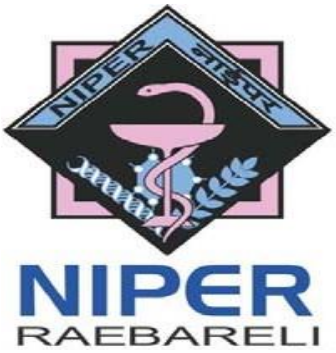

SYLLABUS
M. Tech Biotechnology

M. Tech Biotechnology

Course No.	Course Name	Credits
Semester -I		
BT-530	Microbiology and Microbial Genetics	**2**
BT-540	Bioengineering and Fermentation Technology: Upstream Processing	**2**
***BP-510**	Analytical Tools for Biopharmaceuticals	**2**
***BP-520**	Regulatory Affairs in Biopharmaceuticals	**2**
***GE-510**	Biostatistics	**2**
GE-511	Seminar	**1**
LG-510	General Laboratory Experience	**7**
#Opt for Any One of the Below Elective Courses		
BT-520	Cell Biology	**2**
BT-550	Biochemistry	**2**
	Total Credits	**20**
Semester-II		
BT-620	Recombinant DNA Technology	**2**
BT-630	Immunology and Immunotechnology	**3****
BT-650	Bioengineering and Downstream Bioprocessing	**2**
BT-660	Computational Biology	**2**
GE-611	Seminar	**1**
LS-610	General Lab Experience in the Area of Specialization	**8**
#Opt for Any One of the Below Elective Courses		
***GE-830**	Cell-Based Therapies	**2**
BT-610	Molecular Biology	**2**
	Total Credit	**20**
Semester-III		
TH-598	Synopsis	**15**
TH-599	Presentation	**5**
	Total Credits	**20**
Semester-IV		
TH-698	Thesis	**15**
TH-699	Defense of Thesis	**5**
	Total Credits	**20**
	Grand Total (I-IV semesters)	**80**

*Common with other disciplines
**Courses include 2 credits for theory classes and 1 credit assigned for tutorial

#Students shall opt for elective courses from either of the following combinations:
1. **BT-520: Cell Biology** and **GE-830: Cell-Based Therapies**
2. **BT-550: Biochemistry** and **BT-610: Molecular Biology**

M. Tech Biotechnology-Semester I

BT-530 Microbiology and Microbial Genetics (2 Credits)

1. **Distinguishing features of various groups of microorganisms and their characteristics:** Actinomycetes, Archaebacteria, bacteria, moulds, yeasts, algae, and viruses.

2. **Microbial growth principles, nutrition, and control:** Growth measurement techniques: Various growth media, culture and their characteristics. Rate of death of bacteria; Conditions influencing antimicrobial action; Mode of action of antimicrobial agents; Control of microorganisms by physical agents; Control of microorganisms by chemical agents.

3. **Isolation and Preservation of Microbial strains:** Strain improvement techniques, preservation methods and applications.

4. **Biochemical pathways:** Energy transduction in microbial systems, phosphoketolase, Enter-doudorff and glyoxalate pathways.

5. **Classical genetics:** 'Transforming factor', Hershey and C.hase's experiment, Replica plating, Types and selection of mutants.

6. **Mechanisms of genetic exchange:** Transformation, Transduction (generalized, specialized), Genetic Mapping using transduction, Triple cross experiments, Cis-trans complementation. Conjugation (Hfr strains, Interrupted mating, time-of- Entry mapping), Lederberg-Tatum experiment, Resistance plasmids. Genetic mapping

7. **Gene regulation in prokaryotes:** Regulation of transcription (lac operon, tryptophan operon, etc.), Feedback inhibition and screening

Recommended books:

