KUMARAGURU COLLEGE OF TECHNOLOGY

An autonomous Institution affiliated to Anna University, Chennai

COIMBATORE -641 049

M.TECH., BIOTECHNOLOGY
REGULATION 2018A

CURRICULUM AND SYLLABI

I-IV Semesters

Department of Biotechnology

VISION

Strong teaching and research foundation in the area of biotechnology and allied fields through knowledge dissemination to students and the public and to scale new heights in the frontier areas of health and environment and ethics for welfare of humankind globally.

MISSION

- Develop dynamic curriculum and syllabus to promote innovative and creative practices.
- Encourage students for innovation and setting start-ups and equip leadership and entrepreneurial skills
- Train students on issues related to social welfare.
- Groom students to uphold professional and leadership qualities.

PROGRAM EDUCATIONAL OBJECTIVES (PEOs)

- **PEO-1** – To apply professional knowledge and skills in academia, industry and research.
- **PEO-2** – To enable the students to evaluate real life problems and to propose biotechnological solutions with economical and social impact.
- **PEO-3** – To train the students individually/ or in a team for intellectual independence to provide innovative solutions.

PROGRAM OUTCOMES (POs)

PO1: An ability to independently carry out research / investigation and development work to solve practical problems.
PO2: An ability to write and present a substantial technical report / document.
PO3: An ability to demonstrate a degree of mastery over the area as per the specialization of the program.
PO4: An ability to employ bio-based techniques to address issues related to health with professional ethics.
PO5: An ability to develop/ utilize sustainable technology to address environmental issues.
PO6: An ability to apply modern engineering tools for the implementation of interdisciplinary projects.

KUMARAGURU COLLEGE OF TECHNOLOGY
COIMBATORE -641 049
DEPARTMENT OF BIOTECHNOLOGY
M.TECH BIOTECHNOLOY
REGULATION 2018A

CURRICULUM								
S.NO	**COURSE CODE**	**COURSE TITLE**	**COURSE MODE**	**L**	**T**	**P**	**J**	**C**
SEMESTER - I								
1	P18BTI1201	Gene Expression and Analysis	Embedded Theory & Lab	3	0	2	0	4
2	P18BTI1202	Bioprocess Modelling and Simulation	Embedded Theory & Lab	3	0	2	0	4
3	P18BTI1203	Bioproduct Recovery and Purification	Embedded Theory & Lab	3	0	2	0	4
4	P18INT0001	Research Methodology and Statistics	Theory	3	0	0	0	3
							Total Credits	15
							Total Contact hour/ week	18

S.NO	COURSE CODE	COURSE TITLE	COURSE MODE	L	T	P	J	C
SEMESTER - II								
1	P18BTI2201	Quality control and Quality Assurance in Biomanufacturing	Embedded Theory & Lab	3	0	2	0	4
2	P18BTI2202	Bioanalytical Techniques	Embedded Theory & Lab	3	0	2	0	4
3	P18BTI2203	Computational Biology	Embedded Theory & Lab	3	0	2	0	4
4	P18BTE—-	Programme Elective-I	Theory	3	0	0	0	3
5	P18INT0002	Product Design and Development	Theory	3	0	0	0	3
5	P18INR0001	Research Ethics	Theory	1	0	0	0	0
							Total Credits	18
							Total Contact hour/ week	21

S.NO	COURSE CODE	COURSE TITLE	COURSE MODE	L	T	P	J	C
SEMESTER - III								
1	P18BTE—-	Programme Elective-II	Theory	3	0	0	0	3
2	P18BTP3701	Project Phase -I / Industry Project	Project	0	0	0	20	10
							Total Credits	13
							Total Contact hour/ week	23

S.NO	COURSE CODE	COURSE TITLE	COURSE MODE	L	T	P	J	C
SEMESTER - IV								
1	P18BTP4701	Project Phase -II/ Industry Project	Project	0	0	0	40	20
							Total Credits	20
							Total Contact hour/ week	40

Total Credits : 66

LIST OF ELECTIVES								
S.NO	**COURSE CODE**	**COURSE TITLE**	**COURSE MODE**	**L**	**T**	**P**	**J**	**C**
PROGRAME ELECTIVE I & II								
Group I - Bioprocess Technology								
1	P18BTE0001	Biorefinery and Sustainable Technology	Theory	3	0	0	0	3
2	P18BTE0002	Wastewater Treatment Technology	Theory	3	0	0	0	3
3	P18BTE0003	Bioremediation Technology	Theory	3	0	0	0	3
Group II - Biopharmaceutical Technology								
4	P18BTE0004	Molecular Diagnostics and Therapeutics	Theory	3	0	0	0	3
5	P18BTE0005	Cell culture and Vaccine Technology	Theory	3	0	0	0	3
6	P18BTE0006	Clinical Research and Management	Theory	3	0	0	0	3
7	P18BTE0007	Nanomaterials and Applications	Theory	3	0	0	0	3
8	P18BTE0008	Drug Delivery Principles & Engineering	Theory	3	0	0	0	3
9	P18BTE0009	Human Physiology & Allied Diseases	Theory	3	0	0	0	3
10	P18BTE0010	Medical Textiles	Theory	3	0	0	0	3
11	P18BTE0011	Structural Biology	Theory	3	0	0	0	3
12	P18BTE0012	Biopolymers	Theory	3	0	0	0	3

LIST OF ONE-CREDIT COURSES		
S.NO	**COURSE CODE**	**COURSE TITLE**
1	P18BTI0101	Pharmacovigilance
2	P18BTI0202	Mushroom Production
3	P18BTI0203	Natural Products
4	P18BTI0204	Protein Purification using FPLC
5	P18BT—-	

* Any new course to be included after approval

P18BTI1201 GENE EXPRESSION AND ANALYSIS

L	T	P	J	C
3	0	2	0	4

Course Objectives:

- To understand the role of genetic elements, vectors and host systems for gene expression.
- To acquire skill set to carry out gene expression analysis in bacterial and eukaryotic systems.

Course Outcomes (COs):
After successful completion of the course, the students should be able to

CO1: Comprehend the role of various genetic elements influencing gene expression in prokaryotes.
CO2: Applying gene regulation for recombinant protein expression.
CO3: Critique the role of various genetic elements influencing the gene expression eukaryotes.
CO4: Acquire skill set required to characterize recombinant proteins from various host systems.
CO5: Apply the knowledge to understand the genetic diseases and gene expression.
CO6: Quantify the gene expression for molecular diagnosis of diseases.

CO/ PO MAPPING (S/M/W indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak						
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**
CO1	3					
CO2	3					
CO3					3	3
CO4		3	3			
CO5	3		3		3	3
CO6	3			3	3	3

Course Assessment Methods	
Direct	
1	Continuous Assessment Test
2	Assignments
3	End Semester Examination

Course Content **45 hour**

1. **PROKARYOTIC GENE EXPRESSION** **12 hour**

Replication in prokaryotes, Coupled transcription and translation, operon and regulation, operator and repressor, inducer and Transcription enhancers, natural and synthetic inducers, attenuation model, key genetic elements in expression vectors, expression systems and their genetic modification for heterologous gene expression, codon optimization and overexpression, Case studies of prokaryotic gene expression: catabolite repression, pH shock, Heat Shock, porin response, oxidative responses.

2. **EUKARYOTIC GENE EXPRESSION** **12 hour**

Replication in Eukaryotes, Effect of hormones on timing of gene expression, transcription enhancing factors, Nuclear RNA, turnover, hnRNA export and splicing, MicroRNA and connection between gene expression, cis acting and transacting element gene expression, chromosome remodeling and control of gene expression, DNA looping, regulation of mitochondrial gene expression, codon de-optimization and under expression.
Case study : SV40 enhancer

3. **ANALYSIS OF RECOMBINANT PROTEIN** **12 hour**

Affinity tags, purification of poly-histidine tagged proteins, purification of GST tagged proteins, Purification of biotinylated proteins, Subcellular localization of proteins, Western blotting to detect protein, cell free protein synthesis, protein expression analysis using cDNA microarray

Signature of BOS Chairman

4. **GENE EXPRESSION AND DISEASES** **9 hour**

Aberrant splicing, defective DNAmethylation andgenome imprinting, defects of mitochondrial gene expression and diseases. Case studies : Cystic fibrosis, Dangue, sickle cell anemia, Huntington disease, Thalassaemia, and Duchenne Muscular Dystrophy.

Theory	Tutorial	Practical	Project	Total
45 hour	0 hour	0 hour	0 hour	45 hour

References:

1. Benjamin Lewin, (2016). Genes IX, 9th Edition,Jones & Bartlett Publishers Inc.,U.S.A.
2. Sambrook J and Russell DM. (2014). Molecular Cloning: A Laboratory Manual.
3. Weaver, R.F. (2005). Molecular Biology, 3^{rd} Edition, McGraw Hill.
4. Waston, J.D. (2004). Molecular Biology of the Gene, 5^{th} Edition, Pearson Education.
5. Alberts, Bruce *et.al.,* (2004). Essential Cell Biology, 2nd Edition, Garland Science.
6. Harvey Lodish, Arnold Berk, S.L Zipursky, Paul Matsudaira, David Baltimore and James Danell (2002). Molecular Cell Biology, 4^{th} Edition, New York: W.H Freeman and company.

