeleton, The microtubule cytoskeleton, molecular motors, the movement of cilia and flagella, myosin and kinesins in the movement of vesicles.
8. **Protein Synthesis and Targeting:** Ribosome and endoplasmic reticulum, Secretory pathway, targeting and sorting of proteins, nuclear localization signal, organelle specific signal sequence, ATP driven translocation, glycosylation, transport of protein, endocytosis, exocytosis, macropinocytosis.
9. **Stem cells:** Stem cells and their classification, Tissue-resident stem cells, Stem cells in clinical practice and regenerative medicine, Cell therapy, Tissue engineering.
10. **Cell-cell communications:** Gap junctions and nano tubes, neuronal signaling: action potential, nerve impulse propagation, synapse, mechanism of neurotransmitter release; vesicular fusion.

#### Recommended Books/Literature:

1. Bruce Alberts, Alexander Johnson, Julian Lewis, David Morgan, Martin Raff, Keith Roberts, and Peter Walter. Molecular Biology of Cell (6<sup>th</sup> Edition). Garland Science Publishing.
2. Geoffrey M. Cooper. The Cell: A molecular Approach (8<sup>th</sup> Edition). Oxford University Press.

**BT-520:- Microbiology: Basics, Genetics And Genomics (2 Credits)**

1. **Structure and Function of Microbes:** Overview of microbes and microbial cell organization. Structure and functions of microbial cell membrane, Outer membrane lipopolysaccharide, Cell wall, Nucleoid, Ribosomes, Cell inclusions, Flagella, Pili and Fimbriae. Overview of Archaeal and Asgardarchaeota diversity, Cell structure and model organisms.
2. **Microbial Growth and Cell Division:** Measurement of growth, Growth physiology, Cell division, Growth yields, Growth kinetics, Steady state growth and continuous growth, Culture media.
3. **Microbial Infections:** Introduction to pathogenic microbes. Sepsis: Causes, Symptoms, Treatment, and Prevention. Typhoid: Causes, Symptoms, Treatment, and Prevention. Diarrhoea: Causes, Symptoms, Treatment, and Prevention. Tuberculosis: Causes, Symptoms, Treatment, and Prevention. COVID-19: Causes, Symptoms, Treatment, and Prevention. AIDS: Causes, Symptoms, Treatment, and Prevention.
4. **Microbial Biotechnology:** Industry (Food industries, Pharmaceutical Industries), Introduction to fermentation technology and microbial mass production, Research (Cloning, recombinant protein production, functional validation of unknown gene), Therapeutics (antibiotics, vaccines, probiotics).
5. **Microbial Genetics:** Basic understanding of gene, Allele, Chromosome, genome. Vertical and horizontal gene transfer, Conjugation, Transformation, transduction, Fusion. Genetic analysis of bacteria, Transposon, Gene knockout, CRISPR-Cas and genome editing.
6. **Bacterial Genome:** Composition, Diversity, Organization and functions of genome, Linear and circular microbial genome, Dynamics and plasticity of bacterial genome, Core and shell genomes.
7. **Introduction to Virology:** Introduction, Classification, Life cycle of Viruses, provirus, Lytic and Lysogenic Phage, Viroid, Prions, Virus genome types, double stranded DNA (dsDNA), Gapped DNA genomes, Single-stranded (ssDNA) genomes, Double stranded RNA (dsRNA), Single stranded RNA (ssRNA), (+) Strand RNA, Single stranded (+) sense RNA with DNA intermediate, Single-stranded RNA (-) sense, Ambisense RNA genomes.
8. **Therapeutics against bacterial and viral pathogens:** Antibiotics, Antifungal agents, Anti-viral drugs, Drug resistance in bacteria and viruses, multidrug efflux pumps, extended spectrum beta-lactamases (ESBL), antibiotic modification enzymes. Vaccines, probiotics. Recombinant vaccines, subunit vaccines, DNA vaccines, Vaccinia-BCG- and HIV vector-based vaccines.

