NOIDA INTERNATIONAL UNIVERSITY
GAUTAM BUDH NAGAR, UP

EVALUATION SCHEME & SYLLABUS

FOR

MASTER OF TECHNOLOGY

In

BIOTECHNOLOGY (Regular)

AS PER
AICTE MODEL CURRICULUM
[Effective from the Session: 2019-20]

Program Outcomes (POs)

Students will be able to

1. Apply the knowledge of science, mathematics, and engineering principles for developing problem solving attitude.

2. Acquire knowledge on the fundamentals of biotechnology for sound and solid base which enables them to understand the emerging and advanced engineering concepts in life sciences.

3. Acquire knowledge in domain of biotechnology enabling their applications in industry and research.

4. Empower the students to acquire technological knowhow by connecting disciplinary and interdisciplinary aspects of biotechnology

5. Recognize the importance of Bioethics, IPR, entrepreneurship, Communication and management skills so as to usher next generation of Indian industrialists.

Semester-1

Paper code	Subject	L	T	P	Marks(ISE)	Marks(ESE)	Total	Credit
BPCT1	Applied Biochemistry & Molecular Biology	3	0	2	40	60	100	3
BPCT2	Bioprocess Engineering & Technology	3	0	2	40	60	100	3
BPE1x	Program Elective-1 1. Immunology & Vaccine Technology 2. Quality Control in Biotechnology 3. Applied Clinical Research 4. Agricultural Biotechnology	3	0	0	40	60	100	3
BPE2x	Program Elective-2 1. Biological treatment of waste water 2. Quality control in Biotechnology 3. Applied clinical research	3	0	0	40	60	100	3
MTC01	Research Methodology and IPR	2	0	0	40	60	100	2
	Audit Course-1	2	0	0	40	60	100	0
BPCL1	Applied Biochemistry & Molecular Biology Lab	0	0	2	40	60	100	2
BPCL2	Bioprocess Engineering & Technology Lab	0	0	2	40	60	100	2
Total							**800**	**18**

Semester-2

Paper code	Subject	L	T	P	Marks(ISE)	Marks(ESE)	Total	Credit
BPCT3	Bioinformatics	3	0	0	40	60	100	3
BPCT4	Recombinant DNA Technology	3	0	0	40	60	100	3
BPE3x	Program Elective-3 1. Genetic Engineering 2. Applied Food Biotechnology 3. Molecular Modeling & Industrial Application	3	0	0	40	60	100	3
BPE4x	Program Elective-4 1. Bioreactor Analysis & Design 2. Enzyme Technology & Industrial Application 3. Applied Bioenergy	3	0	0	40	60	100	3
	Audit Course-2	2	0	0	40	60	100	0
MTC02	Mini Project with Seminar	0	0	4	100	0	100	2
BPCL3	Bioinformatics Lab	0	0	2	40	60	100	2
BPCL4	Recombinant DNA Technology Lab	0	0	2	40	60	100	2
Total							**800**	**18**

Audit course 1 & 2

MAC01. English for Research Paper Writing
MAC02. Disaster Management
MAC03. Sanskrit for Technical Knowledge
MAC04. Value Education
MAC05. Constitution of India
MAC06. Pedagogy Studies
MAC07. Stress Management by Yoga
MAC08. Personality Development through Life Enlightenment Skills

Semester-3

Paper code	Subject	L	T	P	Marks(ISE)	Marks(ESE)	Total	Credit
BPE5x	Program Elective-5 1. Tissue Culture Techniques 2. Diagnostic Techniques in Biotechnology 3. Fundamentals of Stem Cell Technology	3	0	0	40	60	100	3
	Open Elective	3	0	0	40	60	100	3
MTC03	Dissertation Phase-1	0	0	20	500	0	500	10
Total							**700**	**16**

Semester-4

Paper code	Subject	L	T	P	Marks(ISE)	Marks(ESE)	Total	Credit
MTC04	Dissertation Phase-2	0	0	32	500	200	700	16
Total							**700**	**16**
GRAND TOTAL							**3000**	**68**

Open Elective

MOE01. Business Analytics

MOE02. Industrial Safety

MOE03. Operations Research

MOE04. Cost Management of Engineering Projects

MOE05. Composite Materials

MOE06. Waste to Energy

M. Tech Biotechnology (Regular)

Course Code: BPCT1 **Course Name:** Applied Biochemistry & Molecular Biology

Course Credit Hour: 3hr **Total Contact Hour:** 60hr

Course Objective:

The objective of the course is to enable the students to develop understanding in the basics of Molecular Biology and biochemistry. To provide basic knowledge on replication. Transcription and Translation. To provide knowledge on structures and functions of Bio-molecules.

Course Description:

Brief introduction to biomolecules, Interplay of macromolecules in a living cell, Major molecular events in the cell cycle, Architecture of microbial, animal and plant genome, Replication & transcription and their control in prokaryotes and eukaryotes, Features of genetic code, translation and its control, Posttranslational modifications, Gene structure & function, Molecular mechanism of gene expression, silencing of gene function, Extrachromosomal genetic elements, Transposable genetic elements and retroviruses, Molecular basis of cellular differentiation, Oncogenes and cancer, Epigenetic effects, Regulatory RNA, Genetic and metabolic disorders, Programmed cell death, Aging and senescence.

Course Content:

UNIT I

Structures and functions of Bio-molecules: Carbohydrates: classification, mono, di, oligo and polysaccharides. Lipids: fatty acids, simple, complex & derived lipids. Protein: Amino Acids Structure and function, Protein Structure Hierarchy. Nucleic acids: nucleosides, nucleotides, DNA & RNA.

UNIT II

Bioenergetics: Overview of principles of bioenergetics (free energy, enthalpy and entropy). Energy relationships between catabolic and anabolic pathways. Phosphoryl group transfers and ATP, Free-energy change for ATP hydrolysis.

UNIT III

Metabolism: Glycolysis, Gluconeogenesis, Respiration and Introduction to the Citric Acid Cycle, Electron Transport, Oxidative phosphorylation, Fatty Acid Catabolism: Fatty acid oxidation, Protein Metabolism: The Urea Cycle

UNIT IV

Gene structure, DNA & RNA as a genetic material, RNA World, packaging of DNA as chromosome, DNA replication- Prokaryotic and eukaryotic DNA replication, Mechanism of replication. Telomeres, telomerase and end replication. Role of telomerase in aging and cancer.

UNIT V

Transcription, genetic code, reverse transcription, mRNA processing. Translation, Gene regulation,operons: Lac operon, TRP, operon, transposons.

Course Learning Outcomes (CLOs):

1. Apply chemical principles and energy transfer to molecular life processes,
2. Summarize fundamental concepts across the biological sciences with focus on flow of information and molecular structure/function relationships
3. Demonstrate proficiency in experimental design, laboratory methodology, and data analysis,
4. Implement modes of communication relevant to life-science professions, and
5. Create effective team-based work groups

Text / Reference Books

1. Biochemistry- L.Stryer , Third Edition
2. Biochemistry- Voet & Voet.
3. Principles of Biochemistry- A.Lehninger , CBS Publishers and Distributors , 1987.
4. Biochemistry- S C Rastogi, Tata McGraw- Hill Publishing Com. Ltd., II ND Edition, 2003.
5. Zubay. Biochemistry. 4th ed. William C. Brown Publication, 1998.
6. Watson. J. D, Baker. T. A, Bell. S. P, Gann. A, Levine. M, Losick. R. Molecular Biology of Gene. 6th The Benjamin / Cummings Pub. Co. Inc.,2008.
7. Darnell, Lodish and Baltimore. Molecular Cell Biology, Scientific American Publishing Inc, 2000.
8. Bruce Alberts, Alexander Johnson, Julian Lewis, Martin Raff, Keith Roberts, Peter Walter. Molecular biology of the Cell. 4th ed. Garland publishing Inc., 2002.
9. Benjamin Lewin. Gene VII. Oxford University Press, Nelson Cox.

Online links for study & reference materials:

https://www.easybiologyclass.com/topic-biochemistry/

Assessment method:

(Continuous Internal Assessment = 40%, Final Examination = 60%)

Assessment -1	- 05%	
Assessment-2	- 05%	
Assessment-3 (Mid exam)	- 20%	
Assessment-3	- 05%	
Assessment-4	-	05

Course Code: BPCT2 **Course Name:** Bioprocess Engineering & Technology

Course Credit Hour: 3hr **Total Contact Hour:** 30hr

Course Objective:

The objective is to enable students to study a broad base of topics in the fundamentals of engineering focused on the chemical and biological processing of raw materials from sustainable sources.