P18BTI1202 BIOPROCESS MODELLING AND SIMULATION

L	T	P	J	C
3	0	2	0	4

Course Objectives:

- To introduce the different aspects of modeling in bioprocess system and
- To familiarize the simulation of bioprocess modelling

Course Outcomes (COs):

After successful completion of the course, the students should be able to

CO1: Conceptualize mathematical and engineering concepts in bioprocess modeling and simulation
CO2: Identify and analyze mathematical model in biochemical engineering systems
CO3: Select the appropriate components of SuperPro Design software
CO4: Apply the concepts of MATLAB and SIMULINK in bioprocess systems.
CO5: Ability to solve and analyze data using MATLAB
CO6: Apply, design and interpret process flowsheeting using SuperPro Design software

CO/ PO MAPPING (S/M/W indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak						
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**
CO1	3					
CO2	3					
CO3					3	3
CO4		3	3			
CO5	3		3		3	3
CO6	3			3	3	3

Course Assessment Methods	
Direct	
1	Continuous Assessment Test
2	Assignments
3	End Semester Examination

Course Content **45 hour**

1. **BASIC MODELLING PRINCIPLES** **9 hour**

Basic modeling principles – uses of mathematical modeling – classification of modeling techniques; Fundamental laws – energy equations, continuity equation, equations of motion, transport equations, equations of state, equilibrium states and chemical kinetics – examples.

2. **MATHEMATICAL MODELS FOR BIOCHEMICAL ENGINEERING** **9 hour**

Mathematical models for Biochemical engineering systems - continuous flow tanks- enclosed vessel-mixing vessel - mixing vessel mixing with reaction - reversible reaction; Steam jacketed vessel - boiling of single component liquid-open and closed vessel; continuous boiling system, batch distillation.

3. **SUPERPRO DESIGNER FUNDAMENTALS** **9 hour**

Introduction to SuperPro Designer for Material and Energy Balance with and without reaction; Units, Properties, Component library, unknown component registration pure and stock mixtures; Batch, continuous, unit operations – selection criteria.

Signature of BOS Chairman

4. **FLOWSHEETING AND DATA INTERPRETATION USING SUPERPRO** **9 hour**

   Introduction to Flowsheeting Scheduling Equipment utilisation analysis charts: Gantt chart, - Report analysis: Throughput analysis, debottlenecking, COst analysis and economic evaluation, Environmental impact. Examples: monoclonal antibody production plant, Biodiesel from degummed oil.

5. **MATLAB BASICS AND DATA ANALYSIS** **9 hour**

   Basics-Data analysis-curve fittings; Solving problems using MATLAB by numerical integration, Euler and fourth order Runge Kutta methods. Simulation – Simulation of gravity flow tank, Simulation of CSTR in series.

List of Experiements

1. Introduction to SuperPro Designer Material and Energy balance
2. Unit Operations, Component Library and registration, Pure and stock mixtures
3. Simulation of Batch and continuous operations
4. Simulation of monoclonal antibodies production
5. Simulation of biodiesel from degummed oil production

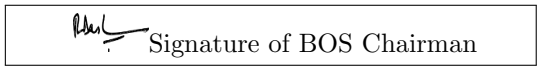
Theory	Tutorial	Practical	Project	Total
45 hour	0 hour	30 hour	0 hour	75 hour

References:

1. Jana, A. K. (2018). Chemical process modelling and computer simulation. PHI Learning Pvt.Ltd.
2. Tyagi, A. K. (2012). MATLAB and SIMULINK for Engineers. Oxford University Press.
3. Kenneth J. Beers.(2007). Numerical Methods for Chemical Engineering Applications in MATLAB ®, Massachusetts Institute of Technology, Cambridge University press.
4. William J. Palm. (2005). Introduction to Matlab 7 for Engineers, III, McGraw Hill 2005.
5. Biquette W.B. (1998). Process Dynamics-Modeling analysis with simulation, Prentice Hall.

Web References:

1. `https://nptel.ac.in/courses/103103037/2`



R24XXX	BIOPRODUCT RECOVERY AND PURIFICATION	L	T	P	J	C
		3	0	2	0	4

Course Objectives:

- To provide knowledge using various downstream processing principles for recovery of bioproducts
- To understand various product purification steps

Course Outcomes (COs):
After successful completion of the course, the students should be able to

CO1: Understand the various principles involved in bioseparation and cell disruption techniques
CO2: Explain the different types of filtration and centrifugation techniques used in bioproduct recovery
CO3: Understand the various techniques in different unit operations involved for the isolation and extraction of bio-products from biological samples
CO4: Select and use various methods of chromatography in protein purification
CO5: Illustrate different methods of final polishing for bio-products produced at lab and industrial level
CO6: Develop a process design and choose the appropriate purification steps and perform the techno-economical analysis for purification of bioproducts

CO/ PO MAPPING (S/M/W indicates strength of correlation) S-Strong, M- Medium, W - weak						
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**
CO1	3		2	2	2	
CO2	3	3	2	3	2	
CO3	3	3	2	3	2	
CO4	3	3	3	3	3	
CO5	3	2		2	2	
CO6	3	3	3	3	3	

Course Assessment Methods	
Direct	
1	Continuous Assessment Test
2	Assignments
3	End Semester Examination

Course Content **45 hour**

1. **INTRODUCTION TO BIOPRODUCT AND BIOSEPARATION** **6 hour**

Introduction to bioproducts and bioseparation technology. Basics of cell wall and its structure, Cell lysis: Osmotic, chemical and mechanical methods of cell disruption techniques-problem solving.

2. **PRIMARY SEPARATION AND CELL LYSIS** **8 hour**

Conventional Filtration: Batch Filtration, Crossow Filtration; Filter Media and Equipment, Membrane Fouling, Scale-up and Design of Filtration Systems: Conventional Filtration and Rotary Vacuum Filtration; Dialtration Mode in Crossow Filtration; Production Centrifuges: Comparison and Engineering Analysis: Tubular Bowl Centrifuge: Disk Centrifuge; Ultracentrifugation: Determination of Molecular Weight using ultracentrifugation.

3. **ISOLATION OF PRODUCTS** **10 hour**

Adsorption, Extraction Principles: Phase Separation and Partitioning Equilibria, Countercurrent Stage Calculations, Separation of a Bioproduct and an Impurity by Countercurrent Extraction. Precipitation: Precipitate Formation Phenomena Initial Mixing Nucleation, Growth Governed by Diffusion, Calculation of Concentration of Nuclei in a Protein Precipitation. Precipitation by salts, organic solvents and polymers. Aqueous Two phase separation Electrophoresis separation.

4. **PRODUCT PURIFICATION** **12 hour**

Theory, practice and selection of media for gel-filtration chromatography, Ion exchange chromatography, Hydrophobic interaction chromatography, reverse phase chromatography, Affinity chromatography – Metal affinity chromatography, dye affinity chromatography, immunosorbent affinity chromatography; Scale-up criteria for chromatography, calculation of number of theoretical plates and design. Application of FPLC, HPLC and GC in bioproduct purification.

5. **FINAL POLISHING AND CASE STUDIES** **9 hour**

Lyophilization, spray drying and crystallization; Process Analysis: Spreadsheets, Process Simulators, Using a Biochemical Process Simulator; Process Economics, Capital Cost Estimation, Operating Cost, Estimation, Protability Analysis; Illustrative Example of Citric Acid Production, Human Insulin Production; Therapeutic Monoclonal Antibody Production

List of Experiements

1. Solid-liquid separation using micro filtration
2. Cell disruption using sonicator and Homogenizer
3. Purification of enzyme using ion exchange chromatography
4. Separation of enzyme using size exclusion chromatography
5. Purification of enzyme using affinity chromatography
6. Purification of high value product using Fast protein liquid chromatography (FPLC)
7. Freeze-Drying
8. New product development from various biological sources

Theory	Tutorial	Practical	Project	Total
45 hour	0 hour	30 hour	0 hour	75 hour

References:

1. Doble, M. (2016). Principles of Downstream Techniques in Biological and Chemical Processes. Apple Academic Press.
2. Harrison, R. G., Todd, P. W., Todd, P., Rudge, S. R., & Petrides, D. P. (2015). Bioseparations science and engineering. Oxford University Press, USA.
3. Sivashankar, B .(2015). Bioseparation : Principles and Techniques Prentice Hall of India, New Delhi.
4. Walsh, G. (2013). Pharmaceutical biotechnology: concepts and applications. John Wiley & Sons.
5. Keller, K., Friedmann, T., & Boxman, A. (2001). The bioseparation needs for tomorrow. Trends in Biotechnology, 19(11), 438-441.