**Recommended Books**

1. Prescott, Harley and Klein's Microbiology, Seventh Edition – 2008, M. Willey et. al. McGraw Hills Publication.
2. Microbiology: An Introduction, VIIIth Edition – 2006, Tortora et.al. Pearson Education.
3. General Microbiology, Fifth Edition – 2007, R. Stanier et.al., Macmillan Press.

**BT-530 :- Biochemistry****(2 Credit)**

1. **Biomolecules:** Introduction, different classes of biomolecules viz carbohydrates, lipids, Protein nucleic acids, organization of prokaryotic and eukaryotic cells, structures and functions of biomolecules, pharmaceutical importance.
2. **Protein and Nucleic acids:** Synthesis, Structure (primary, secondary, tertiary and quaternary), properties, transport, signal transduction, pharmaceutical importance.
3. **Enzymes:** Classification, mode of action (activation, specificity), enzyme kinetics, enzyme inhibitors and regulators, allosteric enzymes, isoenzymes, multienzyme system, pharmaceutical importance.
4. **Coenzymes and cofactors:** Coenzymes, classification of vitamins, role and mechanism of action of some important coenzyme (NAD<sup>+</sup>/NADP<sup>+</sup>, FAD, lipoic acid, tetrahydrofolate, B12- coenzyme), role of cofactors with specific examples.
5. **Biochemical energetics:** Free energy, , concept of standard free energy, laws of thermodynamics, anabolism and catabolism, cellular respiration, photosynthesis etc exergonic and endergonic reactions, energy rich compounds, coupling of reaction, biological oxidation-reduction.
6. **Carbohydrate metabolism:** Glycolysis, gluconeogenesis, pentose phosphate pathways (PPP), TCA cycle, glyoxylic acid cycle, regulation of carbohydrate metabolism, electron transport chain and oxidative phosphorylation, disorders of carbohydrate metabolisms.
7. **Lipid metabolism:** Hydrolysis, absorption and transport of lipids, catabolism of lipids, beta and omega oxidation of fattyacids, ketone bodies formation, biosynthesis of fatty acids, disorders of lipid metabolisms.
8. **Amino acid metabolism:** Hydrolysis, of proteins, pathways of amino acid degradation, urea cycle and formation of uric acid, assimilation of ammonia, biosynthesis of amino acids, inborn error of protein metabolism.
9. **Nucleic Acid Metabolism:** Purine and pyrimidine biosynthesis, salvage pathway, degradation of nucleotides, role of ribonucleotide reductase, pharmaceutical importance, disorders of purine and pyrimidine metabolisms.

**Recommended Books:**

1. David L. Nelson; Michael M. Cox. Lehninger Principles of Biochemistry. Eighth Edition. 2021.
2. Lubert Stryer; Jeremy Berg; John Tymoczko; Gregory Gatto. Biochemistry. Ninth Edition. 2019.
3. Donald Voet, Judith G. Voet. Biochemistry, 4th Edition.
4. Reginald H. Garrett, Charles M. Grisham. Biochemistry, 6th edition.
5. Denise R. Ferrier, Lippincott Illustrated Reviews: Biochemistry. 7th edition.

**BT-540 :- Applied Bioengineering and Fermentation Technology****(2 Credits)**

1. **Synthetic Biology:** Concept and approaches, Application in antibiotic production, Production of plant metabolites, Future trends.
2. **Biomaterials, Bioprinting and Tissue Engineering:** Controlled release; Bioartificial organs; Cell encapsulation; Organ on Chip technology; Organoid Culture Techniques and Applications.
3. **Antibody Engineering:** Brief Introduction about antibody and Hybridomas; Introduction to Antibody Engineering; Next generation antibody technology; antibody-drug conjugation technologies.

