Savitribai Phule Pune University

PES Modern College (Autonomous), Ganeshkhind, Pune-16

M.Sc.II Biotechnology (CBCS Semester Pattern) Semester-III Revised syllabus w.e.f. June 2023

Semester III

Course code	Course Title	Credits
Core Compulsory Theory Papers (CCTP)		
23MBT- 301	Animal & Stem Cell technology	4 Credits
23MBT- 302	Bioprocess engineering	4 Credits
23MBT- 303	Bioinformatics & Biostatistics	4 Credits
Core Compulsory Practical Course : CCPP-1		
23MBT - 304	Laboratory Course IV- Animal Biotechnology, Bioprocess engineering & Bioinformatics & Biostatistics	4 Credits
Choice Based Optional Papers: CBOP (any One)		
23MBT - 305	Quality Control, Bio safety & Bioethics	4 Credits
23MBT - 306	Agricultural Biotechnology	4 Credits (2T + 2P)
Total		20 Credits

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M.Sc. II Biotechnology (CBCS Semester Pattern) Semester III
Revised syllabus w.e.f. June 2023

Subject Code: 2 3 MBT- 301 **Subject : Animal and Stem Cell Technology**
4 Credit course (Total Lectures:60)

Unit	Topic	Lecture (Total 60L)
I	**Introduction to tissue culture:** • History, basics of animal tissue culture • Importance of maintenance of sterility and use of antibiotics • Detection of Mycoplasma and viral contaminants • Prevention of Cross contamination, eradication of contaminants • Logic of formulation of tissue culture media: natural, synthetic media, seraand substitutes • Introduction to the balanced salt solutions and simple growth medium. • Role of carbon dioxide in animal cell culture • Cell senescence.	5
II	**Various systems of tissue cultures**: Distinguishing features, advantages and limitations. • **Methodology**: i. Primary culture, ii. Explant culture, iii. Suspensionculture. Behavior of cells, properties, utility with different examples • **Cell lines**: Definition, establishment and maintenance, Finite and Continuous Cell line. Normal, Transformed and established cell lines: characteristic features, Contact inhibition, anchorage (in) dependence, Cell and tissue response to various factors	5
III	**Organ culture:** • Methods, behavior of organ explant, and applications of organ culture. • Histotypic and organotypic cultures: methods and applications • Introduction to organ transplants, tissue engineering, bio-artificial organs	5
IV	**Growth studies:** • Cell proliferation, cell cycle, mitosis in growing cells • Cryopreservation of cultured cells • Measurement of viability and cytotoxicity, microscopic examination ofcultures, subculture of cells (monolayer and suspension cells), passagenumber • Cell cloning and types, cell synchronization, Cell transformation • Cell Separation: Various method- advantages and limitations; Scaling up,Cell hybridization	5

V	**Application of animal cell culture**: • For *in vitro* testing of drugs, production of viral vaccines andpharmaceutical proteins, monoclonal antibodies. • Mass production of biologically important compounds. • Propagation of viruses (viral sensitivity of cell lines). • Harvesting of products, purification and assays.	5
VI	**Stem cells technology** –	15
	• Concept, characteristics of adult stem cells, embryonic stem cells, embryonic carcinoma cells, induced pluripotent stem cells • Identification, purifications, assessment of proliferation • Long term maintenance and characterization. • Stem cell self-renewal and pluripotency: molecular mechanisms • Cell cycle regulation in stem cells • Concept of Stem cell niche with examples Neural stem cells,Hematopoietic stem cells, mesenchymal stem cells • Applications of stem cells in therapeutics	
VII	**Transgenic animals:** • Overview of different methods of introduction of a transgene viz. micronuclear injection method, transduction with recombinant viruses,REMI etc. • Targeted gene insertion, gene silencing by RNAi,: • Cre-LoxP recombination for genetic modification • CRISPR/Cas9 for targeted genome editing • Transgenic animals: fish, *Xenopus,* mammals, • Concept of Knockout mice, methods and application • Mouse models for human genetic disorders, neurodegenerative disorders	12
VIII	**Animal husbandry and reproductive biotechnology:** • Overview of livestock breed and their productivity in India • Artificial breeding :-Various methods of semen collection, artificial insemination, estrous synchronization, cryopreservation of germ cells, • *In vitro* fertilization and embryo transfer technology, • Animal cloning: concept and application in conservation	5
IX	**Biosafety issues and Bioethics** associated with Animal Tissue culture, developing transgenic animals and human cloning	3