Course Description:

Bioprocess Engineering Study of the engineering concepts for biological conversion of raw materials to food, pharmaceuticals, fuels, and chemical.

Course Content:

UNIT I

Historical development of bioprocess technology, An overview of traditional and modern applications of biotechnological processes, General requirements of fermentation processes, Basic design and construction of fermenter and ancillaries, Main parameters for monitoring & control of fermentation processes, Different raw materials used in fermentation industry and their pretreatment, Medium for plant cell culture and animal cell culture, Medium design of commercial media for industrial fermentations-Plackett burman design, response surface methodology, simplex design.

UNIT II

Stoichiometry of Cell growth and product formation, elemental balances, degrees of reduction of substrate and biomass, available electron balances, yield coefficients of biomass and product formation, maintenance coefficients Energetic analysis of microbial growth and product formation, oxygen consumption and heat evolution in aerobic cultures, thermodynamic Efficiency of growth.

UNIT III

Mass transfer includes transport phenomena in bioprocesses, Factors affecting oxygen transfer rate in bioreactors, Techniques for measurement of volumetric oxygen transfer coefficient, Fluid rheology and factors affecting bioreactor processes, Flow Patterns in agitated tanks, Mechanism & Power requirements of mixing, Scale up of mixing systems.

UNIT IV

Different regulatory mechanisms involved in controlling the catabolic and anabolic processes of microbes, Induction, nutritional repression, carbon catabolite repression, Crabtree effect, feedback inhibition and feedback repression, Concept of Overproduction of metabolites, Case studies on production of Lactic acid, Glutamic acid, Penicillin, Microbial Lipase And Protease, Recombinant Insulin, Interferons, Hepatitis Vaccines etc. Case studies should deal with strain improvement, medium designs, process optimization technology.

UNIT V

Unit Operation: Filtration, filter aids, filtration Equipment and filtration theory, Centrifugation process and its equipment's, Cell disruption, Aqueous Two-Phase Liquid Extraction. Adsorption process and its operations, Chromatography: Theory and mechanism, Scaling-up chromatography.

Course Learning Outcomes (CLOs):

Students will be able to:

1. Apply the concepts of basic chemical engineering principles in a bioprocess
2. Produce bio-products on an industrial scale using fermenters.
3. Operate and optimize process parameters in a fermenter for producing industrial products.

Text Book

1. Principles of fermentation technology" by P F Stanbury and A Whitaker, Pergamon press.
2. Bioprocess Technology - Kinetics & Reactors" by A Moser, Springer-Verlag.
3. Biochemical Engineering and Biotechnology Handbook" by B. Atkinson & F. Mavituna, 2nd Ed. Stockton Press.
4. Bioprocess Engineering Principles" by Pauline M. Doran, Academic Press.
5. Biochemical Engineering- S. Aiba , A.E. Humphray, University of Tokyo Press.
6. Lee J.M, Biochemical Engineering 2nd ed, Prentice Hall, 2000.
7. Principles of Cell Energetics": BIOTOL series, Butterworth - Heinemann.
8. Biotechnology" Vol.4 Meaning Modelling and Control Ed. K.Schugerl, VCH (1991).
9. Unit operations of Chemical Engineering" 5th ed. by W L McCabe, J C Smith and P. Harriot.
10. Mc Graw-Hill (1993).
11. Diffusion" by E L Cussler, Cambridge University Press (1984).

Online links for study & reference materials :

https://bioprocessing.weebly.com/bioprocess-technology.html

Assessment method:

(Continuous Internal Assessment = 40%, Final Examination = 60%)

Assessment -1	- 05%
Assessment-2	- 05%
Assessment-3 (Mid exam)	- 20%
Assessment-3	- 05%
Assessment-4	- 05%
Total Internal Assessment	**-40%**

Course Code: BPE11 **Course Name**: Immunology & Vaccine Technology

Course Credit Hour: 3hr **Total Contact Hour:** 30hr

Course Objective:

The objective of this course is to provide students with detail understanding of different cells, organs and factors of the immune system and their organization and diversity, and their specialized functions. The course will provide basic concepts of different immunological techniques and knowledge about role of immune system in the pathogenesis of different disease like infectious disease, Cancer, autoimmune disease, AIDS etc.

Course Description:

Immunology is the study of the immune system and is a very important branch of the medical and biological sciences. The immune system protects us from infection through various lines of defense. If the immune system is not functioning as it should, it can result in disease, such as autoimmunity, allergy and cancer. It is also now becoming clear that immune responses contribute to the development of many common disorders not traditionally viewed as immunologic, including metabolic, cardiovascular, and neurodegenerative conditions such as Alzheimer's.

Course Contents

UNIT I

Fundamental concepts and anatomy of the immune system, Components of innate and acquired immunity, Humoral and Cell mediated immunity, Haematopoesis, Antigens , immunogens, haptens, Major Histocompatibility Complex - MHC genes, MHC and immune responsiveness and disease susceptibility, HLA typing.

UNIT II

Immunoglobulins-basic structure, classes and subclasses of immunoglobulins, antigenic determinants, Multigene organization of immunoglobulin genes, Immunological basis of self – non-self-discrimination; Kinetics of immune response, memory; B cell maturation, activation and differentiation; Generation of antibody diversity, Antigen processing and presentation- endogenous antigens and exogenous antigens.

UNIT III

A short history of vaccination, Active and passive immunization, General immunization practices, Vaccination of immunocompromised hosts, Vaccination of human immunodeficiency virus- infected persons, Vaccines, Live, killed, attenuated, sub unit vaccines; Vaccine technology- Role and properties of adjuvants, recombinant DNA and protein

UNIT IV

Licensed vaccines, Viral Vaccine (Poliovirus vaccine-inactivated & Live, Rabies vaccines Hepatitis A & B vaccines), Bacterial Vaccine (Anthrax vaccines, Cholera vaccines, Diphtheria toxoid), parasitic vaccine (Malaria Vaccine).

UNIT V

The vaccine industry, Vaccine manufacturing, Evolution of adjuvants across the centuries, Vaccine additives and manufacturing residuals, Regulation and testing of vaccines, Regulation of vaccines in developing countries, Vaccine safety and Legal issues.

Course Learning Outcomes (CLOs):

Students will be able to

1. explain role of immune cells and their mechanism in preventing the body from foreign attack and infectious disease, cancer and other disease development
2. Apply the knowledge of immune associated mechanisms in medical biotechnology research.
3. design experiment to see effect of drug molecule on immune response
4. Carry out immunological techniques in industry.
5. Able to apply the concept of vaccine technology in new vaccines development.

Text/Reference Books:

1. Kuby, RA Goldby, Thomas J. Kindt, Barbara, A. Osborne Immunology, 6th Edition, Freeman, 2002
2. Brostoff J, Seaddin JK, Male D, Roitt IM., Clinical Immunology, 6th Edition, Gower Medical Publishing, 2002.
3. Janeway et al., Immunobiology, 4th Edition, Current Biology publications. 1999. 4. Paul, Fundamental of Immunology, 4th edition, Lippencott Raven, 1999.
4. Stanley A. Plotkin & Walter Orenstein & Paul A. Offit, Vaccines, 6th Edition 2013 BMA Medical Book Awards Highly Commended in Public Health! Elsevier Publication.
5. Roitt's Essential Immunology. 11th ed. P. Delves, et al., ed., Blackwell Publishing, 2006.

Online links for study & reference materials:

https://www.immunology.org/public-information/what-is-immunology

Assessment method:

(Continuous Internal Assessment = 40%, Final Examination = 60%)

Assessment -1	- 05%
Assessment-2	- 05%
Assessment-3 (Mid exam)	- 20%
Assessment-3	- 05%
Assessment-4	- 05%
Total Internal Assessment	**-40%**

Course Code: BPE21 **Course Name: Biological Treatment of Waste Water**

Course Credit Hour: 3hr **Total Contact Hour: 30 HRS**

Course Objective:

The objective of this course is to address the deficient access to the knowledge by offering a broad and thorough overview on (conventional and innovative) biological wastewater treatment processes and practices. The modern approach of modelling and simulation to wastewater treatment plant design and operation - be it activated sludge, biological nitrogen and phosphorus removal, secondary settling tanks or biofilm systems - can be embraced with deeper insight, advanced knowledge and greater confidence.