4. **Environmental Bioengineering:** Bioconversion, Bioremediation, and microbial fuel cells.
5. **Fermentation Processes:** Overview of fermentation industry; introduction to Pharmaceutical/Biotechnology Products and Businesses; Modes of bioreactor operation & ancillary equipment: Basic configuration of bioreactor and ancillaries; main parameters to be monitored and controlled in fermentation processes; Batch, Fed-batch and continuous operation; Instrumentation and control of bioprocesses; Equipping a research scale fermentation lab for production of value-added products.
6. **Media Design and Raw Materials For Fermentation Process:** Criteria for medium design, medium requirements for fermentation processes: types of medium and its applications; Media Sterilization and Microbial Growth.
7. **Transport Phenomenon and Scale-Up:** Need of agitation in aerobic fermentation; Effect of agitation on aeration; different types of agitation methods; Need of aeration in aerobic fermentation; Effect of aeration; different types of aeration methods; aeration in high cell density fermentation; Mass transfer and heat transfer in bioreactors. Scale-up principles and criteria: Different methods of scale up and design criteria.
8. **Downstream Processing:** Introduction to downstream processing; Cell disruption: mechanical, enzymatic and chemical methods. Physical methods of separation: filtration and centrifugation. Product isolation: Adsorption; liquid-liquid extraction; aqueous two-phase extraction; membrane separation. Product purification: principles of chromatographic techniques; instruments and practice. Product formulation.

#### Recommended Books:

1. Shuler, M.L. and Kargi, F. "Bioprocess Engineering : Basic Concepts", 2nd Edition, PHI.
2. P. M. Doran, Bioprocess Engineering Principles, 2<sup>nd</sup> Edition Elsevier Science & Technology Books, 2013.
3. Bailey, J.E. and Ollis, D.F. "Biochemical Engineering Fundamentals", 2nd Edition, McGraw-Hill, 1986.
4. Markus Schmidt. Synthetic Biology: Industrial and Environmental Applications. 1<sup>st</sup> Edition. Wiley-Blackwell 2012.
5. Jamie A. Davies. Synthetic Biology: A Very Short Introduction. OUP Oxford. 2018.
6. Florian Ruker. Introduction to Antibody Engineering (Learning Materials in Biosciences). Springer, 2020.
7. LG Zhang, L Leong, JP Fisher. 3D Bioprinting and Nanotechnology in Tissue Engineering and Regenerative Medicine. Academic Press Inc. 2022.
8. Lawrence K. Wang. Environmental Bioengineering: Volume 11. Humana. 2010.

#### GE-510 :- Biostatistics

(2 Credits)

1. **Statistics:** Introduction, its role and uses. Collection; Organization; Graphics and pictorial representation of data; Measures of central tendencies and dispersion. Coefficient of variation.
2. **Probability:** Basic concepts; Common probability distributions and probability distributions related to normal distribution.
3. **Sampling:** Simple random and other sampling procedures. Distribution of sample mean and proportion.

4. **Estimation and Hypothesis testing:** Point and interval estimation including fiducial limits. Concepts of hypothesis testing and types of errors. Student-t and Chi square tests. Sample size and power.
5. **Experimental design and analysis of variance:** Completely randomized, randomized blocks. Latin square and factorial designs. Post- hoc procedures.
6. **Correlation and regression:** Graphical presentation of two continuous variables; Pearson's product moment correlation coefficient, its statistical significance. Multiple and partial correlations. Linear regression; Regression line, coefficient of determination, interval estimation and hypothesis testing for population slope. Introduction to multiple linear regression model. Probit and logit transformations.
7. **Non-parametric tests:** Sign; Mann-Whitney U; Wilcoxon matched pair; Kruskal wallis and Friedman two way anova tests. Spearman rank correlation.
8. **Statistical techniques in pharmaceuticals:** Experimental design in clinical trials; Parallel and crossover designs. Statistical test for bioequivalence. Dose response studies; Statistical quality control.

#### Recommended Books:

1. Fundamentals of Biostatistics by Bernard Rosner.
2. Pharmaceutical Statistics: Practical and Clinical Applications by Bolton and Bon.
3. Statistical Misconceptions by Huck GE-520 Fundamentals of Intellectual Property (IP) and Technology