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M.Sc. II Biotechnology (CBCS Semester Pattern) Semester III
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Subject Code: 2 3 MBT- 302 **Subject : Bioprocess Engineering**
4 Credit course (Total Lectures:60)

Sr No	Topic	No. of lectures 60
I	• **Bioprocess development**: An interdisciplinary challenge, Biotechnology & Bioprocess Engineering, Definition of Bioprocess andbioprocess Engineering, over view of bioprocesses with their various components. Aseptic operations and Containment • **Types of Fermentations :** Solid state fermentation, Dual/Multiple, Aerobic, Anaerobic, batch, fed-batch, continuous • **Design of Fermenter/ bioreactors:** Overview of types of Bioreactors, Novel Designs of Bioreactors. • **Kinetics of operation of bioreactors:** Batch, Fed Batch and Continuous processes., Growth Linked and Non growth Linked Products, Kinetic modelling, Model structures, Material balances and energy balances • **Isolation, screening and maintenance** of industrially important microbes • **Strain Improvement:** Product formation and inhibition pathways and their regulations, Strain improvement by: Mutation, Protoplast fusion, parasexual cycle and genetic engineering • **Inoculum Development:** Inoculum Development for bacterial, yeast and mycelial processes, aseptic method of inoculation, achievement andmaintenance of aseptic conditions.	15
II	**Media for industrial fermentations:** Medium requirements for fermentation processes, carbon, nitrogen, minerals, vitamins and other complex nutrients, oxygen requirements, Medium formulation (Statistical design) of optimal growth and product formation, Ingredients for mammalian cell culture and plant cell culture. **Sterilization of media and air**: Thermal death kinetics of microorganisms, Del factor, design organism, Design of sterilization process (batch and continuous), sterilization of bioreactor, feed and liquid waste, sterilization of air, exhaust air, theory of depth filter, designing of depth filters. **Monitoring of process variables:** Types of sensors, Measurement and control of various parameters (pH, Temperature, dissolved oxygen, microbial biomass, inlet and exit gases,fluid flow, Pressure, Foam) P.I. D. control, Computer control of variables. **Scale Up and Scale Down :** Importance, parameters involved	10

III	**Mass transfer, Aeration and agitation of fermentation broth:** • **Mass transfer**: Concept of mass transfer, Molecular diffusion and role in bioprocess, Two–film theory, Convective mass transfer, volumetric mass transfer, Liquid-Solid, Liquid-liquid and Gas- liquid mass transfer equations and significance in bioprocess. • **Aeration** : Oxygen Uptake in cell cultures, Oxygen transfer from Gas bubble to Cell. Gas hold up, KLa importance, Measurement of KLa, Determination of KLa, Factors affecting KLa. • **Agitation:** Design of impellors and their flow patterns. Fermentation Broth rheology–Newtonian and Non Newtonian fluids, Factors affecting broth rheology, Power requirement for mixing Power number, Reynolds number, Flow regimes in fermentation tank (Laminar, turbulent and transition),Correlation between mass transfer coefficient and operating variables.	12
IV	**Downstream Processing:** • Bio separation :- filtration, centrifugation, sedimentation, flocculation; Cell disruption (Physical , Chemical and enzymatic methods); • Extraction(Liquid-liquid, Aqueous two phase, Supercritical fluid); Distillation, • Purification by chromatographic techniques; Reverse osmosis and ultra-filtration; Drying; Crystallization, Whole Broth Processing	8
V	**Industrial Production and Recovery process of:** • Vitamins (Vitamin C), Amino acids (Glutamic acid), Enzymes (Extra and Intra cellular one example each), Antibiotics (Rifamycin), Organic acids (Lactic acid), Recombinant Vaccines, • Biotransformation product(Steroids),Brewing (Beer), Cheese, Exopolysaccharides, Biodiesel.	10
VI	**Quality Control (QC) and Quality assurance(QA)** : • Roles and responsibilities of QC and QA departments, Common Quality control tests, • Standard Operating Procedures (SOP) & Good Manufacturing Practices (GMP) ,Regulations on use and distribution of Biotechnology products.	5