1. Microbiology (4/e) by Lansing Prescott, John Harley and Donald Klein, McGraw Hill
2. Lewin's Genes X by Jocelyn E. Krebs, Elliott S. Goldstein and Stephen T. Kilpatrick.Jones & Bartlett
3. Molecular Biotechnology: Principles and Applications of Recombinant DNA (4/e) by Bernard R. Glick, Jack J. Pasternak and Cheryl L. Patten, ASM Press
4. Microbiology, 5th Edition by Michael J. Pelzer, Jr. E.C.S. Chan, Noel R. Krieg
5. Biotechnology: Atextbook of Industrial Microbiology by Wulf Crueger, Anneliese Crueger,
6. Prescott's Microbiology by Joanne M. Willey, Linda Sherwood, Christopher J. Woolverton, Lansing M. Prescott
7. Brock's Biology of Microorganisms by Michael T. Madigan, John M. Martinko, Jack Parker
8. Principles of Fermentation Technology by Peter F. Stanbury, Allan Whitaker, Stephen J. Hall
9. Principles of Microbe and Cell Cultivation by S.J.Pirt
10. Instant notes in Microbiology by S. Baker, Jane Nicklin.
11. Biotol series (This series has many books pertaining to all fields of Biotechnology,

students have to select the books as per the topics of interest)

BT-540 Bioengineering and Fermentation Technology: Upstream Processing (2 Credits)

1. **Introduction to Upstream Process:** Principal of fermentation, and applications, critical quality attributes (CQAs) and critical process parameters (CPPs) in biopharmaceutical production.

2. **Generation of improved microbial strains:** Isolation of microbial strain, screening and strain improvement to synthesize desired amounts of product

3. **Media Formulation and Kinetics of Sterilization:** Inoculum and production media, batch and continuous sterilization process

4. **Microbial Growth:** Phases and kinetics of microbial growth; Monod's kinetics, metabolic quotient, substrate utilization and product formation

5. **Reactor Design:** Bioreactor design; criteria for bioreactors, Stirred tank; Airlift reactor; Packed bed; surface tissue propagator; Ideal reactor operation; Batch operation of a mixed reactor; membrane bioreactors, applications of artificial intelligence (AI) and machine learning (ML) in bioreactor designing

6. **Agitation and Aeration:** Need/effect of agitation and aeration in fermentation; How agitation helps aeration and vice-versa; Different types of agitation and aeration methods

7. **Mass and heat transfer:** Mass and energy balance in microbial processes; Resistance encountered in fermentation medium by the oxygen molecule; Role of dissolved oxygen concentration in the mass transfer; mechanisms of heat transfer
8. **Potential Critical quality attributes,identification, risk assessment and setting specifications**

Recommended books:

1. Bioprocess Engineering: Basic Concepts by Michael L. Shuler, Fikret Karg
2. Bioprocess Engineering Principles by Pauline M. Doran
3. Biochemical Engineering Fundamentals by James Edwin Bailey, David F. Ollis
4. Principles of Fermentation Technology by Peter F. Stanbury, Allan Whitaker, Stephen J. Hall
5. Biochemical Engineering Fundamentals by James Edwin Bailey, David F. Ollis

*BP-510 Analytical Tools for Biopharmaceuticals (2 Credits)

1. **Introduction to Bioanalysis and Biopharmaceutical Analytics:** Analytical challenges in biologics; structure-function relationship; critical quality attributes (CQAs) such as purity, identity, heterogeneity, and stability.

2. **Electrophoretic Techniques:** Principles and applications of SDS-PAGE, native PAGE, agarose gel electrophoresis; 2D electrophoresis; capillary electrophoresis

3. **Chromatographic Techniques:** Separation principles based on size, charge, and affinity; size exclusion, ion-exchange, and affinity chromatography; applications in purification and analysis of proteins

4. Spectroscopic Methods: UV-Visible and fluorescence spectroscopy; circular dichroism; infrared spectroscopy; basic concepts of NMR and X-ray diffraction

5. Mass Spectrometry: Basic principles and instrumentation; peptide/protein analysis; introduction to hyphenated techniques (LC-MS)

6. Biomolecular Interaction and Stability Analysis: Surface plasmon resonance (SPR), isothermal titration calorimetry (ITC); analytical ultracentrifugation (AUC); light scattering techniques (DLS/SEC-MALS) for aggregation and size analysis

7. Applications in Biopharmaceutical Development: ICH guidelines on quality of Biotechnological products, *ICH Q5A* - Viral Safety Evaluation of Biotechnology Products derived from Cell Lines of Human or Animal Origin Role of analytical tools in quality control, biosimilar comparability, and regulatory submissions