#### GE-520 :- Fundamentals of Intellectual Property (IP) and Technology Management (1 Credit)

10. **Intellectual property:** Concepts and fundamentals; Concepts regarding intellectual property (IP), intellectual property protection (IPP) and intellectual property rights (IPR); Economic importance, mechanisms for protection of intellectual property- patents, copyrights, trademark; Factors effecting choice of IP protection; Penalties for violation; Role of IP in pharmaceutical industry; Global ramifications and financial implications.
11. **Trade related aspects of intellectual property rights:** Intellectual property and international trade; Concept behind WTO (World Trade Organisation), WIPO (World Intellectual Property Organisation) GATT (General Agreement on Tariff and Trade), TRIPs (Trade Related Intellectual Property Rights), TRIMS (Trade Related Investment Measures) and GATS (General Agreement on Trade in Services); Protection of plant and animal genetic resources; Biological materials; Gene patenting; Biotechnology / drug related IPR issues; Status in India and other developing countries; Case studies and examples; TRIPS issues on herbal drugs.
12. **Nuts and bolts of patenting, copyright and trademark protection criteria for patentability, types of patents; Indian Patent Act, 1970; WTO and modifications under TRIPS:** Filing of a patent application; Precautions before patenting- disclosures / non-disclosures, publication-article / thesis; Prior art search-published patents, internet search patent sites, specialized services-search requests, costs; Patent application-forms and guidelines, fee structure, time frames, jurisdiction aspects; Types of patent applications- provisional, non provisional, PCT and convention patent applications; International patenting-requirement procedures and costs; Financial assistance for patenting- introduction to schemes by NRDC and TIFAC; Publication of patents-gazette of India, status in Europe and US; Patent annuity; Patent attorneys technical aspects, criteria for selection, addresses, fee, rights

and responsibilities of a patentee; Practical aspects regarding maintaining of a PATENT FILE; Patent infringement- meaning, scope, litigation, case studies and examples; Patenting by research students, lecturers and scientists University / organisational rules in India and abroad; Thesis research paper publication, credit sharing by workers, financial incentives; Useful information sources for patents related information-internet sites, brochures, periodicals, CD roms; Significance of copyright protection for researchers; Indian Copyright Law and digital technologies-Berne convention, WIPO copyright treaty (WCT), WIPO performance and Phonogram Treaty (WPPT); Protection for computer data bases, multi media works; Trade marks legislation and registration system in India-an introduction, meaning of trademark criteria for eligibility; filling application for trademark registration; Trade secrets-scope modalities and protection; Case studies-drug related patents infringements.

**13. Technology Development/transfer/commercialisation related aspects:**

Technology development-meaning; Drug related technology development; Toxicological studies, bioequivalence (BU), clinical trials-phase-I, phase-II and phase-III; Approved bodies and agencies; Scale-up, semi-commercialisation and commercialisation-practical aspects and problems; Significance of transfer of technology (TOT), bottlenecks; Managing technology transfer-guidelines for research students, scientists and related personnel; TOT agencies in India-APCTD, NRDC, TIFAC, BCIL, TBSE/SIDBI; TOT related documentation-confidentiality agreements, licensing, MOUs, legal issues; Compulsory licensing excess to medicine issues; DOHA declaration, POSTWTO product patent regime from 2005; Challenges for Indian pharmaceutical industry in the context of globalisation of IP; Drug registration and licensing issues-national and global; Drug master file submissions, SOPS; Related registration and marketing issues; Case studies antiretroviral drugs and others.

**14. Funding sources for commercialization of technology:** Preparation of a project report, financial appraisal, business models; GOI schemes and incentives; NRDC, TePP, HGT, TDB schemes. PATSER; Venture capitalists, banks. Incubator concept- Case studies with respect to IIT,CCMB, IMTECH, NIPER. Documentation and related aspects.

**15. Ethics and values in IP:** IP and ethics-positive and negative aspects of IPP; Societal responsibility; Avoiding unethical practices; Echo-responsibility-economic, social and environmental benefits of modern biotechnology; Voluntary adoption of pollution control strategies. 49 60 Courses of Study 2015.