References:

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M.Sc. II Biotechnology (CBCS Semester Pattern) Semester III
Revised syllabus w.e.f. June 2023

Subject Code: 2 3 MBT- 303 **Subject: Bioinformatics and Biostatistics**
4 Credit course (Total Lectures: 60)

Unit	Topic	No. of lectures 60
I	**Major Bioinformatics Resources and Biological databases** • Computers in Biology and medicine, Database concept • NCBI/EBI/EXPASY • Biological literature databases (PubMed) • Nucleic acid sequence databases (NCBI's GenBank + the European Nucleotide Archive [ENA] + the DNA Data Bank of Japan [DDBJ],) • Protein sequence databases (UniProtKb,SwissPort, TrEMBL). • Genome Database: UCSC Genome Browser • Introduction to Python	4
II	**Basic Concepts in Biological sequence Analysis** : • Biomolecular sequence analysis: Overview and Concepts • Pairwise sequence alignment algorithms (Needleman &Wunsch, Smith & Waterman) • Scoring matrices for Protein and Nucleotide sequences (PAM series and BLOSUM series), Gap Penalty and Penalty Scheme • Database Similarity Searches (BLAST, FASTA) • Multiple sequence alignment algorithms, Methods of MSA (Progressive, Iterative, Block-Based Alignment) (CLUSTALW and CLUSTALX,T-Coffee) • Protein profiles and Hidden Markov Model (HMM) • Application of Multiple sequence alignment (Phylogenetic analysis)	8
III	**Structural Bioinformatics** • Major Structural Resources (PDB and PMDB) • PDB File Format • Basic Structure Visualization o Visualization of major secondary structure (helices, beta sheets) and their role in protein structure o Visualization of various interactions : Polar (Hydrogen Bonds), Apolar (Hydrophobic, van der Waals, Pi stacking), Other (Salt Bridges, Coordination with ions) in protein structures and their role. • Protein Structure Classification (SCOP and CATH) • Protein Structure Prediction o Need and Concept of protein structure prediction, protein folding and model generation	6

	○ protein secondary structure prediction methods (Alignment-based and Single sequence-based secondary structure predictions ○ Tertiary structure prediction (Homology modeling and Fold Recognition, ab initio methods) ○ Ramchandran Plot	
IV	**Computer aided drug design** (CADD) • Introduction to CADD • Identification drug targets using molecular modeling, combinatorial libraries and high-throughput screening(HTS) **Pharmacophore modelling and Chemoinformatics** • Pharmocophore: Definition and classes (HBA, HBD, Aromatic etc.) • Pharmacophore-based screenings of compound library, analysis and experimentalvalidation. • Concept of quantitative drug design using Quantitativestructure-activity relationship models (QSAR models) • Identification of pharmacophore features • Chemical Structure representation: 1D, 2D and 3D structures • Molecular file formats (SMILES, WLN, SDF, MOL,PDB etc) • Compound library formatting and filtering (Physicochemicaland substructure filters)	7
V	**Molecular Modeling** • Introduction to modelling protein ligand interactions • Pose Prediction Strategies in molecular Docking: Rigid body docking, Semi-flexible docking, flexible ligand docking (Conformational search method, Fragmentation method, Database method) • Scoring Functions: Force field-based, Empirical, Knowledge-based • Application in Structure Based Drug Designing: Use of Small-molecule libraries, Natural compound libraries for virtual high throughput screenings. • Commonly used docking software	5
	Biostatistics	
I.	**Introduction:** • Biological variables, parameters of statistical data display. • Types of scales: linear, power, log, circular (with biological examples) • Curves and Equations: Linear, saturating, sigmoid, exponential, logistic, power, multinomial, algebraic, differential, partial differential	4
II	**Sampling, distribution and presentation** • Sampling methods; Types of sampling; random sampling, Probability and non-probability sampling, stratified sampling, etc. • Power analysis and sample size calculations • Statistical data distribution, normal and skewed distribution, coefficient of skewness, moments and Kurtosis • Data presentation models; covariance models, spatial statistical model, multivariate spatial model, Gaussian and non-gaussian random process models, etc.	**7**
III	**Hypothesis Testing (with biological examples**) • Principles of hypothesis testing, significance level, null hypothesis • Type I and Type II errors • Examples of hypothesis testing: comparison of means, t-test, Chi-square test	**5**