Recommended books:

1. Protein Biotechnology: Isolation, Characterization, and Stabilization by Felix Franks
2. Proteins by Thomas E. Creighton
3. Current Protocols in Protein Science, Wiley (different collections)
4.ICH Q5A- Q5E Quality of Biotechnological Products

*BP-520 Regulatory Affairs in Biopharmaceuticals (2 Credits)

. Regulatory Systems and Global Landscape: Overview of Indian regulatory system (CDSCO); comparison with major global agencies (USFDA, EMA); international regulatory trends in the pharmaceutical and biopharmaceutical industry, overview of development guidance documents of USFDA and EMA

2. Role of Regulatory Affairs in Product Lifecycle: Functions of regulatory affairs in pharmaceutical organizations; development, approval, and post-marketing phases; interaction with QA, clinical, and manufacturing teams, Global clinical development strategy

3. Regulatory Filings and Submission Formats: Types of applications: IND, NDA, hybrid NDA; dossier formats ICH CTD, ACTD, eCTD; overview of Indian submission framework, Post approval changes (ICH Q5E Comparability of Biotechnological/Biological Products Subject to Changes In Their Manufacturing Process)

4. Regulatory Dossiers and Documentation: Structure and components of regulatory submissions: Chemistry, Manufacturing and Controls (CMC), Non-clinical and clinical data, Pharmacovigilance and risk management, Environmental considerations

5. Regulatory Pathways for Biopharmaceuticals: : Approval pathways for biologics and biosimilars; USFDA purple book, product-specific considerations, Biosimilar innovation, comparability and immunogenicity assessment, regulatory aspects of companion diagnostics

6. Harmonization and Global Regulatory Initiatives: Overview of ICH guidelines; WHO prequalification; regional harmonization efforts (ASEAN, BRICS)WHO regulatory reliance, Real world evidence.

7. Emerging Trends in Regulatory Science: Digital therapeutics, AI/ML in regulatory processes, sustainability and green manufacturing practices in biopharma, challenges and ethics.

Recommended books:

1. Douglas J. Pisano & David Mantus – Textbook of Pharmaceutical Medicine
2. Graham P. Bunn & Rajesh Krishna – Regulatory Affairs for Pharmaceuticals
3. International Council for Harmonization (ICH) Guidelines for Pharmaceutical and Biopharmaceutical Product Development and Regulation

*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 models. Probit and logit transformations.

7. **Non-parametric tests:** Sign; Mann-Whitney U; Wilcoxon matched pair; Kruskal wallis and crossover designs. Statistical test for bioequivalence. Dose response studies; Statistical quality control.

8. **Statistical techniques in pharmaceutics:** 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-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-15 hours/week (7 credits)

1. **Spectral Analysis**

2. **To provide training on various softwares used in specialization**

3. **Biotechnology for pharmaceutical sciences**
   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.

4. **Specialization:**
   Cell biology:
   Day-1: Sterilization by autoclaving and filtration.
   Day-2 : Media preparation and cell counting.
   Day-3 : Sub cellular fractionation by homogenization, solubilization, sonication and protein estimation.
   Day-4 : Running SDS-PAGE and Viva.

   Enzyme biochemistry:
   Day-1: Enzyme kinetics, time course.
   Day-2: Effect of pH and temperature.
   Day-3: Inhibition studies and characterization.
   Day-4: Ionic strength effect and viva.

   Bacterial Culture & Growth Kinetics:
   Day-1: Direct and indirect methods to measure bacterial growth, Media preparation,setting up of primary cultures.
   Day-2: Monitoring growth kinetics, effect of different parameters on growth, plottingof growth curves.
   Day-3: Calculation of mean generation time and growth rate constant, analysis ofresults, discussion of results & viva.

BT-520 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. **Organization of tissues:** Cell-cell and cell-matrix interactions, cell adhesion molecules, components of the extracellular matrix, cellular junctions and role.

3. **Cell cycle:** G1, G2, S and M phase of the cell cycle. Cell cycle analysis and its applications, programmed cell death apoptosis versus necrosis.