Course Description:

This course seeks to address the quantity, complexity and diversity of the developments in the wastewater treatment profession, particularly in developing countries where access is not readily available to advanced level courses in wastewater treatment.

Course Contents:

UNIT I-ACTIVATED SLUDGE PROCESS-PROCESS ANALYSIS AND SELECTION

Characteristics of Activated Sludge (aerobic and anaerobic); Analysis of Data– Mass Balance Analysis. Reactors used in waste water treatment- Up Flow Anaerobic Sludge Blanket (UASB), Two-stage, Aerobic UNI Tank System (TSU-System, Route Zone Treatment, Submerged Aerobic Fixed Film (SAFF) Reactor, and Fluidized Aerobic Bioreactor (FAB).

UNIT II-AEROBIC FIXED-FILM & ANAEROBIC TREATMENT PROCESSES

Biofilm process considerations; Trickling Filters and Biological Towers; Rotating Biological Contactors; Granular – Media Filters; Fluidized – Bed & Circulating Bed- Biofilm reactors. Hybrid Biofilm/suspended growth processes. Anaerobic Processes: Methanogenesis, process chemistry and microbiology; process kinetics and factors for the design of anaerobic digestors.

UNIT III-ADVANCED WASTE WATER TREATMENT

Technologies used in advanced treatment-Classification of technologies; Removal of Colloids and suspended particles-Depth Filtration, Surface Filtration, Membrane Filtration Absorption, Ion Exchange, Advanced oxidation process, Activated Carbon, Air Stripping, Heavy Metals Removal, Steam Stripping, Chemical Precipitation, and Electrolysis.

UNIT IV-BIOLOGICAL PHOSPHORUS REMOVAL

Nitrification & Denitrification Processes**:** Biochemistry and Physiology of Nitrifying Bacteria; Common process considerations; One sludge versus two sludge nitrification. Physiology of Denitrifying Bacteria; Tertiary Denitrification; One- sludge denitrification, Normal Phosphorus Uptake into Biomass; Mechanism for Biological Phosphorus Removal; Enhanced Biological Phosphorus Removal by Bacteria and Algae.

UNIT V-ENVIRONMENTAL CONCERNS & RECYCLING OF WASTES

Environmental regulations and technology- Regulatory Concerns, Technology; Laws, regulations and permits, Air, Water, Solid Waste, Environmental Auditing, National Environmental Policy act, Occupational Safety and Health Act (OSHA), Storm Water Regulations; Technology (waste water); Recycling of Industrial wastes: paper, plastics, leather and chemicals.

Course Learning Outcomes (CLOs):

Students will be able to

1. Describe the prime objective of wastewater treatment and sanitation.
2. Determine the stoichiometric and kinetic parameters of the different metabolic processes of the microorganisms involved during the biological wastewater treatment process
3. Critically determine and analyse quantity and quality characteristics of wastewaters
4. Design and critical assess different wastewater treatment systems and configurations performing biological organic matter, nitrogen as well as phosphorus removal.
5. Design and critically evaluate different disinfection treatments.

Text/Reference Books:

1. Wastewater Engineering: Treatment Disposal Reuse by Metcalf & Eddy
2. Environmental Biotechnology : Principles and Applications by Bruce E. Rittmann
3. Waste water Engineering Treatment and Reuse: McGraw Hill, G. Tchobanoglous,FI Biston, 2002.
4. Industrial Waste Water Managemnet Treatment and Disposal by Waste Water McGraw Hill III Edition 2008.
5. Biological Wastewater Treatment", Second Edition, Marcel Dekker, Inc., New York,
6. Introduction to Waste Water Treatment- R. S. Ramalho, Academic Press.

Online links for study & reference materials:

https://www.cedengineering.com/courses/biological-wastewater-treatment-ii-mbbr-processes

Assessment method :

(Continuous Internal Assessment = 40% , Final Examination = 60%)

Assessment -1	- 05%
Assessment-2	- 05%
Assessment-3(Midexam)	- 20%
Assessment-4	- 05%
Assessment-5	- 05%
Total Internal Assessment	**- 40%**

Course Code: PE22 **Course Name: Quality Control in Biotechnology**

Course Credit Hour: 3hr **Total Contact Hour: 30 HRS**

Course Objective:

The course focuses on the quality requirements for the production and control of biologics and drugs and the differences between quality control and quality assurance and their interaction with manufacturing.

Course Description:

Quality control is an important area in many Biotechnological companies. The people who work in quality control perform different kinds of tests to ensure the identity, purity, and activity of the product the company sells. The exact tests depend on the product. Quality control technicians may also test materials that are purchased from different vendors.

Course Contents:

UNIT I

Concept and evolution of quality control and quality assurance. Total Quality Management, Philosophy of GMP and cGMP. Preparation of audit, Conducting audit, Audit Analysis, Audit Report and Audit follow up Quality control laboratory responsibilities: GLP protocols on non- clinical testing control on animal house, data generation, integration and storage, standard test procedure, retention of sample records. CPCSEA guidelines.

UNIT II

Quality review and batch release document of finished products, annual product quality review and parametric release, Audits, quality audits of manufacturing processes and facilities, audits of quality control.

UNIT III

Good documentation practices, route cause analysis, corrective action preventive action (CAPA), out of specifications (OOS) and out of trend (OOT), Clinical studies- ICH GCP (E6) guidelines, post marketing surveillance, Pharmacovigilance.

UNIT IV

BABE (bioavailability and bioequivalence) studies, Concepts and management of contract manufacturing guidelines, Statistical Tools for Quality Control and Precision, Tools of Problem Solving and Continuous Improvement.

UNIT V

Introduction, scope and importance of IPR, Concept of trade mark, copyright and patents Product registration guidelines – CDSCO, USFDA, Concept of ISO 9001:2008, 14000, OSHAS guidelines, Quality Strategy for Indian Industry, Brief concept of IND, NDA, ANDA, SNDA and PAT.

Course Learning Outcomes (CLOs):

Students will be able to:

1. Develop a thorough understanding of regulatory compliance and good manufacturing practices
2. Interpret research or operational data.
3. Test and evaluate quality of materials or finished products.
4. Record research or operational data.
5. Maintain and calibrate laboratory or technical equipment.
6. Prepare information or documentation related to legal or regulatory matters. Inspect areas for compliance with sanitation standards.

Text / Reference Books:

1. Sharp J. Good Pharmaceutical Manufacturing Practice: Rationale and Compliance. CRC Press; 2005.

2. Gad SC. Pharmaceutical Manufacturing Handbook: Production and Processes. John Wiley & Sons; 2008.

3. Steinborn L. GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Sixth Edition, (Volume 1 - With Checklists and Software Package). Taylor & Francis; 2003.

4. Kolman J, Meng P, Scott G. Good Clinical Practice: Standard Operating Procedures for Clinical Researchers. Wiley; 1998

5. .Waller P. An Introduction to Pharmacovigilance. John Wiley & Sons; 2011.

6. Niazi S. Handbook of Bioequivalence Testing. CRC Press; 2007.

7. Chalmers AA. International Pharmaceutical Registration. Interpharm Press; 2000.

8. Edwards AJ. ISO 14001 Environmental Certification Step- by-Steps: Revised Edition. Butterworth-Heinemann; 2003.

9. Mantus D. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices, and Biologics. Informa Healthcare USA; 2008.

Online links for study & reference materials:

https://www.mobiloitte.com/quality-control-in-biotechnology

Assessment method :

(Continuous Internal Assessment = 40% , Final Examination = 60%)

Assessment -1	- 05%
Assessment-2	- 05%
Assessment-3(Midexam)	- 20%
Assessment-3	- 05%
Assessment-4	- 05%
Total Internal Assessment	**- 40%**

Course Code: BPE23 **Course Name: Applied Clinical Research**

Course Credit Hour: 3hr **Total Contact Hour: 30 HRS**

Course Objective:

The Clinical Research course is rooted in the belief that clinical research training is critical to professional development in health care. Clinical research course Designed to provide learners with the foundational knowledge and skill sets required to produce high-quality clinical research.