P18INT0001 RESEARCH METHODOLOGY AND STATISTICS

L	T	P	J	C
3	0	0	0	3

Course Objectives:

- Understand and apply the concepts of research
- Apply statistical and other research tools to analyze and interpret data
- Demonstrate skills in writing research topics

Course Outcomes (COs):
After successful completion of the course, the students should be able to

CO1: Understand and apply the concepts of research
CO2: Apply statistical and other research tools to analyze and interpret data
CO3: Demonstrate skills in writing research topics

CO/ PO MAPPING (S/M/W indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak						
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**
CO1	3					
CO2						
CO3		3				1

Course Assessment Methods	
Direct	
1	Continuous Assessment Test
2	Assignments
3	End Semester Examination

Course Content **45 hour**

1. **INTRODUCTION TO RESEARCH METHODS** **9 hour**

Definition and Objectives of Research, Scientific Methods, Various Steps in Scientific Research, Research planning , Selection of a Problem for Research , Formulation of the Selected Problems, Purpose of the Research, Formulation of research objectives, Formulation of research questions, Hypotheses Generation and Evaluation, Literature search, and review, Research abstract

2. **INTRODUCTION TO STATISTICS** **9 hour**

Population and Sample, Sampling and sample size, Population Proportion and Population Mean, Sample Proportion and Sample Mean, Estimation of Standard Error and confidence Interval, Identifying the dependent and independent variables, Introduction to data, Types of data and their importance, Descriptive Statistics and Inferential Statistics, Summarizing and describing data, Measures of Central Tendency and Measures of Dispersion, Mean, Median, Mode, Range, Variance, Standard Deviation

3. **STATISTICAL MODELING AND ANALYSIS** **9 hour**

Probability Distributions, Normal, Binomial, Poison, Fundamentals of Statistical Analysis and Inference, Hypothesis Testing, Confidence interval, Test of Significance, Comparison of Means (t- test, z-test), Analysis of variance (ANOVA), Measures of association/Relationship, Chi-square test, Simple Regression Analysis, Multiple Regression analysis, Correlation, Data visualization techniques

4. **RESEARCH DESIGN/PLAN** **9 hour**

Types and Methods of Research, Classification of Research, Research Ethics, Sampling Techniques, Methods of Collecting Primary Data, Use of Secondary Data, Experimentation, Design of Experiments, Survey Research and Construction of Questionnaires, Pilot Studies and Pre-tests, Data Collection methods, Processing of Data, Editing, Classification and Coding, Transcription, Tabulation, Validity and Reliability.

5. **RESEARCH REPORTS** **9 hour**

Structure and Components of Research Report/thesis, Types of Report, Planning of Report/thesis Writing, Research Report Format, Layout of Research Report, Presentation of data and Data Analysis Reporting, Mechanism of writing a research report, Principles of Writing, Writing of Report

Theory	Tutorial	Practical	Project	Total
45 hour	0 hour	0 hour	0 hour	45 hour

References:

1. Kothari C.R (2014). Research Methodology Methods and Techniques, 3e, New Age International Publishers.
2. Ranjit Kumar (2014). Research Methodology A Step-by-Step Guide for Beginners, 4^{th} Edition, Sage Publishing.
3. R. Pannerselvam (2014). Research Methodology, 2^{nd} edition, Prentice Hall India.
4. Gurumani, N. (2011). Research Methodology: For Biological Sciences. Mjp Publishers.
5. Devore, J.L.,(2010). Probability and statistics for Engineering and the Sciences, Cengage Learning, ebook, 8^{th} edition.

SEMESTER -II

P18BTI12201	QUALITY ASSURANCE AND QUALITY CONTROL IN BIOMANUFACTURING	L	T	P	J	C
		3	0	2	0	4

Course Objectives:

- To understand the importance of quality assuarance and quality control in biomanufacturing process.
- To describe fundamental knowledge on quality control using basic quality tools.

Course Outcomes (COs):
After successful completion of the course, the students should be able to

CO1: Comprehend concept of quality assurance by design in industrial biomanufacturing practices of different biotechnology products.
CO2: Relate quality attributes, process parameters and target quality product profile and critically evaluate the product development process of bio based products.
CO3: Select appropriate analytical methods for the quality control of bio-based products.
CO4: Develop competency in constructing novel control chart to analyze the variation in data to analyse the probability of non-conforming units.
CO5: Understand Quality Assurance responsibilities.
CO6: Describe validation principles as applied to biomanufacturing.

CO/ PO MAPPING (S/M/W indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak						
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**
CO1			3			
CO2		3				3
CO3			2			
CO4		3				
CO5				3		3
CO6	2					

Course Assessment Methods	
Direct	
1	Continuous Assessment Test
2	Assignments
3	End Semester Examination

Course Content **45 hour**

1. **INTRODUCTION TO BIOMANUFACTURING** **6 hour**

Fundamentals of Biotechnology production, Development and Characterization of Production Organisms, Cell culture Process development, Optimising feeds and medium using spent medium analysis, PD approach and optimization of PQ, Biological potency testing, Parameters to be characterized in Upstream and Downstream process, Quality target product profile (QTPP), critical quality attributes(CQA) and critical process parameters (CPP), Design space: set point, normal operationg range, Manufacturing operation range, proven acceptable range, Life cycle of product development. Case study: Process development- Monoclonal antibody Production

2. **QUALITY CONTROL IN BIOMANUFACTURING** **12 hour**

Roles and responsibilities of quality control department, Quality control assay system for cell culture products, Raw material quality control, Certificates of Analysis, process quality control, finished product quality control, quality control of recovery/purification process,

Concerns in Quality control in biotechnology products, Application of process analytical technology (PAT) in quality control, In-process quality control. Case study: Biological Assays: Their Role in the Development and Quality Control of Recombinant Biological Medicinal Products

3. **ANALYTICAL METHODS IN QUALITY CONTROL** **6 hour**

   Functional flow of analytical department, Method development and characterisation, Method Qualification, Equipment Qualification Equipment Maintenance Equipment Calibration, Selectivity and specificity, Reference standards, Precision, accuracy, and Linearity, Sources of Errors, use of significant figures and their correct usage, Intraday and interlay analysis, System suitability and ruggedness of the method, calibration of equipment, Calibration and validation of various instruments, Case study: Analytical methods for evaluation of protein degradation products, Control charts, Quality control records and reports.

4. **QUALITY ASSUARANCE: QUALITY AUDIT AND SELF INSPECTIONS 9 hour**

   Role and functions of quality assuarance, National GLP Compliance Monitoring Authority(NGCMA), Equipment Change Management, Equipment Maintenance, Equipment Breakdowns, Equipment Maintenance action, Records and documentation, Technical Requirements,User Requirements and Capabilities, Materials specifications, Technical Dimensions and Specifications, Safety features, Environmental Specifications, Equipment Cleaning and Sanitization requirements, Equipment Calibration, Design Qualification Documentation, Quantities of input materials, SOPs, Major Events, Equipment Breakdowns Equipment Maintenance action Deviations Control charts, Out of Specifications (OOS) and Out of trend (OOT), Compliance summaries

5. **VALIDATION** **6 hour**

   Pre-requisites for process validation- Facility qualification, vendor qualification, sterilization validation, SOP preparation, Installation Qualifications, Operational Qualifications Performance Qualifications, Qualification validation and Analytical and bioanalytical method validation, Process validation- Inoculum development, production validation, downstream process validation

List of Experiements

1. Preparation of SOPs and QC reports: Calibration of pipettes
2. Autoclave Validation
3. FTIR Equipment Calibration and Qualification
4. Environmental Monitoring: Settling plate method and Cell count determination for bacteria
5. Validation of a drug using UV/Vis spectrophotometer
6. Bacterial endotoxin test
7. Field Visit - Preparing a checklist of QC documents Demonstration on QA documents.

Theory	Tutorial	Practical	Project	Total
45 hour	0 hour	30 hour	0 hour	75 hour

References:

1. Shah, D.H., (2007). SOP Guidelines, Business Horizons; 2^{nd} edition
2. Robert, I.R., Nash, R.A., Wachter, A.H. and Swarbrick, J.,(2003). Pharmaceutical Process Validation, 3rd Edition, Maarcel Dekker Inc.,
3. Shah, D.H., (2002). Quality Assurance Manual, Business Horizons.

Signature of BOS Chairman

4. Jean F. Huxsoll (1994). Quality Assurance for Biopharmaceuticals, Wiley-Interscience; 1^{st}edition

5. Rhys Bryant (1984). Pharmaceutical Quality Control Handbook, Aster Pub Corp.

Web References:

1. https://www.pharmaguideline.com/p/quality-control.html

2. https://www.pharmaguideline.com/p/quality-assurance.html

3. https://pubs.acs.org/doi/abs/10.1021/ac00174a004

4. https://gmpbio.org/quality-management-system/quality-control/

Signature of BOS Chairman

P18BTI2202 BIOANALYTICAL TECHNIQUES

L	T	P	J	C
3	0	2	0	4

Course Objectives:

- To provide the knowledge of optical microscopy, spectroscopic, chromatographic and flow cytometry instrumentation and methodologies.