4. **Tools and Techniques of Cell Biology:** Histology, staining, fluorescence, confocal microscopy, TEM and SEM., FACS, cell fractionation, cell culture, principles of cell-based

bioassays and their applications in biopharmaceuticals; biosimilars as case studies with examples of selected therapeutic molecules

5. **Cell Signaling:** Receptor concept, receptor signaling and expression, orphan receptors, extra-cellular signals and cell functions, hormones, second messengers and hormone actions, growth factors.

6. **Transport across membranes:** Osmosis, active and passive transport. Protein transporters ion channels, antiporters, symporters, and applications.

7. **Molecular motors and Cellular trafficking:** Molecular motors, the movement of cilia and flagella, Role of myosin and kinesins in muscle contraction.

Recommended books:

1. Molecular Cell Biology by Harvey Lodish
2. Molecular Biology of the Cell by Bruce Alberts
3. Principles of Biochemistry : Lehninger
4. Biochemistry by L. Stryer

BT-550 Biochemistry (2 Credits)

1. **Introduction to Biomolecules**: Various types of Biomolecules, classification. structure and type, Carbohydrates, Lipids, Proteins and Nucleic Acids, biological and pharmaceutical importance.

2. **Biochemical energetics**: free energy, concept of standard free energy, laws of thermodynamics, exergonic and endergonic reactions, energy rich compounds, coupling of reaction, biological oxidation-reduction.

3. **Enzymes, Coenzymes and Co-factors:** Classification, mode of action (activation, specificity), enzyme kinetics, enzyme inhibitors and regulators, allosteric enzymes, isoenzymes, multienzyme system, pharmaceutical importance. Coenzymes, classification of vitamins, role and mechanism of action of some important coenzyme (NAD /NADP, FAD, tetrahydrofolate), role of cofactors with specific examples.

4. **Carbohydrate metabolism:** Glycolysis, gluconeogenesis, pentose phosphate pathways (PPP), glycolysis, TCA cycle, glyoxylic acid cycle, regulation of carbohydrate metabolism, electron transport chain and oxidative phosphorylation, disorders of carbohydrate metabolisms.

5. **Lipid metabolism:** Hydrolysis, absorption and transport of lipids, catabolism of lipids, α-, β- and ω- oxidation of fatty acids, ketone bodies formation, biosynthesis of some important fatty acids, disorders of lipid metabolisms.

6. **Protein metabolism:** Hydrolysis of proteins, pathways of amino acid degradation, urea cycle and formation of uric acid, assimilation of ammonia, biosynthesis of Glycine, Cysteine, Glutamine, inborn error of protein metabolism.

7. **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:

8. Principles of Biochemistry by Lehninger
9. Biochemistry by L. Stryer

M. Tech Biotechnology-Semester II

BT-620 Recombinant DNA Technology (2 credits)

1. **Basic techniques in Gene analysis:** Purification and analysis of nucleic acids: Isolation of DNA and RNA, plasmid purification, agarose, polyacrylamide and pulse field gel electrophoresis, southern, northern and western blotting.

2. **Vectors:** Plasmids, Yeast, Viruses (Adenovirus, adeno-associated virus, and lentivirus, non-viral vectors, Plant vectors (Agrobacterium tumefaciens, Chloroplast).

3. **Tags for purification and visualization:** Affinity Tag, GST tag, His tag, Fluorophores, Biotin label.

4. **Gene targeting:** Random and specific, *Cre/lox P* system, knock-out and knock-in mice.

5. **Transgenic plants and animals:** Principle, Types, Applications and Examples.

6. **Protein 'pharm'ing:** Design of second-generation therapeutic molecules, examples of engineered proteins of therapeutic potential, tools for protein engineering, library-based selection methods.

7. **Industrial based applications of Genetic engineering:**, Ribozymes, Aptamers, Case studies.