**Recommended Books:**

6. Law Relating to Intellectual Property by B.L.Wadhera.
7. IPR Handbook for Pharma Students and Researchers by P.Bansal.
8. The Patents Act, 1970 (Bare Act with Short Notes) (New Delhi: Universal Law Publishing Company Pvt. Ltd. 2012).
9. Patent Agent Examination by Sheetal Chopra and Akash Taneja.
10. Making Innovation Happen- A simple and Effective Guide to Turning Ideas into Reality by Michael Morgan.
11. Making Breakthrough Innovation Happen by Porus Munshi.
12. Innovation X- Why a Company's Toughest Problems are its Greatest Advantage by Adam Richardson.
13. Legal Drafting for the Layman by Nabhi Kumar Jain.
14. How to Write and Publish a Scientific Paper by Rober A Day.



15. Concise Law Dictionary-with Legal Maxims, Latin Terms and Words and Phrases by Justice Y.V.Chandrachud.
16. Biomedical Research- From Ideation to Publication by G.Jagadeesh and others.

**GE-511 :- Seminar****(1 Credit)**

1. Introduction, Information retrieval systems.
2. Writing term papers and reports.
3. Organization of scientific material, thesis, dissertation and references.
4. Reading research papers.
5. Skills in oral presentation.

**Each student has to present a seminar before end of the semester.**

**LG-510 :- General Laboratory Experience****(3 Credits)**

1. **Analytical Techniques (75 hours):**
  - a) Spectral analysis workshop (45 hours).
  - b) Separation techniques (30 hours).
2. **Computer and application in pharmaceutical sciences (100 hours):** Introduction to computers, basic unit and functions, H/W and S/W, operating systems, word processing, spread sheet, graphic programs, dbase, windows, statistical S/W programs and packages. Steps involved in S/W development, computer languages with emphasis to FORTRAN language and programming, hands on experience in pharmaceutical software systems. Use of computers in information retrieval systems.
3. **Pharmacology (25 hours):** Animal handling, route of administration of drugs, dose response relationship, acute toxicity testing of drugs, analgesic activity of a compound, estimation of protein and haematological parameters.
4. **Biotechnology in pharmaceutical sciences (20 hours):** Day -1: Preparation for plasmid miniprep. Day-2: Plasmid miniprep and restriction digestion. Day-3: Gel electrophoresis and molecular weight calculation. Day-4: Discussion of result and viva.
5. **Specialization (50 hours):**
  - a) To prepare granules by dry granulation using Roller compactor.
  - b) To optimize wet granulation process and perform scale up using Rapid Mixer Granulator (RMG)
  - c) Study the dissolution behaviour/ drug release pattern of various conventional, sustained release, enteric coated and nanoparticulate dosage form and establishment of dissolution kinetics. Study of various factors affecting dissolution / drug release
  - d) Study of drug protein binding and effect of competitive agent on binding kinetics
  - e) Plotting and interpretation of pharmacokinetics data and calculation of various pharmacokinetic parameter

# M.S. (Pharm.) Biotechnology

## Semester - II

### BT-610:- Molecular Biology

(2 Credits)

1. **Genes and Chromosomes** : Structure of DNA. Genes. Organization of bacterial genome. Structure of eukaryotic Chromosomes, Chromatin, Histone proteins. Repetitive DNA and Telomers.
2. **Replication**: Replication initiation, elongation and termination in prokaryotes and eukaryotes, enzymes and accessory proteins, fidelity, replication of single stranded circular DNA, gene stability.
3. **Repair & Recombination**: DNA repair-enzymes, photoreactivation, nucleotide excision repair, mismatch correction; SOS repair, recombination, homologous and non-homologous, site specific recombination, chi sequences in prokaryotes.
4. **Prokaryotic Transcription and regulation** Concept of gene expression. transcription unit, Initiation, elongation and termination. Regulation of gene expression: Operon concept - *lac* operon, *trp* operon and r-Protein synthesis.
5. **Eukaryotic transcription and regulation**: RNA polymerase structure and assembly, eukaryotic promoters and enhancers, transcription factors- TATA binding proteins (TBP) and TBP associated factors (TAF), activators and repressors. Nuclear transcription factors. Epigenetic regulation by DNA methylation and CpG Islands. Noncoding RNA. Gene silencing –RNAi.
6. **Post-Transcriptional Modifications**: Processing of mRNA, tRNA, rRNA, 5'-cap formation; 3'-end processing and polyadenylation, RNA Splicing, RNA editing, mRNA stability and localization, catalytic RNA.
7. **Translation & Transport**: Translation machinery - Ribosomes, composition and assembly. Universal genetic code - degeneracy of codons, termination codons, tRNA, Wobble hypothesis. Mechanism of initiation, elongation and termination. Co-and post translational modifications and localization.
8. **Oncogenes and Tumor suppressor genes**: Nonsense, missense and point mutations, Intragenic and Intergenic suppression, Frame shift mutations, Physical, chemical and biological mutagens. Viral and cellular oncogenes, Tumor suppressor genes from humans, structure, function and mechanism of action of PRB and p53 tumor suppressor proteins, activation of oncogenes and dominant negative effect, suppression of tumor suppressor genes, oncogenes as transcriptional activators.