Course Outcomes (COs):
After successful completion of the course, the students should be able to

CO1: Identify, Apply and interpret the biological data using appropriate microscopy based techniques.
CO2: Analyse the data originated using various spectroscopic techniques to solve biological problem
CO3: Analyse the data originated using NMR and Mass spectrometry techniques to solve biological problem
CO4: Analyse the data originated using LC & GC Techniques to solve biological problem
CO5: Understand and analysis data originated from flow- cytometry technique
CO6: Characterize the given samples using analytical techniques

CO/ PO MAPPING (S/M/W indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak						
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**
CO1	3				3	
CO2	3		2		3	
CO3	3		3		3	
CO4	3		3		3	
CO5	3	3	3		3	
CO6	3					

Course Assessment Methods	
Direct	
1	Continuous Assessment Test
2	Assignments
3	End Semester Examination

Course Content **45 hour**

1. **MICROSCOPY TECHNIQUES** **9 hour**

Principles and applications of Microscopy- Phase Contrast, Differential Interference Contrast (DIC), Fluorescence, digital imagingWidefield, Confocal Laser Scanning (CLS), CCD technology, TEM, SEM.

2. **SPECTROSCOPY** **9 hour**

Principle, instrumentation and applications - UV-Vis, IR and atomic absorption spectroscopy; Principle, instrumentation and applications - Fluorometry, nephelometry and circular dichroism (CD); Principle and applications of laser light scattering (LLS) technique

3. **NMR AND MASS SPECTROSCOPIC TECHNIQUES** **9 hour**

NMR: Theory and Principle of NMR-Multinuclear NMR-Analysis of spectra and Interpretations- Case studies of drugs, peptides and proteins. NMR spectra Analysis. Mass Spectrometer: Principles of modern ionization methods and mass analyzers (TOF and FT-ICR), hybrid/tandem mass methods (MS-MS) and applications of MS in the analysis of drugs and macromolecules.

Signature of BOS Chairman

4. **CHROMATOGRAPHY TECHNIQUES** **9 hour**

Gas chromatography with mass spectrometric detection (GC-MS), liquid chromatography with mass Spectrometric detection (LC-MS), GC-MS data; LC-MS spectra. Inductively Coupled Plasma with Mass Spectrometric detection (ICP-MS). Metal analysis by ICP-MS; Analysis of data: HPLC chromatograms - trouble shooting to achieve good separation on HPLC.

5. **ADVANCED TECHNIQUES** **9 hour**

Flow Cytometer: Introduction to flow cytometry-Fluorochromes and fluorescence - Experimental Design and fluorescence quantitation. Compensation and gating – Normalization-Comparing Univariate Cell Distributions-Probability Binning-Readings on flow cytometry data analysis.

List of Experiements

1. Cell counting using phase contrast microscopy
2. Analysis of fluorescence signal using ImageJ
3. Identification the functional groups using FTIR spectroscopy
4. Separation and identification of analytes by HPLC/PTLC
5. Separation and purification of biomolecules using FPLC
6. Identification of volatile compounds using gas chromatography (Demo)
7. Structural elucidation using Mass spectroscopic data (Demo)
8. Structural elucidation using NMR data (Demo)

Theory	Tutorial	Practical	Project	Total
45 hour	0 hour	30 hour	0 hour	75 hour

References:

1. Skoog, D. A., Holler, F. J., & Crouch, S. R. (2017).Principles of instrumental analysis. Cengage learning.
2. Mertz, J. (2010).Introduction to optical microscopy(Vol.138). Roberts.
3. Schermelleh, L., Heintzmann, R., & Leonhardt, H. (2010). A guide to super-resolution fluorescence microscopy.The Journal of cell biology,190(2), 165-175.
4. Wilson, K., & Walker, J. (Eds.). (2000).Principles and techniques of practical biochemistry. Cambridge University Press.
5. Fleming, I., & Williams, D. H. (1966). Spectroscopic methods in organic chemistry.

Web References:

1. `https://www.nanophoton.net/raman/raman-spectroscopy.html`
2. `https://www.fei.com/introduction-to-electron-microscopy/sem/`

R24S2 COMPUTATIONAL BIOLOGY

L	T	P	J	C
3	0	2	0	4

Course Objectives:

- Educate the various algorithmic concepts involved in solving biological problems
- Design, analyse, interpret and conclude biological data using computational approaches

Course Outcomes (COs):
After successful completion of the course, the students should be able to

CO1: Apply knowledge of mathematics and science in biological sequence analysis
CO2: Analyse and interpret biological sequence data
CO3: Educate the appropriate selection of tools for protein analysis
CO4: Analyse and interpret protein interactions
CO5: Design a bio-based system/ model using artificial neural networks
CO6: Apply, design and interpret biological data using computational tools

CO/ PO MAPPING (S/M/W indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak						
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**
CO1	S					S
CO2	3			2		3
CO3	3			3		3
CO4	3			3		3
CO5	3	3	3	3		3
CO6	3					

Course Assessment Methods	
Direct	
1	Continuous Assessment Test
2	Assignments
3	End Semester Examination

Course Content **45 hour**

1. **INTRODUCTION TO COMPUTATIONAL BIOLOGY** **9 hour**

Introduction to Biological Databases Classification and Functions; Introduction to sequence alignment – dotplot, Measures of sequence similarity, scoring schemes; Dynamic programing algorithm for optimal pairwise alignment – Scoring matrices – PAM and BLOSSUM. BLAST programs – PSI and PHI BLAST Case Study: Optimizing substitution matrix choice and gap parameters for sequence alignment

2. **SEQUENCE ALIGNMENT** **9 hour**

Multiple sequence alignment (MSA, Assessing the quality of an alignment, Profiles; Hidden Markov models, Phylogeny – Clustering method, Cladistics methods; the problem of varying rates of evolution, Bootstrapping
Case study: Phylogenetic Analysis with a new distance measure

3. **PROTEIN STRUCTURE ANALYSIS** **9 hour**

Protein stability and folding, Superposition of structures and structural alignments – DALI and MUSTANG, Evolution of protein structure – classification, databases; Protein structure prediction and modeling – Aprori and Empirical methods; Secondary structure prediction, Homology modeling, fold recognition, Protein structure comparison

4. **PROTEIN INTERACTIONS** **9 hour**

   Assignment of secondary structures, computation of solvent accessibility – Naccess, Representation of solvent accessibility; residue-residue contacts – short, medium and long-range contacts, Contacts potentials – residue-residue interaction potentials, potentials based on distance criteria, cation- Interactions; Conformational energy calculation

5. **MACHINE LEARNING TECHNIQUES** **9 hour**

   Artificial Neural Network – Perceptron, Characteristics of neural networks, models of neuron, Single and multi-layer ANN perceptron, back propagation, learning, input – hidden and output layer computation, Application of ANN.

List of Experiements

1. Introduction to Unix system Commands and scripts
2. Molecular visualization using Pymol and Chimera
3. Sequence similarity search using BLAST program
4. Multiple Sequence alignment and phylogenetic analysis
5. Construction of a ANN based model for enzyme inhibition studies
6. Structure based drug design – Molecular docking using Autodock and Virtual screening using AutodockVina
7. Molecular Dynamics of protein using GROMACS (Demo only)

Theory	Tutorial	Practical	Project	Total
45 hour	0 hour	30 hour	0 hour	75 hour

References:

1. Da Silva, I. N., Spatti, D. H., Flauzino, R. A., Liboni, L. H. B., & dos Reis Alves, S. F. (2017). Artificial Neural Networks. Cham: Springer International Publishing.
2. Lesk, A. (2014). Introduction to bioinformatics. Oxford University Press.
3. Gromiha, M. M. (2010). Protein bioinformatics: from sequence to function. Academic Press.
4. Baxevanis, A. D., & Ouellette, B. F. (2004). Bioinformatics: a practical guide to the analysis of genes and proteins (Vol. 43). John Wiley & Sons.
5. Jones, N. C., & Pevzner, P. (2004). An introduction to bioinformatics algorithms. MIT press.

Web References:

1. `https://bmcbioinformatics.biomedcentral.com/articles/10.1186/1471-2105-10-396`
2. `https://www.ncbi.nlm.nih.gov/pubmed/30068281`

Signature of BOS Chairman

P18INT0002 PRODUCT DESIGN AND DEVELOPMENT

L	T	P	J	C
3	0	0	0	3

Course Objectives:

- Understand the basic concepts of product design and development.
- Know the implications in product architecture and the importance of industrial design.
- Understand prototyping basics and influence of diverse factors on project success.