Recommended books:

1. Principles of Gene Manipulation and Genomics (7/e) by Sandy Primrose and Richard Twyman, Wiley-Blackwell
2. Analysis of Genes and Genomes by Richard J Reece, John Willey & Sons.
3. Molecular Biotechnology: Principles and Applications of Recombinant DNA (4/e) by Bernard R. Glick, Jack J. Pasternak and Cheryl L. Patten. ASM Press
4. Relevant review & research papers

BT-630 Immunology and Immunotechnology (3** credits)

1. **Immunity:** Innate and adaptive, immune response memory, specificity and recognition of self and non-self, immunogenicity, antigenicity, physiology of immune response, epitope analysis, synthetic peptides and immune response, immunity to virus, bacteria, fungi, Cells and Organs of the immune system

2. **Humoral immunity:** Antigen-antibody interactions, affinity, avidity, immunoglobulins, molecular mechanism of generation of antibody diversity, molecular biology of IgG, Monoclonal antibody, production and applications

3. **Cell mediated immunity:** T cell subsets and surface markers, T cell-dependent and-

independent markers, structure and function of MHC, association of MHC with disease susceptibility, structure of T cell antigen receptor.

4. **Immune memory:** B-cell memory, significance, mutations and switches in memory cells, T-cell memory, lack of mutations and switches in T-cell memory, activation, super activation, loss of memory, Concept and types of vaccines.

5. **Immune tolerance:** B-cell tolerance, reversible and irreversible tolerance, antigen induced tolerance, induction, T-cell tolerance, partial engagement of signal transducer, self-antigens, molecular consequence of tolerance.

6. **Disorders:** Hypersensitivity reaction, immunosuppression, autoimmune disorders, its molecular mechanism, immunodeficiency disorders (AIDS), tumor immunology.

7. **Principles, methods and applications of immuno-diagnostics:** Principles and methods of some clinically used diagnostic immunoassays, e.g., homogeneous and heterogenous immunoassays, fluorescence, immunoblot, immunoaffinity, immunoprecipitation, biotinylation, immunosensors, advanced analytical methods such as NMR-based immunogenicity analysis

Recommended books:

1. Cellular and Molecular Immunology by Abdul K. Abbas, Andrew H. Lichtman and Shiv Pillai
2. Kuby Immunology by Thomas J. Kindt, Barbara A. Osborne, and Richard A. Goldsby
3. Refer to relevant research and review articles.

BT-650 Bioengineering and Downstream Bioprocessing (2 credit)

1. Introduction to Downstream Processing: Importance of downstream processing in bioprocess economics and product quality

2. Production of Industrial Metabolites and Bio-pharmaceuticals: Process technology for the production of primary and secondary metabolites and their uses; methods of production, strain, process control, product recovery

3. Biotransformation and Stereoselective Production of Drug Intermediates: Definition of biotransformation; advantages and disadvantages of biocatalysis over chemical catalysis; biocatalysis for the synthesis of some chirally pure pharmaceutical intermediates etc.

4. Pre-treatment: Importance of pre-treatment; dealing with high viscosity fermentation broth; coagulation; flocculation; pasteurization; sterilization; adsorption on filter aids; heating etc.

5. Solid–Liquid Separation, Cell Disruption and Product Isolation: Filtration and centrifugation, different methods of cell disruption, factors affecting the rate of cell disintegration

6. Product Concentration and Drying: Evaporation, crystallization, precipitation and drying mechanism

7. Scale-up, Scale-down, and Case Studies: Principles, criteria, and control of bioprocess; different methods of scale up, scale down, instrumentation and control of bioprocesses, applications of artificial intelligence (AI) and machine learning (ML) in process optimization, predictive modeling, process monitoring, and downstream bioprocess

analytics; detailed analysis with case studies. .Formulation aspects of Biopharmaceuticals

Recommended books:

1. Process Biotechnology Fundamentals by S. N. Mukhopadhyay
2. Bioprocess Engineering Principles by Pauline M. Doran
3. Principles of Fermentation Technology (Biotol Series) by Peter F. Stanbury, Allan Whitaker, Stephen J. Hall
4. Biotechnological Innovations in Chemical Synthesis (Biotol Series) by J. A. M. van Balken
5. Product Recovery in Bioprocess Technology (Biotol Series) by Butterworth-Heinemann
6. Industrial Sterilization by Richards

BT-660 Computational Biology (2 credits)

1. **Basics of Computational Biology:** Database concept; Protein and nucleic acid databases, structural databases, publicly available tools, Resources at NCBI and EBI, DNA and protein information resources on the web

2. **DNA Sequence Analysis:** Databases and search tools; Biological background for sequence analysis. Retrieval of DNA sequences and searching of databases for similar sequence. Submitting DNA sequence to databases, where and how to submit. Analysis of sequencing chromatogram editing and contig building. Sequence-function relationship; Detection of protein-coding regions, promoters, transcription factor binding sites, restriction enzyme cleavage sites and intron-exon boundaries.