### Recommended Books/Literature:

1. Jocelyn E. Krebs; Elliott S. Goldstein; Stephen T. Kilpatrick. Lewin's GENES XII. 12th Edition. 2018.
2. David P. Clark, Nanette J. Pazdernik and Michelle R. McGehee. Molecular Biology. Third Edition. 2019.
3. Malacinski, George M. Freifelder's Essentials of molecular biology. 4<sup>th</sup> Edition.
4. Harvey Lodish et al., Molecular Cell Biology. Ninth Edition. 2021.
5. David L. Nelson; Michael M. Cox. Lehninger Principles of Biochemistry. Eighth Edition. 2021.

**BT-620 :- Recombinant DNA Technology (2 Credits)**

1. **Basic of Recombinant DNA Technology:** Foundation and Evolution of Recombinant DNA Technology.
2. **Key reagents and their importance in Recombinant DNA technologies:** Nucleic Acids, Plasmids, Enzymes – Restriction Enzymes, Reverse Transcriptase, Ligases, Polymerases, Alkaline phosphatase, Poly nucleotide kinase etc.
3. **Key tools in nucleic acid therapeutics:** Antisense technology, siRNA/shRNA, trans-splicing, ribozymes, aptamers.
4. **Applications of DNA Recombinant Technologies:** Understanding the biology of specific genes or pathways; viral vector systems and their uses, Development of biopharmaceuticals and Biosimilar.
5. **Genetically Engineered Animal Models:** Transgenic, knock-out and knock-in mouse generation and their utilization in drug discovery.
6. **Applied Research in Plant Biotechnology:** High yield and insect resistant crops, antibody generation in plants, edible vaccines.
7. **Gene Therapy:** Gene Therapy for hereditary/ genomic diseases.
8. **Gene Editing by CRISPR:** Basic technology, Applications in Clinic (Disease control/prevention and therapeutics-hereditary/cancer/rare diseases); Ethical vs legal issues.

**Recommended Books/Literature:**

1. Bernard J Glick and Jack J Pasternak, Molecular Biotechnology: Principles and Applications of Recombinant DNA (4<sup>th</sup> Edition). ASM Press, Washington DC.
2. Richard M Myers and Amy A Caudy. Recombinant DNA: Genes and Genomes – a Short Course (3<sup>rd</sup> Edition). Cold Spring Harbor Laboratory Press.
3. K Rajagopal. Recombinant DNA Technology and Genetic Engineering, Tata McGraw Hill Press.
4. Keya Chaudhury. Recombinant DNA Technology. Published by TERI Press.