Course Outcomes (COs):
After successful completion of the course, the students should be able to

CO1: Apply concepts of product development and outline product planning process
CO2: Apply relative importance of customer needs in establishing product specifications
CO3: Identify concept generation activities and summarize the methodology involved in concept selection and testing
CO4: Outline supply chain considerations in product architecture and understand the industrial design process
CO5: Apply design for manufacturing concepts in estimating manufacturing costs
CO6: Apply principles of prototyping in product development economics and highlight importance of managing projects

CO/ PO MAPPING (S/M/W indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak						
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**
CO1	3				3	
CO2	3		2		3	
CO3	3		3		3	
CO4	3		3		3	3
CO5	3	S	3		3	3
CO6	3					3

Course Assessment Methods	
Direct	
1	Continuous Assessment Test
2	Assignments
3	End Semester Examination

Course Content **45 hour**

1. **INTRODUCTION - DEVELOPMENT PROCESSES AND ORGANIZATIONS PRODUCT PLANNING** **9 hour**

   Characteristics of successful product development to Design and develop products, duration and cost of product development, the challenges of product development. A generic development process, concept development: the front-end process, adapting the generic product development process, the AMF development process, product development organizations, the AMF organization. The product planning process, identify opportunities. Evaluate and prioritize projects, allocate resources and plan timing, complete pre project planning, reflect all the results and the process.

2. **IDENTIFYING CUSTOMER NEEDS - PRODUCT SPECIFICATIONS** **9 hour**

   Gathering raw data from customers, interpreting raw data in terms of customer needs, organizing the needs into a hierarchy, establishing the relative importance of the needs and reflecting on the results and the process. Specifications, establish specifications, establishing target specifications setting the final specifications.

3. **CONCEPT GENERATION, CONCEPT SELECTION, CONCEPT TESTING** **9 hour**

   The activity of concept generation clarify the problem search externally, search internally, explore systematically, reflect on the results and the process, Overview of methodology, concept screening, concept scoring, caveats. Purpose of concept test, choosing a survey population and a survey format, communicate the concept, measuring customer response, interpreting the result, reflecting on the results and the process.

4. **PRODUCT ARCHITECTURE - INDUSTRIAL DESIGN - DESIGN FOR MANUFACTURING** **9 hour**

   Meaning of product architecture, implications of the architecture, establishing the architecture, variety and supply chain considerations, platform planning, related system level design issues. Assessing the need for industrial design, the impact of industrial design, industrial design process, managing the industrial design process, is assessing the quality of industrial design. Definition, estimation of manufacturing cost, reducing the cost of components, assembly, supporting production, impact of DFM on other factors.

5. **PROTOTYPING - PRODUCT DEVELOPMENT ECONOMICS - MANAGING PROJECTS** **9 hour**

   Prototyping basics, principles of prototyping, technologies, planning for prototypes, Elements of economic analysis, base case financial mode,. Sensitive analysis, project trade-offs, influence of qualitative factors on project success, qualitative analysis. Understanding and representing task, baseline project planning, accelerating projects, project execution, postmortem project evaluation.

Theory	Tutorial	Practical	Project	Total
45 hour	0 hour	0 hour	0 hour	45 hour

References:

1. Mosey, S. (2016). Encouraging Technology Entrepreneurship for All. In Engineering and Enterprise (pp. 115-127). Springer, Cham.
2. Karl Ulrich,T. (2015). Steven Eppinger, D, Product Design and Development, McGrawHill
3. Chitale, AK, Gupta, RC (2013). Product Design and Manufacturing, PHI
4. Geoffery Boothroyd, Peter Dewhurst and Winston Knight,A (2011). Product Design for Manufacture and Assembly, CRC Press
5. Timjones (1997). New Product Development:An Introduction to a multifunctional process, Butterworth-Heinemann

Signature of BOS Chairman

SEMESTER -III

P18BTP3701 PROJECT PHASE -I/ INDUSTRY PROJECT	L	T	P	J	C
	0	0	0	20	10

Course Objectives:

- Identify important social needs and problems for research
- To formulate a research component for solve the problem and collect relevant literature survey
- Carry out standardization and foundational work

Course Outcomes (COs):
After successful completion of the course, the students should be able to

CO1: Formulate an experimental design to solve biotechnological problems
CO2: Ability to conduct survey of literature
CO3: Acquire knowledge on scientific presentation skills
CO4: Analysis and apply technical skill for carry out standardization and foundational work
CO5: Evaluate and interpretation of obtained results

CO/ PO MAPPING (S/ M/ W indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak						
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**
CO1	3	3		3	3	2
CO2	3	3		3	3	2
CO3	3	3		3	3	2
CO4	3	3		3	3	2
CO5	3	3		3	3	2

Course Assessment Methods			
	Direct		**Indirect**
1.	Internal Review Assessment Test	1.	Course End survey
		2.	Faculty survey
		3.	Industry survey
		4.	Alumni survey

SEMESTER -IV

P18BTP4701	PROJECT PHASE -I/ INDUSTRY PROJECT	L	T	P	J	C
		0	0	0	40	20

Course Objectives:

- Identify important social needs and problems for research
- To formulate a research component for solve the problem and collect relevant literature survey
- Carry out standardization and foundational work

Course Outcomes (COs):
After successful completion of the course, the students should be able to

CO1: Formulate an experimental design to solve biotechnological problems
CO2: Ability to conduct survey of literature
CO3: Acquire knowledge on scientific presentation skills
CO4: Analysis and apply technical skill for carry out standardization and foundational work
CO5: Evaluate and interpretation of obtained results

CO/ PO MAPPING (S/ M/ W indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak						
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**
CO1	3	3		3	3	2
CO2	3	3		3	3	2
CO3	3	3		3	3	2
CO4	3	3		3	3	2
CO5	3	3		3	3	2

Course Assessment Methods			
	Direct		**Indirect**
1.	Internal Review Assessment Test	1.	Course End survey
		2.	Faculty survey
		3.	Industry survey
		4.	Alumni survey

ELECTIVES

P18BTE0001	BIOREFINERY AND SUSTAINABLE TECHNOLOGIES	L	T	P	J	C
		3	0	0	0	3

Course Objectives:

- To introduce the students about the biorefining using sustainable processing of biomass into a various spectrum of bio-based products(food, feed, chemicals, materials and bioenergy)

Course Outcomes (COs):
After successful completion of the course, the students should be able to

CO1: Describe the various biorefinery concepts using sugar based feed stocks
CO2: Understand the different starch based biorefineries with a focus on ethanol production stoichiometry and generation of different bio-based and co-products
CO3: Describe the lignocellulosic based biorefinery for the conversion of biomass constituents into fuels, chemicals and power
CO4: Understand the lipid-based biorefinery to conversion of vegetable oils, animal oils and waste cooking oil to biodiesel and focus on stoichiometry of biodiesel production and its by-products
CO5: Understand the basics of techno-economical assessments for bioenergy systems
CO6: Understand the basics of life cycle assessments for the analysis of bioenergy system

CO/ PO MAPPING (S/M/W indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak						
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**
CO1		2		3	3	3
CO2		2		3	3	3
CO3		2		3	3	3
CO4		2		3	3	3
CO5		2		3	3	3
CO6		2		3		3

Course Assessment Methods	
Direct	
1	Continuous Assessment Test
2	Assignments
3	End Semester Examination

Course Content **45 hour**

1. **SUGAR BASED REFINERY** **9 hour**

Introduction; Stoichiometry; Sugarcane Ethanol Ethanol production process, Sugarcane to Ethanol Biorefinery; Sweet Sorghum Ethanol; Sugar Beet Ethanol; Biochemicals & Biopolymers Lactic acid, Succinic acid, 1,3-Propanediol, 3-Hydroxypropionic acid.

2. **STARCH BASED REFINERY** **9 hour**

Introduction; Stoichiometry of Starch to Ethanol Corn Based Ethanol Biorefinery, Corn to Ethanol plants & Sorghum to Ethanol plants, Cassava Based Ethanol Biorefinery; Integrated farm scale Biorefinery.

3. **LIGNOCELLULOSE BASED BIOREFINERY** **9 hour**

Introduction; Cell structure of lignocellulosic feedstocks; Stoichiometry & energy content – Stoichiometry, Energy content; Lignocellulosic biomass conversion to Fuel; co-products from lignocellulose Based Biorefinery – Products from Lignin, Products from Hemicellulose; Industrial Lignocellulose Based Biorefinery.

Signature of BOS Chairman

4. **LIPID BASED BIOREFINERY** **9 hour**

Introduction to Lipid Based feedstocks – Plant oils, Animal Fats, Waste cooking oils; Chemical properties of Lipids – Chemical composition of Lipids, Average molecular weight of Triglycerides, Seed oil extraction; Biodiesel from Lipids – Biodiesel production Via Transesterification, Parameters affecting Biodiesel production, Quality of Biodiesel; Lipid Based Biorefinery – High value Biobased products from Seed oils, Seed meals & their applications, Utilization of glycerol from Biodiesel production.