3. **Protein sequence analysis:** Comparison of protein sequences and database searching. Predictive methods for protein sequences. Methods for discovering conserved patterns in protein sequences and structures and protein motifs.

4. **BLAST, various methods of DNA and protein BLAST and interpretation of output:** Sequence alignment, Pairwise alignment, Techniques, Multiple Sequence Alignment.

5 **Predicting secondary structure from protein sequences:** Protein structure prediction, homology modelling. Comparison of protein three-dimensional structures. Protein family- based methods for homology detection and analysis.

6. **Phylogenetic analysis sequence-based taxonomy:** Overview and assumptions from Multiple Alignment to phylogeny. Neighbour joining, maximum likelihood vs. parsimony. Computational tools for phylogenetic analysis.

7. **Next generation sequencing, Platforms and Applications:** Concept theory, library preparation and applications in sequence detection and analysis, platforms; Illumina (Miseq, Hiseq, Novaseq), Oxford nanopore, Pacbio, ***In-silico*** **analysis of nextgen sequences**

Recommended books*:*

1. Essential Bioinformatics, by Jin Xiong
2. Bioinformatics: Sequence and Genome Analysis, by David W. Mount
3. Systems Biology by Bernhard Palsson
4. Systems Biology in Practice, Concepts, Implementation and Application by E. Klipp, R. Herwig, A. Kowald, C. Wierling, H. Lehrach.
5. Relevant Research and Review Papers.

GE-611 Seminar (1 credits)

Students are required to submit written record and present details of the project to be pursued in semester-III and IV. This should include the purpose and basis of the project, stating aims, objectives and probable outcomes, be able to supplement these with necessary information, literature review towards it, and process for the project itself.

LS-610 General Laboratory Experience (8 credits)

1. **Cell Biology**
   Expt-1: Cell proliferation/cytotoxicity assay (MTT).
   Expt-2: Western transfer and immunoblotting.
2. **Recombinant DNA technology:**
   Expt-1: Sequence retrieval and analysis
   Expt-2: PCR primer generation
   Expt-3: PCR and gel electrophoresis
   Last day: Discussion of results and viva
3. **Enzyme isolation:**
   Day-1-9: Extraction of α-amylase from wheat germ and its partial purification
4. **Enzyme biochemistry:**
   Day-1-9: Expression, partial purification and characterization of a recombinant enzyme.
5. **Bacterial Transformation:**
   Day-1-7: Commonly used methods for bacterial transformation, preparation of competent cells, comparison of transformation by electroporation and heat shock, estimation of transformation efficiency.

*GE-830 Cell-Based Therapies (2 credit)

1. Introduction to therapeutic cells and potential applications: Differences between cell therapy and gene-modified cell therapy; cell-based transfer; multicellular therapies; application of cell therapy in different diseases such as neurodegenerative diseases, cancer, rheumatoid arthritis, metabolic diseases; administration and delivery of cell-based therapeutics; promises and challenges for cell-based therapeutics.

2. Introduction to technologies for the development of cell-based therapy: Cell immortalization technologies; gene modification; viral vector-based technologies; cell plasticity and three-dimensional technologies.

3. Stem cell technology: Different sources of stem cells, preparation, identification; biomarkers, collection methods; Cell transplantation; stem cells in reprogramming and its application as regenerative medicine; the role gene-editing methods including CRISPR/Cas9; designing of human iPS cells; stem cell-banking; current trends of stem cells therapies.