**BT-630:- Basic and Applied Immunology (2 Credits)**

1. **Introduction to Immunology:** History of Immunology, Innate and Adaptative Immunity, Types of Immune Responses (self and nonself), Role of Antigens in Immune Responses, physiology of immune responses.
2. **Haematopoiesis and Major Cells of Immune System:** Myeloid and Lymphoid Lineage, Phagocytes, Granulocytes, Lymphocytes (B and T), Natural Killer Cells, newly discovered immune cells, Primary and secondary Lymphoid Organs.
3. **Humoral and Cell Mediated Immunity:** Introduction, Cells Involved in Humoral and Cell Mediated Immunity, Their mechanism of actions.
4. **Antibodies:** Types, Structure, Source, Functions, Antigen-antibody interactions, generation of antibodies.
5. **Infection, Inflammation and Immunity:** Introduction, Inflammation, Chemotaxis, Cytokines, Inflammatory Diseases, Vascular modifications, Healing and Fibrosis, Basics of Tumor Immunology, Immune disorders with examples.
6. **Immune Tolerance and Autoimmunity:** Immune tolerance, immunosuppression, Auto immunity, Cells Involved, Molecular Mechanism, Hypersensitivity reaction, Autoimmune disorders and therapies, Gut microbiota and Immunity.
7. **Modern Immunotherapy Technologies:** Introduction, types of immune therapies and target diseases, Hybridoma technology, Bi-specific antibodies, Tumor immunotherapy techniques, CAR-T cell therapy, PDL1 Therapy, Oncolytic viruses.
8. **Vaccines:** Introduction, Different types of Vaccines and their mode of action, Challenges, COVID-19 vaccines.

**Recommended Books/Literature:**

1. Kuby Immunology- Kindt, Goldsby, Osborne.
2. Basic Immunology (Functions and Disorders of the Immune System)- AK Abbas, AH Lichtman, Shiv Pillai.

**BT-640:- Principles and Techniques for Diagnostics and Cell Based Screening)  
(2 Credits)**

1. **Analytical Methods for QC of Bio-samples:** Protein impurities, contaminants, electrophoretic analysis, HPLC based analysis, Spectrophotometric Analysis, DNA and RNA content analysis, immunological assays for impurities, combined immunological and electrophoretic methods.
2. **Immuno-diagnostics:** Principles and methods of some clinically used diagnostic immunoassays, e.g., homogeneous immunoassays, fluorescence, chemiluminescence and bioluminescence enzyme immunoassays, immunoblot, immunoaffinity, immunoprecipitation, biotinylation, immunosensors. Multiplexing ELISA.
3. **Molecular diagnostics:** DNA probe-based diagnostics, sample preparation, hybridization, separation, detection, PCR-RFLP in paternity and forensic cases SNP detection MALDI and DHPLC. PCR and its application for clinical diagnostics. Real Time PCR and Multiplexing.
4. **Molecular Pathology:** Basic pathological assays for routine diagnostics using H&E (infectious diseases, cancer), Disease specific pathological markers using Immunohistochemistry and In Situ Hybridization. Multiplex Immuno Fluorescence Analysis, Introduction of Machine Learning to Clinical Pathology.
5. **Introduction to Drug Discovery:** Drug Targets. Assay Development and assay formats: luminescence, fluorescence, etc. Cell free and Cell based assays.
6. **Cell Based Screening:** Functional cell-based assay – Reporter gene assay. Automated Cell Based Assays for drug discoveries, Application of Microfluidic Technologies for single cell assay. Application of Flowcytometry in research and clinic.
7. **High-throughput screening:** Chemical Libraries for High-throughput Screening. Biochemical and cell-based assays for High-throughput screening. Laboratory automation – assay miniaturization and automation. Target selection to confirmed Hits – the HTS workflow. Assay technologies for High-throughput screening – ALPHA Screening, etc.
8. **High Content Screening.** Introduction to Image-based High-content screening. Cellomics. HCS applications in drug discovery.

**Recommended Books/Literature:**

1. David Wild. The Immunoassay Handbook. 4th Edition - 2013. ISBN: 9780080970370.
2. Lela Buckingham. Molecular Diagnostics: Fundamentals, Methods, and Clinical Applications. 3rd Edition. ISBN-13: 978-0803668294.
3. Joshua A Bittker, Nathan T Ross. High Throughput Screening Methods: Evolution and Refinement. 2017. ISBN- 978-1-78262-471-4.
4. Frank H. Stephenson. Calculations for Molecular Biology and Biotechnology. 3rd Edition. 2016. ISBN - 978-0-12-802211-5.
5. Taosheng Chen. A Practical Guide to Assay Development and High-Throughput Screening in Drug Discovery. 2010. ISBN-9780367384708.