IV	**Design, correlation and regression analysis** • Statistical design of experiments, single and multifactorial designs, fractional factorial designs. • Principles of experimental designs; randomization, replication and local control; Complete, incomplete and randomized block designs; • Covariance and correlation, Pearson's, Kendal's and Spearman's correlations, use of correlation and regression in biological analyses • Univariate, Bivariate and Multivariate data; linear, multilinear, and non-linear regression, generalized linear model and other models of regression analysis (nonparametric regression, Bayesian linear regression, etc.)	**8**
V	**Statistical Methods:** • Analysis of variance table (ANOVA), • Post hoc Tests- • Tukey's test for pairwise comparison of treatments • Dunnet's test for comparison of treatment means with control • Duncan's multiple range test • Mann–Whitney U test	**6**

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M.Sc. II Biotechnology (CBCS Semester Pattern) Semester III
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Subject Code: 2 3 MBT- 304 Subject: Laboratory Course IV
(4 Credit course)
(Laboratory course in Animal Biotechnology, Bioprocess Engineering, Bioinformatics and Statistics)

Sr. No.	Animal Biotechnology Practical	No. Of Practical
1.	Initiation of primary culture from chick embryo	1
2.	Subculture and establishment of cell line	2
3.	Growth curve analysis of cell line	1
4.	Demonstration of cryopreservation of cell	1
5.	Chromosome spread preparation from cell line	1
Sr No	**Bioprocess Engineering Practical**	
1.	Screening and identification (Genus Level) of a production strain (enzyme /antibiotic) from soil samples. Maintenance of the isolated production organism (Agar slants/ glycerol stocks /soil culture/ lyophilization) at least two methods.	2
2.	Medium optimization for laboratory scale production of enzyme/antibiotics.	1
3.	Study of Working of lab bench fermenter (with production of enzyme or antibiotic using screened organism)	1
4.	Recovery and Assay of product formed (Bioassay or Enzyme assay).	1
5.	Solid state fermentation : Lab scale production of a product.	1
6.	Visit to fermentation industry and Report writing	1
Sr. No.	**Bioinformatics and Biostatistics Practical**	
1.	Using online resources like NCBI, PubMed(GenBank, UniProtKB, PDB), Genome Browser	1
2.	Sequence alignment using BLAST/ Database Similarity searching using BLAST	1
3.	Phylogenetic analysis using Phylip or Mega	1

4.	Basic Structure visualization using DeepView (Performing basic tasks like Selecting and Displaying structures, Colouring, Measuring distances and labeling)	1
5.	Prediction of protein tertiary structure using any method (CPH, MODELLER, SWISS Model, EasyModeler)	1
6.	Molecular Docking using AutoDock and Molecular visualization of docked complexes (using Pymol or Chimera)	1
7.	**Biostatistics practical based on theory course :**	4
i.	Determination of Karl-Pearson's coefficient of correlation/ Spearman's rank correlation coefficient from the given grouped and ungrouped data.	
ii.	Examples based on t – test , Chi-square test for goodness of fit and independent attributes.	
iii.	Analysis of variance on the given data (ANOVA)	
iv.	Measures of skewness and measures of Kurtosis (grouped and ungrouped data).	