4. Non-stem cell-based cell therapies: Different cell types; mesenchymal stromal cells (MSCs), dendritic cells (DCs) and their uses in cellular therapies; introduction to lymphatic system; Natural killer (NK) cell biology; NK cell receptors and ligands; application of NK cell-based therapy in cancer; CAR T cell therapy; structure, generations and productions of CAR T cells; advantages and limitations of CAR T cells as therapeutics; recent advances on macrophages (CAR-M) as cell-based treatments

5. Cell-based vaccines: Types of vaccines; designing vaccine delivery system and applications; stem cell-based vaccines; dendritic cell-based vaccines; exosome-based vaccines.

6. **Translational aspects of cell-based therapies:** Guidelines for understanding the best practices for working with cells.

Recommended books:

1. Daniel Scherman (2019). Advanced Textbook on Gene Transfer, Gene Therapy And Genetic Pharmacology: Principles, Delivery And Pharmacological And Biomedical Applications Of Nucleotide-Based Therapies: 2nd edition World scientific.
2. Stewart Sell (2013). Stem Cells Handbook: 2nd edition Humana Press.
3. Anthony Atala, Robert Lanza, Tony Mikos, Robert Nerem (2018). Principles of Regenerative Medicine: 3rd Edition Elsevier Academic Press.
4. Stephen H. and George M. Church (2017). Precision Medicine, CRISPR, and Genome Engineering: Moving from Association to Biology and Therapeutics. 1st Edition Springer.
5. Dwaine F. Emerich, Gorka Orive (2017). Cell Therapy: Current Status and Future Directions (Molecular and Translational Medicine): 1st Edition Humana Press.
6. Matthias Giese (2014). Molecular Vaccines: From Prophylaxis to Therapy – Volume 2. 2014th Edition Springer.
7. Daniel D. Karp, Gerald S. Falchook, JoAnn D. Lim (2022). Handbook of Targeted Cancer Therapy and Immunotherapy: 3rd edition LWW publishers.
8. Xiao-Dong Chen (2018). A Roadmap to Nonhematopoietic Stem Cell-Based
9. Therapeutics: From the Bench to the Clinic: 1st edition Academic Press.

BT-610 Molecular Biology (2 credits)

1. **Genome Organization:** Organization of bacterial genome, structure of eukaryotic chromosomes, role of nuclear matrix in chromosome organization and function, matrix binding proteins, heterochromatin and euchromatin, DNA re-association kinetics (Cot curve analysis), repetitive and unique sequences, satellite DNA, DNA melting and buoyant density, nucleosome phasing, DNase I hypersensitive regions, DNA methylation & imprinting, epigenetic regulation, DNA structure.

2. **Prokaryotic Replication, Transcription, and Regulation:** Replication initiation, elongation and termination in prokaryotes , enzymes and accessory proteins, fidelity, replication of single stranded circular DNA, gene stability, Prokaryotic transcription, transcription unit, Promoters- constitutive and inducible, operators, regulatory elements, initiation attenuation, termination-Rho-dependent and independent, anti-termination, transcriptional regulation-positive and negative, Regulation of gene expression, negative and positive, trans acting products and cis acting sequences, control of structural gene clusters, induction, and repression of genes

3. **Eukaryotic Replication, Transcription and Regulation:** Replication initiation, elongation and termination in eukaryotes, RNA polymerase structure and assembly, RNA polymerase I, II, III, eukaryotic promoters and enhancers, general transcription factors, TATA binding proteins (TBP) and TBP associated factor (TAF), activators and repressors, transcriptional and post transcriptional gene silencing, Post transcriptional modifications of RNA.

4. **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.

5. **Translation & Post Translational Modifications:** Translation machinery; Ribosomes, composition and assembly, universal genetic code, degeneracy of codons, termination codons, Iso-accepting tRNA, Wobble hypothesis, Mechanism of initiation, elongation and termination, Co-and post translational modifications, genetic code in mitochondria, protein stability, protein turnover and degradation**.**

6. **Mutations, 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 suppressorgenes 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.

7. **Transposable elements:** Transposition Transposable genetic elements in prokaryotes and eukaryotes, mechanisms of transposition, role of transposons in mutation.

Recommended books :

1. Genes VIII by Benjamin Lewin
2. Principles of Genetics by Gardner, Simmons and Snustard