Course Description:

Clinical trials and regulatory affairs publishes innovative, developmental and original research on validated experimental design, methods, representation and interpretation of clinical research and drug trials. Additionally, the journal publishes original research articles, reviews, short communications and thematic journal issues. Published work is based on solid clinical, scientific and statistically relevant results that lead to advancements in clinical medicine, clinical research, regulatory affairs and human subject protection in the areas of biological advances, drugs, bio-therapeutics and devices.

Course Contents:

UNIT I: Introduction to clinical research

Basic pharmacology and drug development process, clinical research definition, Basic terminology used in clinical research, preclinical studies, Introduction to pharmaco economics, Types of clinical trials, single blinding, double blinding, open access, randomized trials and their examples, interventional study, Good Clinical Practices, Types and Scope of Clinical Research.

UNIT II: Clinical trials

New drug discovery process- purpose, main steps involved in new drug discovery process, timelines of each steps, advantages and purposes of each steps, Pre clinical toxicology: General principles, Systemic toxicology (Single dose and repeat dose toxicity studies), Carcinogenicity, Mutagenicity, Teratogenicity, Reproductive toxicity, Local toxicity, Genotoxicity, animal toxicity requirements, Phase-I, II, III, IV trials: Introduction and designing, Various phases of clinical trials, Post Marketing surveillance, methods & Principles of sampling, Inclusion and exclusion criteria, Methods of allocation and randomization, Informed consent process in brief monitoring, treatment outcome, Termination of trial, Safety monitoring in clinical trials.

UNIT III: Ethics & Regulations in Clinical research

Ethical Theories and Foundations, Ethics Review Committee and Informed Consent Process,Integrity & Misconduct in Clinical Research , unethical trials, thalidomide tragedy, Conflicts of Interest, Evolution and History of Regulations in Clinical Research, Study of various clinical trials (completed or ongoing) ,Patents US Regulatory Structure, Clinical Trial Application in India Import & Export of Drug in India , Investigational New Drug application (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Post Drug Approval Activities, PMS, FDA Audits and Inspections EU Regulatory Affairs, EMEA Organization and Function, INDIAN Regulatory system, Schedule Y- Rules and Regulations.

UNIT IV: Principles of controlled clinical trials

Clinical trial design (observational and interventional) protocol, consent in clinical trials, placebo, bias and methods to prevent bias, ethics in clinical trials, monitoring, problems and solutions of controlled clinical trials. Multicentre clinical trials, Requirements, regulations and feasibility, Designing of Protocol, CRF, e-CRF, IB, ICF, SOP BA/BE Studies Report writing, Publication, Improving patient enrolment and retention in Clinical Trials Other Clinical Studies- Pharmacoepidemiology, ADR monitoring, pharmacokinetic trials, quality of life studies.

UNIT V: Biostatistics and data management

Preparation of a successful clinical study, Study management, Project management Documentation, Monitoring, Audits and Inspections Pharmacovigilance Training in clinical research Budgeting in clinical research, Supplies and vendor management. Importance of statistics in clinical research Statistical considerations at the design, analysis and reporting stage. Data management, Data validation, SAE reconciliation, query management Software considerations.

Course Learning Outcomes(CLOs) :

Students will be able to:

1. Describe Good Clinical Practice (GCP) requirements and explain the legal and regulatory issues in clinical research
2. Construct a clinical research protocol and critique flawed and exemplary studies
3. Differentiate the key elements of successful study and site management
4. Examine ethical issues in clinical research and select appropriate approaches strategies to navigate
5. Practice the leadership and communication skills needed in a clinical research setting

6. Demonstrate an awareness of ethical practices and professional standards applicable to the field of clinical research
7. Exemplify the skills, attitudes and behaviours required to effectively communicate with various stakeholder groups engaged in clinical trails
8. Demonstrate personal management, leadership and project management skills

TEXT BOOKS and REFERENCES:

1. Basic and Clinical Pharmacology, Prentice hall, International, Katzung, B.G.
2. Clinical Pharmacology, Scientific book agency, Laurence, DR and Bennet PN.
3. Clinical pharmacokinetics, Pub. Springer Verlab, Dr. D.R Krishna, V. Klotz
4. Remington Pharmaceutical Sciences, Lippincott, Williams and Wilkins
5. Drug interaction, Kven Stockley. Hamsten
6. Clinical pharmacology and drug therapy Grahame smith and Aronson,
7. Text Book of Therapeutics Drug and Disease Management Hardbound. Richard A Helms,
8. Clinical Pharmacy and therapeutics Herfindal E T and Hirschman JL, Williams and Wilkins,
9. Methodology of Clinical Drug Trials, 2nd Edition. Spriet A., Dupin-Spriet T., Simon P. Publisher: Karger.

Online links for study & reference materials :

https://lecturenotes.in/download/note/18532-note-for-applied-physics-phy-by-anshuman

Assessment method :

(Continuous Internal Assessment = 40% , Final Examination = 60%)

Assessment -1	- 05%	
Assessment-2	- 05%	
Assessment-3(Midexam)	- 20%	
Assessment-3	- 05%	
Assessment-4	- 05%	
Total Internal Assessment	-	**40%**

BPCL1: APPLIED BIOCHEMISTRY& MOLECULAR BIOLOGY LAB

1. Quantitative estimation of amino acids by ninhydrin reaction.
2. Quantitative estimation of proteins.
3. To separate lipids with the help of thin layer chromatography (TLC).
4. To verify the Lambert Beer's law with the help of UV absorption spectra of proteins.
5. Protein purification by ammonium sulfate precipitation.
6. Isolation of DNA and RNA from animal tissue and planttissue.
7. Gel electrophoretic analysis of various DNA and their restrictiondigests
8. Transformation with plasmid and bacteriophage DNA
9. Restriction mapping of plasmid DNA
10. Blotting: northern blotting, southern blotting
11. PCR technique

BPCL2: BIOPROCESS TECHNOLOGY & ENGINEERING LAB

1. Determination of kinetic parameters for batch cultivation of yeast under shake flask conditions.
2. Determination of volumetric oxygen transfer coefficient (K_{La})
3. Determination of activation energy (Ea) of microbial strains.
4. Process optimization for enzyme production using specific experimental design.
5. Preparation of immobilized enzymes & cells and evaluation of kinetic parameters.
6. Computational Design of Fermentative Process.
7. Fermenter designing and the study of various parts of fermenter and their function for microbial cell culture.
8. Fermentative production of Penicillin by using *Penicilium chrysogenum*.
9. Microbial production of enzymes Cellulase & Protease.
10. Ethanol production from molasses or starchy raw material.
11. Fermentative production of Wine from grapes.
12. Separation and purification of microorganisms from yogurt and cheese.
13. Fermentative production of alpha amylase under solid & submerged conditions.
14. Protein profiling of fermentation broth through dialysis procedure.
15. To study the Scale-up and Sterilization in Bioreactors.

Course Code: BPCT3 **Course Name:** Bioinformatics

Course Credit Hour: 3hr **Total Contact Hour:** 30hr

Course Objective :

The objective of this course is to provide students with basic understanding and application of bioinformatics. The course will provide the basic concepts behind the sequence and structural alignment, database searching, protein structure prediction and computer based drug designing.

Course Description :

Bioinformatics is a new multidisciplinary field that includes the development and implementation of computational methods and tools suitable to handle, decipher and interpret the plethora of biomolecular data derived nowadays, acting as a bridge between bio- information and biological knowledge extraction.

Course Contents:

UNIT I

Introduction to Bioinformatics, Need for informatics tools and exercises, Bioinformatics resources: NCBI, EBI, ExPASy, RCSB. Significance of databases towards informatics projects. Primary and Secondary Databases. GenBank, DDBJ, EMBL, PIR, Uniprot-KB, SWISS-PROT, TrEMBL. Specialized databases: Pubmed, OMIM, Medical databases, KEGG, EST databases; Genome databases at NCBI, EBI, TIGR, SANGER. Overview of other popular tools for various bioinformatics exercises.

UNIT II

Introduction, The evolutionary basis of sequence alignment, the Modular Nature of proteins, Optional Alignment Methods, Substitution scores, substitution matrices, PAM, BLOSUM, Gap penalties, Statistical significance of Alignments, Pair wise sequence alignment algorithms, Practical Aspect of Multiple Sequence Alignment, Progressive and Iterative Alignment Methods, CLUSTALW, Database similarity searching, FASTA, BLAST, Low-Complexity Regions. PSI- BLAST, PHI-BLAST.