5. **TECHNO-ECONOMIC ASSESSMENT** **9 hour**

Introduction to Techno-Economic analysis (TEA). Basic steps in TEA; Tools, Software & Data source for performing TEA – Tools available for performing TEA, Procedure for TEA using commercial software, Data source for performing TEA, Process optimization using TEA.

Theory	Tutorial	Practical	Project	Total
45 hour	0 hour	0 hour	0 hour	45 hour

References:

1. Li, Y. (2016).Bioenergy: Principles and Applications. John Wiley & Sons.

2. Yang, Shang-Tian, Hesham El-Ensashy, and Nuttha Thongchul, *eds.*(2013).Bioprocessing technologies in biorefinery for sustainable production of fuels, chemicals, and polymers. John Wiley & Sons.

3. Gnansounou, E. and Dauriat, A., (2011). Technoeconomic Analysis of Lignocellulosic Ethanol. InBiofuels.

4. Van Gerpen, Jon H., and Brian He.(2010).Biodiesel production and properties. InThermochemical Conversion of Biomass to Liquid Fuels and Chemicals, RSC Publishing Cambridge.

5. Himmel, Michael E., *ed.* (2008).Biomass recalcitrance: deconstructing the plant cell wall for bioenergy. Oxford: Blackwell Pub., 2008.

6. Huang, Hua-Jiang, Shri Ramaswamy, U. W. Tschirner, and B. V. Ramarao.(2008). A review of separ ation technologies in current and future biorefineries.Separation and Purification Technology62,

Web References:

1. `https://nptel.ac.in/courses/105105157/`

Signature of BOS Chairman

P18BTE0002	WASTEWATER TREATMENT TECHNOLOGY	L	T	P	J	C
		3	0	0	0	3

Course Objectives:

- To familiarize the concepts of various wastewater treatment technologies

Course Outcomes (COs):
After successful completion of the course, the students should be able to

CO1: Learn the basics of biochemical operations
CO2: Understand the principles of traditional biological treatment processes
CO3: Study the different applications of traditional biological treatment processes
CO4: Interpret the advanced bioreactors for water treatment
CO5: Apply knowledge on advanced bioreactors for water treatment
CO6: Gain insight on future challenges in water treatment

CO/ PO MAPPING (S/M/W indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak						
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**
CO1	2			3	2	
CO2	2			3	2	
CO3	2		2	3	2	3
CO4	2			3	2	
CO5	2		2	3	2	3
CO6	2		2	3	2	3

Course Assessment Methods	
Direct	
1	Continuous Assessment Test
2	Assignments
3	End Semester Examination

Course Content **45 hour**

1. **INTRODUCTION TO BIOCHEMICAL OPERATIONS** **9 hour**

Classification of Biochemical Operations, Fundamentals of Biochemical Operations, Stoichiometry and Kinetics of Biochemical Operations

2. **TRADITIONAL BIOLOGICAL TREATMENT PROCESSES** **9 hour**

Theory, Modeling of Ideal Suspended Growth Reactors, Modeling Suspended Growth Systems, Aerobic Growth of Heterotrophs in a Single Continuous Stirred Tank, Reactor Receiving Soluble Substrate, Multiple Microbial Activities in a Single Continuous Stirred Tank Reactor, Multiple Microbial Activities in Complex Systems, Techniques for Evaluating Kinetic and Stoichiometric Parameters.

3. **APPLICATION OF TRADITIONAL BIOLOGICAL TREATMENT PROCESSES** **9 hour**

Suspended Growth Reactors, Design And Evaluation of Suspended Growth Processes, Activated Sludge, Biological Nutrient Removal, Aerobic-digestion, Anaerobic Processes, Lagoons. Case studies

Signature of BOS Chairman

4. **BASIC OF ADVANCED BIOREACTORS FOR WATER TREATMENT** **9 hour**

   Modeling of Ideal Attached Growth Reactors, Bio-film Modeling, Aerobic Growth of Biomass in Packed Towers, Aerobic Growth of Heterotrophs in Rotating Disc Reactors, Fluidized Bed Biological Reactors. Case studies

5. **APPLICATIONS OF ADVANCED BIOREACTORS FOR WATER TREATMENT** **9 hour**

   Attached Growth Reactors, Trickling Filter, Rotating Biological Contactor, Submerged Attached Growth Bioreactors, Future Challenges, Fate and Effects of Xenobiotic Organic Chemicals, Industrial wastewater treatment. Case studies

Theory	Tutorial	Practical	Project	Total
45 hour	0 hour	0 hour	0 hour	45 hour

References:

1. Grady Jr, C. L., Daigger, G. T., Love, N. G., & Filipe, C. D. (2018). Biological wastewater treatment. CRC press.
2. Patwardhan, A. D. (2017). Industrial wastewater treatment. PHI Learning Pvt. Ltd.
3. Bushra Zaman. (2012). Biological Treatment of Wastewater, LAP Lambert Academic Publishing.
4. Muga, H. E., & Mihelcic, J. R. (2008). Sustainability of wastewater treatment technologies. Journal of environmental management, 88(3), 437-447.
5. Cheremisinoff, N. P. (2001). Handbook of water and wastewater treatment technologies. Butterworth-Heinemann.

Web References:

1. `http://www.acroamawatertreatment.com/`
2. `https://www.trivenigroup.com/water-solutions/solutions/projects/water-treatment.html`

P18BTE0003 BIOREMEDIATION TECHNOLOGY

L	T	P	J	C
3	0	0	0	3

Course Objectives:

- To familiarize the principles and concepts of different bioremediation technologies for water, soil and air

Course Outcomes (COs):
After successful completion of the course, the students should be able to

CO1: Learn about the principles of physicochemical and biological treatment
CO2: Understand the overview of bioremediation strategies
CO3: Demonstrate concepts phytoremediation
CO4: Acquire knowledge on in-situ and ex-situ bioremediation
CO5: Study the concepts of biostimulation and bioaugmentation
CO6: Learn the scientific challenges related to bioremediation

CO/ PO MAPPING (S/M/W indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak						
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**
CO1	2			3	2	
CO2	2			3	2	
CO3	2		2	3	2	2
CO4	2			3	2	
CO5	2		2	3	2	2
CO6	2		2	3	2	

Course Assessment Methods	
Direct	
1	Continuous Assessment Test
2	Assignments
3	End Semester Examination

Course Content **45 hour**

1. **INTRODUCTION TO PHYSICOCHEMICAL AND BIOLOGICAL TREATMENT** **9 hour**

Physicochemical treatment: excavation, dredging Groundwater extraction, soil washing, thermal extraction, free-product recovery, surfactant flooding, cosolvent washing, heating, wet oxidation, redox manipulation, reactive barrier, acid leaching. Biological Treatment: extraction and above ground treatment, biostimulation, bioaugmentation

2. **OVERVIEW OF BIOREMEDIATION STRATEGIES** **9 hour**

Aerobic and anaerobic bioremediation, biostimulation and Bioaugmentation, *Ex-situ* and *In-situ* Bioremediation, Microbial and Plant-based bioremediation, Fungal and Algal Bioremediation

3. **PHYTOREMEDIATION** **9 hour**

Principles of phytoremediation: Phytoextraction, Rhizofiltration, Phytodegradation, Hydraulic Control, Phytovolatilization, Rhizoremediation, Phytostabilization

4. **IN-SITU AND EX-SITU BIOREMEDIATION** **9 hour**

In-situ bioremediation: five stages, Site Investigation, Physical Measures to Prevent Spreading of the Contamination, Choice of Nutrient and Stimulatory Material Delivery System. Ex-situ bioremediation: Slurry Reactors, Composting, Land Farming, Treatment trains, Monitored natural attenuation. Case studies on In-situ bioremediation.

Signature of BOS Chairman

5. **BIOSTIMULATION AND BIOAUGMENTATION** **9 hour**

Biostimulation: Bioventing, Water Circulation Systems, Air Sparging, biobarriers, case studies for Biostimulation techniques. Bioaugmentation: Principle, Types of cultures, principal delivery methods, case studies for Bioaugmentation techniques

Theory	Tutorial	Practical	Project	Total
45 hour	0 hour	0 hour	0 hour	45 hour

References:

1. Fulekar, M. H. (Ed.). (2012). Bioremediation technology: recent advances. Springer Science & Business Media.
2. Alvarez, P. J., & Illman, W. A. (2008). Bioremediation and natural attenuation: process fundamentals and mathematical models (Vol. 27). John Wiley & Sons.
3. Singh, S. N., & Tripathi, R. D. (Eds.). (2007). Environmental bioremediation technologies. Springer Science & Business Media
4. Kuhad, R. C., & Ward, O. P. (2009). Advances in applied bioremediation,.Berlin: Springer-Verlag
5. Crawford Ronald, L.,& Crawford Don, L. (2005). Bioremediation: principles and applications, Cambridge university press.