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Subject code: 23MBT- 305 **Subject – Quality Control, Biosafety & Bioethics**
4 Credit Course (Total Lectures: 60)

Units	Topic	No. of Lectures 60
	Quality Control	
I	• Quality Standard & Quality assurances: Concept of quality Assurance & Quality control their function and adventage, Quality assurance and quality management in Biotech Industy • Critical quality point in different stages of production includingraw materials & processing material • Types of validation in pharma industry, Importance of validationElements of validation (Q,OQ, PQ,DQ) Toxicity, clinical trials, studies, clinical research & clinicaldata management, • Export, Import of product, Rules & Regulations for startup companies GMP , cGMP	10
II	**Essential Documents & Regulatory Submission, Compliance AndAudits** – • Preparation, production and quality control of regulatorydocuments, creating editorial timelines and work flow specifications, SOP • Scheduling and tracking documents, writing and proofreading. • Development and updates on specifications for the design, tracking of regulatory documents and artwork used in regulatorydocument • Regulatory requirements for Biotech/pharma productdevelopment	10
	Bioethics	
III	**Introduction** □ Introduction to Ethics and Bioethics, Framework for ethicalDecision Making □ National Ethical Guidelines for biomedical and health research. □ Bioethical issues related to Healthcare & medicine Food & agricultureGenetic engineering	10
IV	**Ethical Issues:** • Animal cloning & human cloning • Human genome project, biopiracy, biowarfare • Public education of producing transgenic organism • Legal & socioeconomic impacts of Biotechnology • Hazardous materials used in biotechnology: Handling & disposal • Experimenting on Animals: Animal right activities Bluecross in India- society for prevention of cruelty against animals.	10

	CPCSEA committee, Ethical limits of Animal use. • Publication ethics and regulations • Biodiversity	
	Biosafety	
V	**Biosafety** • Introduction, Biosafety in Laboratory & Institution, Laboratory associated infections & other hazards. • Introduction to Biological Safety Cabinets, Primary Containment for Biohazards • Biosafety Levels, Biosafety Levels of Specific Microorganisms, Recommended Biosafety Levels for Infectious Agents and Infected animals • Safety & hazards: Chemical & radiation hazards Control of exposure to radiation, Fire prevention methods • Industrial Hygiene & toxicology: Introduction , evaluation & control, Personal protective equipment • Risk Analysis, Risk Assessment, Risk management and communication	14
VI	**Biosafety guidelines** – • Guideline & regulations(National & International) • GMOs & LMOs Guidelines of India • Environmental release issues of GMOs, • Risk Analysis, assessment, risk management and communication • Roles of Institutional Biosafety Committee RCGM, GEAC etc	6

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M.Sc. II Biotechnology (CBCS Semester Pattern) Semester III
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Subject Code: 2 3 MBT- 306T **Subject : Agricultural Biotechnology**

2 Credit Course (Total Lectures: 30)

Unit	Topics	No. of Lectures 30
I	• **Introduction to agricultural Biotechnology** • Importance of Agriculture at national economy • Advantages of biotechnological methods over conventional methods of cropimprovement. • *In-Vitro* Plant propagation- a) Virus indexing, virus free plants, b) fruit crop c) flower crops d) Cereals and e) oil seeds plants • Endosperm culture & production of triploids for production of seedless plantvarieties with examples • Use of bioreactors in plant production & Scale-up for Commercialization • Beneficial microorganisms in Agriculture: Biofertilizer (Bacterial Cyanobacterial and Fungal), microbial Bioinsecticides • Major pest and diseases of horticultural crops and their control byBiotechnological methods	**10**
II	**Crop improvement** – • Improvement of crop quality (FlavrSavr tomato, Golden rice) • Chloroplast manipulations for production of therapeutic proteins, vaccines,antibodies and increased production,	**3**
III	**Recent advances** – • Species Conservation: Seed Bank, Gene Bank. • Plant genotyping by different methods PCR, Plant fingerprinting,Microsatellite, Nanotechnology. • Homogenous assays – Qualitative Real Time PCR assays, applications • CRISPR based technology: Introduction, techniques, and its application inplants • Plant DNA Barcoding- Introduction, Barcoding Markers (matK, rbcl, ITS,tm HpsbA), Recent advances in plant bar coding Benefits, Limitations	**8**
IV	• **Development and formulation (with various carrier materials) ofbioinoculants, for better Agricultural productivity, using:** i. Growth promoting , ii. Nitrogen fixing, iii. Phosphate solubilizing, iv. Metal chelating, (siderophores) v. Growth hormone producing microorganisms • Agricultural biotechnology and agribusiness • Opportunities in the Agriculture Biotechnology	**8**