UNIT III

Introduction to Phylogenetic analysis, rooted and unrooted trees, Elements of phylogenetic Models, Phylogenetic Data Analysis: Alignment, Substitution Model Building, Tree Building, and Tree Evaluation, Tree - Building Methods-Distance based and character based methods, Evaluating Trees and Data- Boot strapping (parametric and non parametric), Phylogenetic softwares (CLUSTALW, PHYLIP etc), Conceptual numericals.

UNIT IV

Restriction mapping, Utilities, DNA strider, MacVector and OMIGA, gene construction KIT, Vector NTI, Web based tools (MAP, REBASE); Primer design – need for tools, Primer design programs and software (PRIME3).

UNIT V

Sequencing methods, Bioinformatics tools and automation in Genome Sequencing, analysis of raw genome sequence data, Utility of EST database in sequencing, Bioinformatics in detection of Polymorphisms, SNPs and their relevance, Bioinformatics tools in microarray data analysis. Tools for comparative genomics: BLAST2, AVID, Vista, MUMmer, COG, VOG. Usages of visualization software available in public domain like VMD, Rasmol, Pymol, SpdbViewer, Chime, Cn3D and GRASP. Rotameric Structures of Proteins (Conformational Flexibility), Canonical DNA Forms (DNA Sequence Effects).

Course Learning Outcomes(CLOs) :

Students will be able to:

1. Apply key concepts of different bioinformatics tools
2. Analyse sequence and structure bio-macromolecule data
3. Apply the knowledge of bioinformatics in the biotechnology research and industry
4. Use system biology for application in biotechnology

Text/ Reference Books:

1. Bioinformatics (Sequence and Genome Analysis)- David W. Mount, Cold Spring Harbor Laboratory Press, 2001.
2. Bioinformatics- Zoe Lacroix, Terence Critchlow, Morgan Kaufmann Publishersm, 2004.
3. Bioinformatics – From Genomics to Drugs, Violume 1; Basic Technoliges, Thomas Lengauer, Wiley- VCH, 2001.
4. Bioinformatics (Practical Approach): Sequence, Structure and Databanks – Des Higgins, OXFORD Univ. Press, 2003.
6. Bioinformatics Computer Skills - Gibas & Jambeck, O' Reilly, 2001, I Ed.
7. Bioinformatics Computing- Bryan Berjeron, Prentice-Hall of India, Private Ltd., 2003.
8. Computational Molecular Biology (An Algorithmic Approach)- Pavel A. Pevzner, Prentice- Hall of India, Private Ltd., 2004.

9. Introduction to bioinformatics- T K Attwood, D J Parry-Smith, Pearson Education, 2004.

Online links for study & reference materials :

https://www.coursera.org/lecture/bioinformatics-pku/what-is-bioinformatics-vQo1i

Assessment method :

(Continuous Internal Assessment = 40% , Final Examination = 60%)

Assessment -1	- 05%
Assessment-2	- 05%
Assessment-3(Midexam)	- 20%
Assessment-3	- 05%
Assessment-4	- 05%
Total Internal Assessment	**-40%**

Course Code: BPCT4 **Course Name :** Recombinant DNA Technology

Course Credit Hour: 3hr **Total Contact Hour :** 30hr

Course Objective:

To familiarize the student with emerging field of biotechnology i.e. Recombinant DNA Technology as well as to create understanding and expertise in wet lab techniques in genetic engineering.

Course Description:

Recombinant DNA technology: A series of procedures that are used to join together (recombine) DNA segments. A recombinant DNA molecule is constructed from segments of two or more different DNA molecules. Under certain conditions, a recombinant DNA molecule can enter a cell and replicate there, either on its own or after it has been integrated into a chromosome

Course Contents:

UNIT I

Introduction to recombinant DNA Technology, Safety guidelines of rDNA research. Restriction endonucleases, DNA modifying enzymes, Vectors: plasmids, phage vectors, cosmids, phagemids, Yeast cloning vectors, Animal viruses, yeast artificial chromosomes, bacterial artificial chromosome. Cloning &Cloning strategies in yeast and *E. coli*, cloning of PCR product, construction and screening of genomic and cDNA library.

UNIT II

Sequencing of DNA, Molecular probes, PCR, Blotting and hybridization techniques, mutagenesis, mRNA isolation and cDNA synthesis, RFLP, RAPD, RT PCR. Selection of rDNA clones and their expression products: Direct and indirect methods, Gene Targeting, Gene Silencing.

UNIT III

Tailoring model plants and animals: transgenic animals and plants, techniques and experiments involved in creating transgenic mice, knockout mice.

UNIT IV

Nucleic acid sequence as diagnostic tools, DNA fingerprinting in consideration to clinical diagnosis & forensics, New drugs and therapies for genetic diseases, Metabolite engineering, Metabolic pathway engineering.

Course Learning Outcomes(CLOs) :

1. Major events in the development of rDNA technology. Introduction of rDNA into bacterial cells. Selection of transformants and recombinants – lac selection.
2. Learning tools and techniques in rDNA technology- DNA manipulative enzymes.
3. Acquire skills on techniques of construction of recombinant DNA - Cloning vectors and isolation of gene of interest.

Text Books:

1. Ausubel et al. (2002). Short Protocols in Molecular Biology. Wiley
2. Brown (2006). Gene Cloning and DNA Analysis - An Introduction. Blackwell
3. Glick and Pasternak (2003). Molecular Biotechnology. ASM Press
4. Krenzer and Massey (2000). Recombinant DNA and Biotechnology. ASM
5. Robertson et al. (1997). Manipulation & Expression of Recombinant DNA. AP
6. Sambrook et al. (2001). Molecular Cloning. CSHL
7. Primrose and Twyman (2006). Principles of Gene Manipulation and Genomics. Blackwell

Online links for study & reference materials :

https://ocw.mit.edu/courses/biology/7-01sc-fundamentals-of-biology-fall-2011/recombinant-dna/

Assessment method :

(Continuous Internal Assessment = 40% , Final Examination = 60%)

Assessment -1	- 05%
Assessment-2	- 05%
Assessment-3(Midexam)	- 20%
Assessment-3	- 05%

Assessment-4	- 05%
Total Internal Assessment	**- 40%**

Course Code: BPE31 **Course Name:** Genetic Engineering

Course Credit Hour: 3hr **Total Contact Hour:** 30hr

Course Objective:

1. This course offer students to learn the tools and techniques used in genetic engineering and recombinant DNA technology.
2. To make students learn the application of recombinant DNA technology in the field of biomedical, agriculture and environment.

Course Description:

Genetic engineering is the process of using recombinant DNA (rDNA) technology to alter the genetic makeup of an organism. Traditionally, humans have manipulated genomes indirectly by controlling breeding and selecting offspring with desired traits. Genetic engineering involves the direct manipulation of one or more genes. Most often, a gene from another species is added to an organism's genome to give it a desired phenotype.

Course Contents :

UNIT I

DNA Structure and properties; Enzymes used in Genetic Engineering; Cohesive and blunt end ligation; Linkers; Adaptors; Homopolymeric tailing; Labeling of DNA: Nick translation, Random priming, Radioactive and non-radioactive probes, Hybridization techniques, Hybridization techniques; Chromatin Immunoprecipitation; DNA-Protein Interactions-Electromobility shift assay; DNaseI footprinting; Methyl interference assay

UNIT II

Plasmids; Bacteriophages; M13 mp vectors; PUC19 and Bluescript vectors, Phagemids; Lambda vectors, Insertion and Replacement vectors; Cosmids; Artificial chromosome vectors (YACs; BACs); Animal Virus derived vectors; Expression vectors; Inclusion bodies; Methodologies to reduce formation of inclusion bodies; Baculovirus and pichia vectors system, Plant based vectors, Ti and Ri as vectors, Yeast vectors, Shuttle vectors

UNIT III

Insertion of Foreign DNA into Host Cells; Transformation; Isolation of mRNA and total RNA; cDNA and genomic libraries and its construction; cDNA and genomic cloning; Expression cloning; Jumping and hopping libraries;

Southwestern and Far-western cloning; Protein-protein interactive cloning and Yeast two hybrid system; Phage display; Principles in maximizing gene expression

UNIT IV

Primer design; Fidelity of thermostable enzymes; DNA polymerases; Concept of PCR, Types of PCR, Gene specific and degenerate primer design, linkers, adaptors, Fidelity of uDNA polymerase. Application of PCR. Chimeric protein engineering by PCR

UNIT V

Sequencing methods; Enzymatic DNA sequencing; Chemical sequencing of DNA; Automated DNA sequencing; RNA sequencing; Chemical Synthesis of oligonucleotides; Introduction of DNA into mammalian cells; Transfection techniques; Gene silencing techniques; siRNA technology; Micro RNA; Construction of siRNA vectors; Principle and application of gene silencing; Gene Therapy; Suicide gene therapy; Gene replacement; Gene targeting; Transgenics; cDNA and intragenic arrays; Differential gene expression and protein array.