P18BTE0004	MOLECULAR DIAGNOSTICS AND THERAPEUTICS	L	T	P	J	C
		3	0	0	0	3

Course Objectives:

- To impart knowledge on various genetic disorders and diagnostic methods.
- To learn the production of recombinant proteins and immunotherapeutics.
- To relate the technique of gene silencing in therapeutics.

Course Outcomes (COs):
After successful completion of the course, the students should be able to

CO1: Comprehend mutations and abnormalities in chromosome and be able to understand genetic disorder.
CO2: Diagnostic methods on gene editing tools.
CO3: Learn the production of recombinant products and their significance in therapy
CO4: Illustrate the strategies of immunotherapy using monoclonal antibodies and vaccines
CO5: Understand the mechanism of gene silencing related to therapeutics
CO6: Describe the procedures used for reproductive cloning.

CO/ PO MAPPING (S/M/W indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak						
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**
CO1		2	3		3	3
CO2		2	3		3	3
CO3		2	3		3	3
CO4		2	3		3	3
CO5		2	3		3	3
CO6		2	3		3	3

Course Assessment Methods	
Direct	
1	Continuous Assessment Test
2	Assignments
3	End Semester Examination

Course Content **45 hour**

1. **MUTATION AND GENETIC DISORDERS** **9 hour**

Mutation and Chromosome abnormality, Point Mutation, Deletion Mutation, Trinucleotide repeat disorders, Down syndrome, Haemophilia, Klinefelter syndrome, Cystic fibrosis, Polycystic kidney disease, Turner syndrome, Color blindness, Spinal muscular atrophy, Sickle-cell disease, Prader Willi syndrome. Autoimmune Diseases: Types, Symptoms, and case study on Rheumatoid arthritis and Multiple sclerosis

2. **DIAGNOSTIC AND GENE EDITING TOOLS** **9 hour**

Fluorescence in situ hybridization (FISH), Identification of Single Nucleotide Polymorphisms (SNPs), Quantitative PCR, and Gene chip (or) microarrays ,ZFNs (Zinc Finger Nucleases), TALENs (Transcription Activator Like Effector Nucleases), CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats),

3. **RECOMBINANT THERAPY** **9 hour**

Clinical applications of recombinant technology; Production of Recombinant proteins: organisms, production systems insect cells, mammalian cells, plants, transgenic animals, Source, production and applications of recombinant proteins - Erythropoietin; Insulin analogs and its role in diabetes; Recombinant human growth hormone; Streptokinase and urokinase in thrombosis; Recombinant coagulation factors (Factor VIII).

4. **IMMUNOTHERAPY** **9 hour**

Monoclonal antibodies and their role in cancer; Therapeutic monoclonal antibodies; Role of recombinant interferon's; Immunostimulants; Immunosupressors in organ transplants; Role of cytokine therapy in cancers; Vaccines: types, recombinant vaccines and clinical applications

5. **CLINICAL DIAGNOSTIC TOOLS** **9 hour**

Instruments for diagnostic, therapeutic, and assistive purpose; Magnetic Resonance Imaging (MRI), X-ray radiography, and Computed Tomography (CT; Generalized medical instrumentation system; Transducers and measurement of physiological events; Photoelectric transducers and Chemical Biopotentials, bioelectrodes and biosensors.

Theory	**Tutorial**	**Practical**	**Project**	**Total**
45 hour	0 hour	0 hour	0 hour	45 hour


Signature of BOS Chairman

References:

1. Palsson, B. O., & Bhatia, S. N. Tissue Engineering (2004). Upper Saddle River, New Jersey, 7458.
2. Greenwell, P., & McCulley, M. (2008). Molecular therapeutics: 21st century medicine. John Wiley & Sons.
3. Khandpur, R.S (2014).Handbook of Biomedical Instrumentation, McGraw-Hill Education.
4. Burtis CA and Bruns DE. (2014). Tietz Fundamentals of Clinical Chemistry and Molecular Diagnostics, Elsevier.
5. Williamson, (2014). Wallach's Interpretation of Diagnostic Tests, Wolters Kluwer India Pvt. Ltd.

P18BTE0005	CELL CULTURE AND VACCINE TECHNOLOGY	L	T	P	J	C
		3	0	0	0	3

Course Objectives:

- To differentiate between primary vs continuous culture, normal cells vs transformed cells, monolayer vs suspension culture.
- To provide knowledge on advancement of therapeutic vaccines preparation methods and technological applications
- To impart fundamental research knowledge to implement rational vaccine design, using computational tool

Course Outcomes (COs):

After successful completion of the course, the students should be able to

CO1: Comprehend knowledge about the animal cell culture and for Control of large scale Cell culture
CO2: Classify and understand about different microbial vaccine preparation methods
CO3: Understand advancement of therapeutic vaccines and technological applications
CO4: Acquire fundamental research knowledge to implement rational vaccine design
CO5: Develop and design vaccine research using computational tool
CO6: Understand the in vitro experimental validations through software predictions Animal testing, commercialization, quality control

CO/ PO MAPPING (S/M/W indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak						
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**
CO1	3	2	3	3		3
CO2	3	2	3	3		3
CO3	2		2	2	2	
CO4	2		2	2	2	
CO5	3		3	3	2	3
CO6		2	2		3	

Course Content **45 hour**

1. **ANIMAL CELL CULTURE** **9 hour**

Primary culture – Mechanical and enzymatic mode of disaggregation, establishment of primary culture; Subculture – passage number, criteria for subculture. Primary cell culture;

Course Assessment Methods	
Direct	
1	Continuous Assessment Test
2	Assignments
3	End Semester Examination

nutritional requirements for animal cell culture; techniques for mass culture of animal cell lines; Measurement of cell death. Scaling-up of animal cell culture. Application of animal cell culture: Stem cell cultures, embryonic stem cells and their applications, Hybridoma technology, Cell culture based vaccines.
Case study: Measurement of cell death and Apoptosis.

2. **CLASSIFICATION OF VACCINES AND ITS PREPARATIONS** **9 hour**

Active and passive immunization; Viral/bacterial/parasite vaccine differences, methods of vaccine preparation Live, killed, attenuated, sub unit vaccines; Vaccine technology - Role and properties of adjuvants, recombinant DNA and protein based vaccines, plant - based vaccines, reverse vaccinology, combination vaccines, therapeutic vaccines; Peptide vaccines, conjugate vaccines.
Case study: Cell based vaccines

3. **VACCINE DESIGN** **9 hour**

Fundamental approach for rational vaccine design, T - Cell expression cloning for identification of vaccine targets (intracellular pathogens), implications for manipulating the T - Cell repertoire, Targeting Dendritic cells ; Rational design of new vectors , CpG adjuvant activity, recent advances in Malaria, Tuberculosis and HIV vaccine

4. **COMPUTATIONAL TOOLS FOR VACCINE DESIGN** **9 hour**

Antigen Sequence analysis, Epitope Mapping, Predictions of Immunogenic peptides of T Cell and B - Cells. Prediction of HLA binding peptides, Comparative Genomics as a tool for vaccine design, introduction to online epitope databases.
Case study: Epitope Mapping

5. **ANIMAL TESTING, COMMERCIALISATION, QUALITY CONTROL** **9 hour**

Quality control and regulations in vaccine research, In - vitro experimental validations for predictions of vaccines by software, Animal testing, Rational design to clinical trials, Large scale production, Commercialization, ethics.

Theory	Tutorial	Practical	Project	Total
45 hour	0 hour	0 hour	0 hour	45 hour

References:

1. Plotkin, S., Orenstein, W., Offit, P., & Edwards, K. M. (2018). Plotkins vaccines. Ljugman P. Cap, Elsevier 69, 1381.
2. Tong, J. C., & Ranganathan, S. (2013). Computer-aided vaccine design. Elsevier
3. Castilho, L., Moraes, A., Augusto, E., & Butler, M. (Eds.). (2008). Animal cell technology: from biopharmaceuticals to gene therapy. Garland Science.
4. Burdman, J. R. (2012). Vaccine design: the subunit and adjuvant approach (Vol. 6). Springer.
5. Freshney, R. (2004). Culture of Animal Cells: A Manual of Basic Technique 4th Edition Wiley-Liss Inc.
6. Davis, J. M. (2002). Basic cell culture: a practical approach, Oxford University press, oxford.

P18BTE0006	CLINICAL RESEARCH AND MANAGEMENT	L	T	P	J	C
		3	0	0	0	3

Course Objectives:

- Understand the scope of clinical research and clinical trial monitoring and management.
- Understand the basic concepts, and methods for clinical data monitoring, analysis and reporting.