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Subject Code: 2 3 MBT- 306P **Subject : Agricultural Biotechnology**
(2 Credit Practical Course)

Sr. No.	Laboratory Course - Agricultural Biotechnology	No. Of Practical
1.	Production of virus free plants Virus indexing- ELISA and PCR, (Demonstration)	2
2.	Suspension culture and study the parameters to scale-up the production of in-vitro plants Monitoring of growth and differentiation of cells,	2
3.	Endosperm culture for regeneration of seedless plants Hardening /Acclimatization of regenerated plants, Transfer to soil	2
4.	Non gel techniques for plant genotyping and CRISPR based technology (Demonstration using web resources)	1
5.	Preparation, formulation (using suitable carrier material) and application (pot trials) of bio inoculants (Nitrogen fixing and Phosphate solubilising Microorganisms)	1

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M.Sc.II Biotechnology (CBCS Semester Pattern) Semester-IV
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Semester IV

Course code	Course Title	Credits
Core Compulsory Theory Papers (CCTP)		
23MBT- 401	Genomics and Proteomics	4 Credits
23MBT- 402	Advanced Bio analytical Techniques	4 Credits
Core Compulsory Practical Paper : CCPP-1		
23MBT- 403	Research Project	4 Credits
Choice Based Optional Papers: CBOP (any Two)		
23MBT - 404	Bio entrepreneurship & Start up Designing	4 Credits
23MBT - 405	Pharmaceutical Biotechnology& Drug Designing	4 Credits
23MBT - 406	Research Methodology & Scientific Communication	4 Credits (2T + 2P)
23MBT - 407	Clinical Research, Database Management and IPR	4 Credits
Total		20 Credits

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M.Sc.II Biotechnology (CBCS Semester Pattern) Semester-IV
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Subject code : 23MBT-401 **Subject - Genomics and Proteomics**
4 Credit Course (Total Lectures: 60)

Units	Topic	No. of Lectures 60
	Genomics	
I	• Genomics and Proteomics overview, omes and omics, • Concepts and applications Genome overview with model organisms example • Whole Genome sequencing – Methods, Assembly and Analysis, NGS Platforms • Comparative genomics - Goals, bioinformatics of genome annotation, methods and limitations. • Structural genomics –Goals, methods, applications. • Functional genomics –Goals, methods, applications.	8
II	**Transcriptomics and Microarray** • Introduction to transcriptomics and expression profiling DNA and RNA Microarray –Preparation, working and analysis • Investigative techniques –EST, SAGE, SNP, MPRAs • DNA and RNA Microarray –Preparation, working and analysis. Microarray databases and bioinformatics tools.	10
III	**Applications of genomics** • Metagenomics • Toxicogenomics • Pharmacogenomics • Basic research • Medical Genetics	12
	Proteomics	
IV	Introduction & concept of proteomics, Protein structure-function relationship, **Types of Proteomics:** • Protein expression proteomics • Structural Proteomics, • Functional Proteomics	5 L
V	**Techniques in Proteomics**: • Protein Isolation and Separation techniques • Structural analysis of proteins- X-ray crystallography and NMR spectroscopy • 2 D electrophoresis • Peptide mapping & sequencing • Protein structure prediction- homology modelling	12

	• Mass Spectrometry: MALDI_TOF, ESI Tandem, Ion Trap, Peptide mass fingerprinting • LC-MS, (SILAC) - Chemical tagging, fluorescence, radio-labeling	
VI	**Applications of Proteomics** • Protein expression profiling • Protein-protein & Protein-DNA interaction (Chip Technique) • Methods for detection of protein-protein interactions - Yeast 1, 2 and 3 `hybrid systems – Phage display – • Proteomics and Protein microarrays, databases and allied bioinformatics tools.	8
VII	**Applications** • Health care**,** Biomarkers in disease diagnosis, -Biomarker, drug development and their target identification • Identification and characterization of novel proteins	5