Course Learning Outcomes(CLOs):

1. **Understand, define** and **explain** the tools in recombinant DNA technology.
2. **Understand** techniques in recombinant DNA technology.
3. **Identify**, **select** and **implement** the PCR and its types in molecular biology and recombinant DNA technology.
4. **Understand and analyze** knowledge of mutagenesis.
5. **Apply** knowledge of genetic engineering in current applications of biotechnology.
6. **Comprehend** and **analyze** the impact of Human Genome Project in genetic engineering programme.

Text/References:

1. S.B. Primrose, R.M. Twyman and R.W.Old; Principles of Gene Manipulation. 6th Edition, S.B.University Press, 2001.
2. J. Sambrook and D.W. Russel; Molecular Cloning: A Laboratory Manual, Vols 1-3, CSHL, 2001.
3. Brown TA, Genomes, 3rd ed. Garland Science 2006
4. Selected papers from scientific journals.
5. Technical Literature from Stratagene, Promega, Novagen, New England Biolab etc.
6. Ausubel et al (2002). Short Protocols in Molecular Biology. Wiley

7. Robertson et al (1997). Manipulation & Expression of Recombinant DNA. AP.

Online links for study & reference materials:

https://www.sciencedirect.com/topics/neuroscience/genetic-engineering

Assessment method :

(Continuous Internal Assessment = 40% , Final Examination = 60%)

Assessment -1	- 05%
Assessment-2	- 05%
Assessment-3(Midexam)	- 20%
Assessment-3	- 05%
Assessment-4	- 05%
Total Internal Assessment	**- 40%**

Course Code: BPE32 **Course Name:** Applied Food Biotechnology

Course Credit Hour: 3hr **Total Contact Hour:** 34hr

Course Objective:

This course aims to impart a strong basic knowledge on processing criteria of foods (both traditional and emerging technologies) concepts applied in food processing industries, delivery of finished food products. Microbial safety, regulations in practice, traceability methods and state- of- the art analytical techniques used for assessing contamination of food

Course Description:

Technology of manipulating or modifying DNA for the purpose of improving the quality and or safety of foods - Use of genetics to improve plants animals and microorganisms for food production.

Course Contents:

UNIT I

Food Biotechnology: Introduction & Applications; Methods for the microbiological examination of water and foods; Control of Microbiological quality and safety; Food borne illnesses and diseases; Microbial cultures for food fermentation, their maintenance, strain development

UNIT II

Starter cultures–types, designing and development, micro encapsulation and packaging, scopes and challenge; Development and formulation of novel products such as probiotic foods. Nutrogenomics-concept, working, significance and relevance. Biosensors and novel tools and their application in food science & Technology

UNIT III

GM foods: Introduction and controversies related to GMOs. Ethical issues concerning GM foods; testing for GMOs; current guidelines for the production, release and movement of GMOs; labelling and traceability; trade related aspects; biosafety; risk assessment and risk management. Public perception of GM foods. IPR. GMO Act–2004. New products and processes in various food commodities including plant and animal products.

UNIT IV

Production of organic acids (vinegar, lactic acid), alcoholic beverages (beer, wine, and distilled alcoholic beverages such as whiskey, rum, vodka), glycerol; Propagation of baker's yeasts;

UNIT V

Microbial production of vitamins (B2 and B12), antibiotics (penicillin, streptomycin, tetracycline); Enzymatic production of glucose, fructose, starch, SCP and mushrooms

Course Learning Outcomes(CLOs):

Students will be able:

1. acquire an understanding of relevance of food components,
2. acquire an understanding application and detection techniques in food.
3. apply regulatory techniques in real time scenarios
4. acquire an understanding in industrial operations in food, role of microbes

Text/References:

1. Industrial Microbiology Prescott & Dunn, CBS Publishers
2. Modern Food Microbiology by Jay JM, CBS Publishers
3. Comprehensive Biotechnology by Murray & Mooyoung, Academic press
4. Industrial Microbiology by Casida L.R., New Age International Pvt. Ltd.
5. Food Microbiology; Frazier WC; 4th ed, Tata-McGrowhill Pub.
6. Microbiology by Pelczar, Chan, and Krieg, TMH
7. Fermentation Biotechnology, Principles, Processed Products by Ward OP, Open University Press.

Online links for study & reference materials:

https://www.brainkart.com/article/Food-biotechnology_33990/

Assessment method :

(Continuous Internal Assessment = 40% , Final Examination = 60%)

Assessment -1	- 05%
Assessment-2	- 05%
Assessment-3(Midexam)	- 20%
Assessment-3	- 05%
Assessment-4	- 05%
Total Internal Assessment	**-40%**

Course Code: BPE33 **Course Name: Molecular Modeling and Application**

Course Credit Hour: 3hr **Total Contact Hour:** 34hr

Course Objective:

The objective of the course is to enable the students to understand basic modelling techniques to explore biological phenomena at the molecular level. To emphasize Modelling drug/receptor interactions in detail by molecular mechanics, molecular dynamics simulations and homology modelling.

Course Description:

Molecular modeling tools are used in drug discovery and materials design, and how you can incorporate these tools into research projects. In addition to utilizing modern techniques such as active learning and multimodal teaching, these courses will also provide a chance to work hands-on with Schrödinger software.

Course Contents:

UNIT I

Molecular Modelling: Introduction; Useful Concepts in Molecular Modelling; The Molecular Modelling Literature; Molecular Modelling software: BIOSUITE; Force Fields

UNIT II

Energy Minimisation and Computer Simulation: Minimisation and Related Methods for Exploring the Energy Surface. Non-Derivative method, 1st and 2nd order minimisation methods. Results of a Simulation and Estimating Errors. GROMACS and CNS. Molecular Dynamics & Monte Carlo Simulation;

UNIT III

Drugs: An introduction, Overview of drug discovery process, Trends in drug discovery process. Rationale of Drug Discovery: Medical needs, Target identification, Target validation, Receptors and assay development.

UNIT IV

Herbal Drugs: Definition, Trade scenario, Phytochemical standardization and fingerprinting, Marker compounds, Polyherbal formulations. Drug Development and Pre-Clinical Studies: Drug receptor interactions; enzyme inhibition and inactivation, In-vitro and in-vivo pharmacodynamic models, Therapeutic index, Pharmacokinetics - Microbial and animal models, In-vitro and insilico toxicological models, Drug formulations.

UNIT V

Applications of microbes for designing vaccines: case study.

Course Learning Outcomes (CLOs):

Students will be able:

1. Implement the principles and practice of modern drug discovery
2. Carry out molecular modelling principles and practice of molecular modelling
3. Use the concepts of rational drug design by understanding the three-dimensional structures and physicochemical properties of drugs and receptors.

Text/References:

1. Patwardhan B, Drug Discovery and Development - Traditional Medicine and Ethnopharmacology, New India Publishing (2007).
2. Larsen PK, Leljifore T and Medsan U, Text Book of Drug Design and Discovery, CRC Press (2009).
3. Hillisch A and Hilgenfeld R, Modern Methods of Drug Discovery, Birkhauser (2003).