Course Outcomes (COs):
After successful completion of the course, the students should be able to

CO1: Understand key areas of drug development, clinical research regulations, trial management
CO2: Classify the roles and responsibilities of clinical research professions
CO3: Develop skills in clinical research documentation
CO4: Understand the general principles on ethical considerations involving human subjects
CO5: Identify and classify different types of trial designs
CO6: Apply and demonstrate critical analysis skills using tools of CDM

CO/ PO MAPPING (S/M/W indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak						
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**
CO1	3		3			3
CO2	2		3			3
CO3	3	3	2			3
CO4	2		2			3
CO5	2		3			3
CO6	3		2			3

Course Assessment Methods	
Direct	
1	Continuous Assessment Test
2	Assignments
3	End Semester Examination

Course Content **45 hour**

1. **INTRODUCTION TO CLINICAL RESEARCH** **9 hour**

Introduction & Overview of Drug Development & Clinical Research; Definition, Types and Scope of Clinical Research, Good Clinical Practices, ethics in clinical research, Ethics Review Committee and Informed Consent Process, Integrity & Misconduct in Clinical Research, Conflicts of Interest, Clinical Trials The National Perspective and Global perspective, Roles and Responsibilities of Clinical Research Professionals.

2. **GOOD CLINICAL PRACTICE** **9 hour**

Historical guidelines in Clinical Research: Nuremberg code, Declaration of Helsinki, Belmont report. International Conference on Harmonization (ICH): Brief history of ICH, Structure of ICH ICH Harmonization Process, Guidelines for Good Clinical Practice, The Principles of ICH GCP, Institutional Review Board / Independent Ethics Committee, Investigator Sponsor, Clinical Trial Protocol and Protocol Amendment(S,) Investigator's Brochure, Essential Documents for the conduct of a Clinical Trial

3. **REGULATIONS IN CLINICAL RESEARCH** **9 hour**

History of Regulations in Clinical Research, Patents US Regulatory Structure, IND, NDA, ANDA, Post Drug Approval Activities, PMS, FDA Audits and Inspections EU Regulatory Affairs, EMEA Organization and Function, INDIAN Regulatory system, Indian GCP guidelines (CDCSO guidelines), ICMR Guidelines - Ethical Guidelines for Biomedical Research on Human Subjects Schedule Y, Schedule Y- Rules and Regulations, Health Insurance Portability and Accountability Act (HIPAA)

4. **CLINICAL TRIAL MANAGEMENT AND ESSENTIAL DOCUMENTS** **9 hour**

Project Management, Protocol in Clinical Research, Informed Consent, Case Report Form, Investigators Brochure (IB), Selection of an Investigator and Site and Clinical Trial Stakeholders, Contract Research Organization (CRO), Site management organizations (SMO), Ethical and Regulatory Submissions, Recruitment Techniques, Retention of Clinical Trial Subjects, Monitoring Visits, Investigator Meeting, Documentation in Clinical Trials, Regulatory Binder, Record Retention, Pharmacovigilance, Clinical Trial life cycle and study designs.

5. **CLINICAL RESEARCH METHODOLOGY AND CLINICAL DATA** **9 hour**

Designing of Protocol, CRF, e-CRF, IB, ICF, SOP, Pharmaco-epidemiology, BA/BE Studies, Report writing, Publication, Introduction to CDM, tools for CDM, CDM process, CRF Design, Clinical Data Entry, Electronic Data Capture, Data Validation, Discrepancy Management, Clinical Data Coding, SAE Reconciliation, Quality Assurance & Clinical Data Management, Guideline & Regulation in Clinical trial data.

Theory	Tutorial	Practical	Project	Total
45 hour	0 hour	0 hour	0 hour	45 hour

References:

1. Alice Kuruvilla, Paul A.D., (2013). Clinical Trials A Beginner's Guide, Paras Medical Publisher
2. John I. Gallin, M.D, Frederick P Ognibene (2012), Principles and Practice of Clinical Research, Academic Press, 3 edition
3. S.K. Gupta (2007). Basic Principles of Clinical Research and Methodology, JPB; First edition.
4. Central Drugs Standard Control Organization (2001). Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health
5. Giovanna di Ignazio, Di Giov, anna and Haynes (2001). Principles of Clinical Research, Routledge; first edition, search
6. Deborah Rosenbaum, Michelle Dresser (2002). Clinical Research Coordinator Handbook: GCP Tools and Techniques, Practical Clinical Trials Series, Second Edition, CRC Press

Web References:

1. http://www.cdsco.nic.in/writereaddata/CDSCO-GuidanceForIndustry.pdf
2. http://cdsco.nic.in/html/GCP1.html

Signature of BOS Chairman

3. http://www.thepharmajournal.com/archives/2017/vol6issue4/PartC/6-4-4-176.pdf

4. http://research.library.gsu.edu/c.php?g=115595&p=755213

P18BTE0007 NANOMATERIALS AND APPLICATIONS

L	T	P	J	C
3	0	0	0	3

Course Objectives:

- To develop knowledge on Nanomaterials synthesis, characterization of various techniques and their applications in biotechnology

Course Outcomes (COs):
After successful completion of the course, the students should be able to

CO1: Describe the various synthesis methods of nanomaterials
CO2: Apply the various techniques for characterization of nanomaterials
CO3: Analyze and evaluate the synthesized nanomaterials in agriculture, textile and cosmetics
CO4: Analyze and evaluate the synthesized nanomaterials in health care, food and environment
CO5: Analyze and evaluate the synthesized nanomaterials in biomedical applications
CO6: Analyze and evaluate the synthesized nanomaterials in immuno assay

CO/ PO MAPPING (S/M/W indicates strength of correlation) 3-Strong, 2-Medium, 1-Weak						
	PO1	**PO2**	**PO3**	**PO4**	**PO5**	**PO6**
CO1	3		2	3	3	
CO2	3		2	2	2	3
CO3	3		2	3	3	3
CO4	3		2	3	3	3
CO5	3		2	3		3
CO6	3		2	2		

Course Assessment Methods	
Direct	
1	Continuous Assessment Test
2	Assignments
3	End Semester Examination

Course Content **45 hour**

1. **INTRODUCTION TO NANOMAERIALS** **9 hour**

Introduction to nanoscience and nanotechnology: Definition of nanomaterials, properties of nanoscale, synthesis of nanomaterials: top down and bottom up approaches – Mechanical alloying and mechanical ball milling, Chemical approaches – Sol-gel method, spray pyrolysis, Precipitation and electro spraying. Physical approaches – vapor deposition, CVD and pulsed laser deposition. Case study: Synthesis of nanomaterials (Metallic)

2. **CHARACTERIZATION TECHNIQUES** **9 hour**

X ray differactometer (XRD), Four Transform Infrared Spectroscopy (FTIR), Scanning Electron Microscopy (SEM), Transmission Electron Microscopy (TEM), Energy Dispersive Spectroscopy (EDAX), Atomic Force Microscopy (AFM) and Particle size analyser.
Case study: Characterization of nanomaterials using XRD.

3. **NANOTECHNOLOGY IN AGRICULTURE, TEXTILE AND COSMETICS** **9 hour**

Nanotechnology in Agriculture: Precision farming, Smart delivery system, Insecticides using nanotechnology, Potential of nano-fertilizers. Nanofibre preparation: Electrospinning, Controlling morphologies of nanofibers, Tissue engineering application. Cosmetics: Formulation of Gels, Shampoos, Hair-conditioners (Micellar self-assembly and its manipulation) – Sun-screen dispersions for UV protection using Titanium oxide Color cosmetics.
Case study: Nanofertilizer for sustainable agriculture

4. **NANOTECHNOLOGY IN HEALTH CARE, FOOD AND ENVIRONMENT** **9 hour**

Drug delivery: nanoscale devices for drug delivery, micelles for drug delivery, targeting, bioimaging. Nanotechnology in Food industry: Packaging, Food processing, Food safety and bio-security, Contaminant detection, Smart packaging. Nanotechnology in Environment – nanomaterials and nanomembranes in waste water treatment.
Case study: Nanomaterials in degradation of toxic pollutants.

5. **NANOTECHNOLOGY IN BIOMEDICAL AND IMMUNO ASSAY** **9 hour**

Nanoparticles in bone substitutes and dentistry, Implants and Prosthesis, Reconstructive Intervention and Surgery, Nanorobotics in Surgery. Nanoimmunoassay and nano-immunosensors, Bio-Barcode Assay – use of magnets, gold, DNA and antibodies.
Case study: Nanotechnology in bone tissue engineering.

Theory	Tutorial	Practical	Project	Total
45 hour	0 hour	0 hour	0 hour	45 hour

References:

1. Mirkin, C. A., & Niemeyer, C. M. (Eds.). (2007).Nanobiotechnology II: more concepts and applications. John Wiley & Sons.
2. Rao & Reddy (2006). Encyclopedia of Nanotechnology, vol.5: Nanotechnology in Environment. Campus Books International.
3. Chella Kumar (2006). Biological and Pharmaceutical Nanomaterials. Wiley Publisher.
4. Guozhong, C. (2004).Nanostructures and Nanomaterials: synthesis, properties and applications. World scientific.
5. Edelstein, A.S., & Cammaratra, R.C. (1998). Nanomaterials: Synthesis, Properties and Applications, Second Edition, CRC Press.

Web References:

1. `https://nptel.ac.in/courses/118107015/`