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M.Sc.II Biotechnology (CBCS Semester Pattern) Semester-IV
Revised syllabus w.e.f. June 2023

Subject Code: 23MBT- 402 Subject: Advanced Bio-analytical Techniques
4 Credit Course (Total Lectures: 60)

Units	Topic	Lectures
I	**Microscopic Techniques:** • Staining and Visualization of cells and subcellular components. • Cryotomy, Scanning and Transmission microscopes, different fixation and staining techniques for EM • Freeze-etch and freeze- fracture methods for EM, Image processing methods in microscopy, confocal microscopy, single cell imaging.	13
I	**Histochemical and Immunotechniques** • Antibody generation, Detection of antigen using ELISA, RIA, Western blot • Immunoprecipitation, Flow cytometry and FACS • Detection of antigens in living cells (Stem Cell Markers) • *in situ* localization by techniques such as FISH and GISH.	12
II	**Advanced Application of Spectroscopy** • UV visible spectrophotometer, Fluorescence spectroscopy, Circular dichroism, NMR , IR and ESR spectroscopy , • Molecular structure determination using X-ray diffraction and X ray crystallography • Molecular analysis using light scattering, Mass spectrometry and LC-MS and surface plasma resonance methods.	15
IV	**Advanced Chromatography and Electrophoretic technique:** • Introduction, principle and applications of HPTLC, HPLC, GLC,GC • Affinity chromatography: Principle, types, Application, • IF and 2 D electrophoresis, Capillary Electrophoresis, DGGE (Denaturing gradient gel electrophoresis)	12
V	• **Advanced Bio-analytical Techniques and Automated Systems** • Advances in PCR technology & its applications (modifications), • Next Generations Sequencing (NGS): Principles and instrumentation, NGS data procession tools, • Automated microbial identification system, Automated DNA/ RNA Microarry systems.	08

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2. Biophysics. 1st edition (2002), Pattabhi V and Gautham N. Kluwer Academic

Publisher, USA.
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4. Modern experimental biochemistry. 3rd edition. (2000) Rodney Boyer. Prentice Hall Publisher, USA.
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13. Next Generation Sequencing Methods and Protocols: Editors: Head, Steven R., Ordoukhanian, Phillip, Salomon, Daniel R. (Eds.) 2018.
14. Statistical Analysis of Next Generation Sequencing Data: Editors Somnath DattaDan Nettleton.
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M.Sc.II Biotechnology (CBCS Semester Pattern) Semester-IV
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Subject Code: 23MBT- 403 **Subject : Research Projects (4 Credit Course)**

Project work , Thesis Submission & presentation

- Project work / Thesis / Dissertation shall be carried out under the supervision of a qualified teacher in the concerned Department./Research Institute/Industry

- Project work / Thesis / Dissertation shall be pursued for a minimum of 12 weeks during the final semester, following the preliminary plan of work carried out in during the previous semester.

- The Project Report/Thesis / Dissertation report is to be prepared as per standard scientific research methodology and duly signed by the supervisor(s) and the Head of the Department shall be submitted to the concerned department.

- The assessment (Internal and external) of the project work will be as per SPPU guidelines.

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M.Sc.II Biotechnology (CBCS Semester Pattern) Semester-IV
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Subject Code: 2 3 MBT - 404 Subject : Bio-entrepreneurship & Start up Designing
4 Credit Course (Total Lectures: 60)