Online links for study & reference materials:

http://www.drugdiscoverytoday.com/view/25419/molecular-modeling/

Assessment method : (Continuous Internal Assessment = 40% , Final Examination = 60%)

Assessment -1	- 05%
Assessment-2	- 05%
Assessment-3(Midexam)	- 20%
Assessment-3	- 05%
Assessment-4	- 05%
Total Internal Assessment	**-40%**

Course Code: BPE41 **Course Name:** Bioreactor Analysis and Design

Course Credit Hour: 3hr **Total Contact Hour:** 30hr

CourseObjective:

The course introduces the student to design principles of batch, fed-batch and continuous bioreactors. Mass and heat transfer requirements for a given fermentation system will be discussed. The student will also be able to identify suitable criterion for the scale-up of bioprocesses and characterize non-ideality in bioreactors, if present

Course Description:

A bioreactor provides a controllable environment enabling the biological, biochemical and biomechanical requirements to manufacture engineered product. As the bioreactor aims to create a desired biological product, it is important to closely monitor the reaction parameters like internal and external mass transfer, heat transfer, fluid velocity, shear stress etc

Course Contents:

UNIT I

Introduction; General design information; Material and energy balance calculations; Process Flow sheeting, 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 I

Basic aspects of bioreactor designing, Physical, chemical and biological sensors and control, Advanced control strategies viz. PID controllers, Fuzzy logic based controllers and Artificial Neural Network (ANN) based controllers, Basic concepts of computer modelling and optimization in bioprocess applications.

UNIT III

Ideal bioreactors: Batch reactors, Fed-batch reactors, enzyme-catalyzed reaction in CSTRs, CSTR reactors with recycle and wall cell growth, the ideal plug-flow tubular reactor, Reactors with nonideal mixing: Mixing times in agitated tanks, residence time distribution, models for nonideal reactors, Mixing-bioreaction interactions.

UNIT IV

Reactor dynamics and stability, Multiphase bioreactors: conversion of heterogeneous substrates, packed-bed reactors, bubble column bioreactors, fluidized bed bioreactors, trickle-bed reactors, airlift reactor, Immobilized

Enzyme reactors, Photo bioreactors, Hollow fiber membrane bioreactors. 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.

UNIT V

Facility design aspects; Utility supply aspects; Equipment cleaning aspects; Culture cell banks; cGMP guidelines; Validation; Safety. Process economics; Case studies, Scale up of downstream processes: Adsorption (LUB method); Chromatography (constant resolution etc.); Filtration (constant resistance etc.); Centrifugation (equivalent times etc.); Extractors (geometry based rules).

Course Learning Outcomes (CLOs):

1. **Understand, define** and **explain** the types of bioreactors
2. **Understand** techniques for bioreactor design.
3. **implement** the Chromatography filtration centrifugation techniques in biotech industries.
4. **Handling of bioreactor equipment's.**
5. **Apply** knowledge of bioreactors tools in current biotechnological industries.

Text Books:

1. Moser, Anton, Bioprocess Technology: Kinetics and Reactors, Springer Verlag, 1988.
2. Bailey J.E. & Ollis, D.F. Biochemical Engineering Fundamentals, 2nd ed., McGraw Hill, 1986
3. Lee, James M. Biochemical Engineering, PHI, USA.
4. Atkinson, Handbook of Bioreactors, Blanch, H.W. Clark, D.S. Biochemical Engineering, Marcel Decker, 1999
5. Biochemical Engineering fundamentals" 2nd ed. -J E Bailey and D F Ollis, McGraw-Hill (1986) Chapters 8,9&10.
6. Biochemical Engineering" -S Aiba, A E Humphrey and N Millis, 1978, University of Tokyo Press.
7. Biotechnology" Vols. 3 & 4 Eds., S Rehm and G Reed. VCH (1991).
8. Biochemical Engineering and Biotechnology Handbook" 2nd Ed., .Atkinson & F.Mavituna, Stockton Press (1991).
9. Biorector Design & Product Yield" , BIOTOL series, Butterworth - Heinemann (1992).
10. Principles of fermentation technology" - F Stanbury and A Whitaker, Pergamon press (1984) Unit operations of Chemical Engineering" 5th ed. by W L McCabe, J C Smith and P. Harriot Mc Graw-Hill (1993).
11. Bioprocess Engineering Principles" by Pauline M.Doran, Academic Press.

12. Feedback and Control systems- Schaum's outline series, McGraw-Hill Book Comp., 1967
13. Unit Operations of Chemical Engineering- Mc Caba Smith, Harriott, Mc Graw – Hill Chemical Engg. Series. V Ed., 1985.

Online links for study & reference materials:

https://www.classcentral.com/course/swayam-bioreactor-design-and-analysis-22924

Assessment method:

(Continuous Internal Assessment = 40% , Final Examination = 60%)

Assessment -1	- 05%
Assessment-2	- 05%
Assessment-3(Mid exam)	- 20%
Assessment-3	- 05%
Assessment-4	- 05%
Total Internal Assessment	**- 40%**

Course Code: BPE 42 **Course Name:** Enzyme Technology & Industrial Application

Course Credit Hour: 3hr **Total Contact Hour:** 30hr

Course Objective:

The objective of the course is to inform the students about basic principles for optimization, modelling *etc* in which both, free and immobilized enzymes play a role. Students will be able to implement both biochemical and engineering knowledge in order to design new and improve current enzymatic processes.

Course Description:

The **enzyme** is a substance that acts as a catalyst in living organisms, regulating the rate at which chemical reactions proceed without itself being altered in the process. The study of industrial enzymes and their uses is called enzyme technology.

Course Content:

UNIT I-ENZYME TECHNOLOGY

Introductions: Enzymes- Michaelis-Menten kinetics. Kinetics and StatisticsInhibition- Effect of pH and temperature-Enzymology- Immobilized enzymes: Methods, Mass transfer considerations and Industrial enzymes.

UNIT II-METABOLISM, STOICHIOMETRY AND MICROBIAL GROWTH KINETICS

Introduction to metabolism- Nutrient transport- Glycolysis - TCA cycle and other pathways - Control of metabolism. Factors affecting microbial growth – Stoichiometry- mass balances and energy balances. Growth kinetics Measurement of growth.

UNIT III-BIOREACTORS, STERILIZATION, SENSORS AND INSTRUMENTATION

Introduction to bioreactors - Batch and Fed-batch bioreactors, Continuous bioreactors,Immoblized cells. Bioreactor operation, Sterilization, Aeration, Sensors. Instrumentation, Culture – specific design aspects: plant/mammalian cell culture reactors.

UNIT IV-PRIMARY & SECONDARY SEPARATION PROCESS

Biomass removal - Biomass disruption – Membrane based techniques. Extraction -solvent, aqueous two phases, super critical, and Adsorption. Chromatography, Precipitation (Ammonium Sulfate, solvent), Electrophoresis (capillary), Crystallization, Drying and Freeze drying.

UNIT V- INDUSTRIAL APPLICATION

White Biotechnology: Few industrial process using enzymes for production of drugs and fine chemicals, Enzyme based biosensors, Enzyme in organic catalysis, Molecular Imprinting. Enzyme engineering, selection of chiral molecules and their enzymatic separation, functional expression of enzymes protein engineering by modification of protein folding invitro and invivo, Case study.

Course Learning Outcomes(CLOs) :

Students will be able to:

1. Produce, isolate and purify enzymes at lab/industry scale
2. Apply reaction parameters and systems in order to develop an efficient enzymatic process.
3. Apply the biochemical knowledge to specific enzymatic process, 4. Predict the course of an enzymatic process by kinetic calculation

   5. Design new enzymatic processes

REFERENCES

1. Michael Shuler and FikretKargi. “Bioprocess Engineering: Basic Concepts”, 2nd Edition, Prentice Hall, and Englewood Cliffs, NJ, 2002.
2. Pauline Doran. “Bioprocess engineering principles”, Academic Press, 1995.
3. Colin Ratledge, Bjorn Kristiansen, “Basic Biotechnology”, 2nd Edition, Cambridge University Press, 2001.
4. Roger Harrison et al., “Bioseparation Science and Engineering”, Oxford University Press, 2003.

Online links for study & reference materials:

https://microbenotes.com/enzyme-technology/

Assessment method:

(Continuous Internal Assessment = 40%, Final Examination = 60%)

Assessment -1	- 05%
Assessment-2	- 05%
Assessment-3(Mid exam)	- 20%
Assessment-3	- 05%
Assessment-4	- 05%
Total Internal Assessment	**- 40%**

Course Code: BPE 51 **Course Name: Tissue Culture Techniques**

Course Credit Hour: 3hr **Total Contact Hour:** 30hr

Course Objective:

To make the students aware of the principles, practices and application of the plant tissue culture. Students acquire the necessary theoretical skills on animal tissue culture perspective. First, it provides detailed insights regarding the isolation of animal cells for *in vitro* studies, maintenance of animal cells *in vitro*, manipulation of animal cells *in vitro*, application of molecular techniques to *in vitro* situations. Furthermore the students will acquire knowledge in areas of cloning, large animal models for disease and development of therapies and treatments

Course Description:

Tissue culture (TC) is the cultivation of plant cells, tissues, or organs on specially formulated nutrient media. Under the right conditions, an entire plant can be regenerated from a single cell. Plant tissue culture is a technique that has been around for more than 30 years. Tissue culture is seen as an important technology for developing countries for the production of disease-free, high quality planting material and the rapid production of many uniform plants.

Course Content:

UNIT I

Basic cell culture techniques, Types of cell culture media; Ingredients of media; Physiochemical properties; CO2 and bicarbonates; Buffering; Oxygen; Osmolarity; Temperature; Surface tension and foaming; Balance salt solutions; Antibiotics growth supplements.

UNIT II

Different tissue culture techniques; Types of primary culture; Chicken embryo fibroblast culture; Chicken liver and kidney culture; Secondary culture; Trypsinization; Cell separation; Continuous cell lines; Suspension culture; Organ culture etc.; Behavior of cells in culture conditions: division, growth pattern, metabolism of estimation of cell number; Development of cell lines.

UNIT III

Cell cloning and selection; Transfection and transformation of cells; Commercial scale production of animal cells,

stem cells and their application; Application of animal cell culture for *in vitro* testing of drugs; Testing of toxicity of environmental pollutants in cell culture; Application of cell culture technology in production of human and animal viral vaccines and pharmaceutical proteins.

UNIT IV

Fundamentals of plant tissue culture, plant regeneration: organogenesis. Somatic embryogenesis; somaclonal variation, its genetic basis and application in crop improvement. Cell/callus line selection for resistance to herbicide, stress and diseases.: Isolation, culture and plant regeneration, protoplast fusion, identification and characterization of somatic hybrids., Field techniques for propagation of regenerated plants.

UNIT V

Explant selection, sterilization and inoculation; Various media preparations; MS, B5, SH PC L- 2; Callus and cell suspension culture; Induction and growth parameters; Chromosomal variability in callus culture. Plant regeneration from embryo, meristem and callus culture. Androgenesis: Anther and pollen culture; Isolation and culture of protoplasts.

Course Learning Outcomes (CLOs):

Students will be able to:

1. **Understand** the **use** of different plant tissue culture (PTC) techniques for PTC Industries as well as research.
2. **Explain** the various components of cell and tissue culture media as well as establishment and optimization of media for particular purposes in different species and cell lines.

Texts/References:

1. B. Hafez and E.S.E Hafez, Reproduction in farm animals, 7th Edition, Wiley Blackwell, 2000
2. G.E. Seidel, Jr. and S.M. Seidel, Training manual for embryo transfer in cattle (FAO Animal Production and Health Paper-77), 1st Edition, W.D. Hoard and sons FAO, 1991
3. I. Gordon, Laboratory production of cattle embryos, 2nd edition, CAB International, 2003.

Online links for study & reference materials:

https://www.isaaa.org/resources/publications/pocketk/14/default.asp

Assessment method:

(Continuous Internal Assessment = 40%, Final Examination = 60%)

Assessment -1	- 05%
Assessment-2	- 05%
Assessment-3(Mid exam)	- 20%
Assessment-3	- 05%
Assessment-4	- 05%

Course Code: BPE53 **Course Name: Fundamentals of Stem Cell Technology**

Course Credit Hour: 3hr **Total Contact Hour:** 34hr

Course Objective:

The objective of this course is to enable students to understand the principles of stem cells. To acquire knowledge in the areas of tissue engineering.

Course Description:

Stem cells are the **foundation cells** for every organ, tissue and **cell** in the body. ... Under proper conditions, **stem cells** begin to develop into specialized tissues and organs. Additionally, **stem cells** can self-renew, that is they can divide and give rise to more **stem cells**

Course Contents:

UNIT –I

Cell Diversification in Early Animal Embryo:

Process of fertilization & stages of development in Eukaryotes, pluripotency & formation of three germ layers, Differentiation, Organogenesis, ICM, cellular mechanism relating to these developments.

UNIT –II

Stem cell differentiation:

The process of stem cell differentiation leading to the formation of epidermal cells, skeletal muscles. Transformation of stem cell into gametes/ fertilization entity, Spermatogenesis & oogenesis. Menstrual Cycle.

UNIT-III

Hemopoietic Stem Cells:

Classification and manifestation of Hemopoietic stem cell disorders, plastic hemopoietic stem cell disorders, myelo dysplastic, myelo proliferative disorders, complications involved in gene therapy, blood transfusion & marrow transplantations, preservation & clinical use of blood, hemapheresis & Apheresis procedures,

UNIT-IV

Concept of stem cells & their applications:

Stem cells & their unique properties, Embryonic stem cells, Adult stem cells, induced pluripotent stem cells, epidermal stem cells & their applications hepatic stem cells & their role in liver regeneration, stem cell treatments, ethical issues of stem cell research.

UNIT-V

Stem cell therapy:

Potential of stem cell therapy for various diseases, eg. AIDS/HIV, Alzhemier's disease, Anaemia, Anti-ageing, Multiple sclerosis, Parkinson disease, Rheumatoid Arthritis.

Course Learning Outcomes (CLOs)

The students will be able

1. Describe the design, fabrication and biomaterials selection criteria for tissue engineering scaffolds.
2. Discuss the challenges of in vivo implantation of biomaterials and scale-up issues relating to human clinical applications
3. Describe the sources, selection, potential manipulations and challenges of using stem cells for tissue engineering. Explain the ethical and regulatory issues of significance in tissue engineering

References:

1. Essential Cell Biology, Bruce Alberts, Dennis Bray, Julian Lewis, Martin Raff, Kieth Roberts and Jamnes D. Watson, Garland Science, Taylor and Francis Group, 2nd Edition, 2003.
2. Stem Cell Biology by Marshak, Cold Spring Harbar Symposium Publication, 2001.
3. Molecular Biology of the Cell, Bruce Alberts, Dennis Bray, Alexander Johnson, Julian Lewis, Martin Raff, Kieth Roberts and Peter Walter, Garland Science, Taylor and Francis Group, 4th Edition, 2003.
4. Molecular and Cell Biology- Schaum's Outline of Theory and Problems by Willam D. Stansfield, Jaime S.Colorne and Raul J. Cano. Tata McGraw Hill Publisher, 2004.

Online links for study & reference materials :

https://www.unmc.edu/stemcells/stemcells/basics.html#:~:text=Stem%20cells%20are%20the%20foundation,and%20cell%20in%20the%20body.&text=Under%20proper%20conditions%2C%20stem%20cells,rise%20to%20more%20stem%20cells.

Assessment method:

(Continuous Internal Assessment = 40% , Final Examination = 60%)

Assessment -1	- 05%
Assessment-2	- 05%
Assessment-3(Midexam)	- 20%
Assessment-3	- 05%
Assessment-4	- 05%
Total Internal Assessment	**- 40%**

BPCL3: BIOINFORMATICS LAB

1. To find out five similar sequences of any Protein and DNA query sequence.
2. To predict open reading frame of any given gene sequence.
3. To perform pair wise local and global sequence alignment for any two proteins and DNA sequences.
4. To perform multiple sequence alignment for any five sequences and predicts the Phylogenetic relationship among them.
5. To predict secondary structure for any given protein sequence using Chou-Fasman, GOR and Neural network algorithms.
7. To visualize tertiary structure of any given protein sequence using Rasmol/PyMol/PMV.
8. To visualize the genomic map of Human genome and find out the size, number of genes and number of proteins encoded on Chr-Y.
9. To predict the homology model of any protein sequence.
10. To find out the RMSD value from any two protein structure alignment.

BPCL4: RECOMBINANT DNA TECHNOLOGY LAB

1. Genomic DNA Isolation
2. Designing of Primers
3. Gel electrophoresis of nucleic acids
4. Optimization of Gel PCR
5. Digestion and Elution of PCR products and Expression vector with respective Restriction Enzyme.
6. Ligation of PCR Product with expression vector
7. Transformation of competent cells with plasmid DNA
8. Screening of Colony PCR
9. Growth Assay in broth/Plate