Unit	Topic	No. of Lectures 60
I	**Introduction to Entrepreneurship**	
	• Meaning Knowledge and concept of entrepreneurship, • Need and Importance of entrepreneurship • The history of entrepreneurship development, • Skills and characteristic of successful entrepreneurs; • Entrepreneurship process; • Factors impacting emergence of entrepreneurship • Role of entrepreneurship in economic development, • Evolution and Growth of Entrepreneurship in India	10
II	**An Entrepreneur and an Entrepreneurship Journey**	
	• Types of Entrepreneurs • Ethical Entrepreneurship • Entrepreneurial Value: Values, Attitudes and Motivation. • The entrepreneurial decision process, and role models, • Self Assessment of Qualities, • Skills, Resources and Dreams. • Role of Society and Family in the growth of an entrepreneur.	11
	Activity : Motivational games to boost the decision power, accuracy and Attitude of the students	
III	**Starting the venture:**	11
	Generating business idea – • Sources of new ideas, • Methods of generating ideas, • Creative problem solving, • Opportunity recognition and assessment • Environmental scanning, • Competitor and industry analysis; • Feasibility study : - Market feasibility:-Marketing plan: marketing research for the new venture, Steps in preparing marketing plan, - Technical/operational feasibility, - Financial feasibility.	
	Activity : **1. Organization of 'Brain Storming' session for generating Creative Business idea** **2. Market survey/Marketing Strategy**	
IV	**Preparing a Business Plan:**	11
	• Introduction to Business and its Environment • Components of a business plan, • Meaning and significance of a business plan • Challenges of New Venture Strategies	

	• Start-up Policy Framework and Incentives • drawing business plan • Preparing project report; • Business Plan Preparation • Presenting business plan to investors • Execution of Business Plan • Business Incubation Centres	
	Activity : Presentation on Business plan /Start-up business plan	
V	**Entrepreneurship as Problem Solving**	**6**
	• Entrepreneurs- as problem solvers. • Risk taking-Concept; types of business risks. • Barriers to Entrepreneurship. • Support structure for promoting entrepreneurship (various government schemes).	
VI	**Dimensions of Entrepreneurship**	6
	• Entrepreneurial Culture • Entrepreneurial Society • Women Entrepreneurship • Rural Entrepreneurship	
VII	**Strategic Frameworks for Decision**	5
	• Vision, Mission, Objective and Goal • Porter's 5-Forces Model • SWOT Analysis • Competitive Strategies • Value Chain Analysis	

References:

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2. Entrepreneurship, , Brace R., and R., Duane Ireland, , Pearson Prentice Hall, New Jersy (USA).
3. Entrepreneurship, Lall, Madhurima, and ShikhaSahai, , Excel Book, New Delhi.
4. Entrepreneurship Development and Small Business Enterprises, Charantimath, Poornima, Pearson Education, New Delhi.
5. Entrepreneurship : New Venture Creation – David H. Holt
6. Entrepreneurship : Hisrich Peters
7. The Culture of Entrepreneurship- Brigitter Berger
8. Dynamics of Entrepreneurship development and Management: Entrepreneurship, Project Management, Finances, Programmes, and Problems – Vasant Desai (2009)
9. Entrepreneurship Development – Dr. P.C. Shejwalkar
10. Thought Leader : Shrinevas Pandit
11. Leadership and new Science : Margrat wheatly
12. Handbook of Entrepreneurship Research: An Interdisciplinary Survey and Introduction (International handbook series on Entrepreneurship) (2003) : Zolten J ACs, David B. Audretch

13. Knowledge-Driven Entrepreneurship (2009) : The Key to Social and Economic Transformation By Martin Curley, Piero Formica and Thomas Anderson
14. Entrepreneurship (3rd ed) Steven Brandt
15. The Entrepreneurial Connection – Gurmit Narula
16. Business Guru Speak –S.N. Cnary
17. Dhirubhai Ambani: Against All Odds: A Story of Courage, Perseverance and Hope Paperback – 1 July 2017 : by A G Krishnamurthy
18. Mythbreaker: Kiran Mazumdar-Shaw and the Story of Indian Biotech Hardcover – 29 April 2016 by Seema Singh
19. The Entrepreneur's Guide to a Biotech Startup: Peter Kolchinsky
20. The Anotomy of your Creativity : Chris Grady

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M.Sc.II Biotechnology (CBCS Semester Pattern) Semester-IV
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Subject Code: 2 3 MBT - 405 **Subject : Pharmaceutical Biotechnology & Drug Designing**
4 Credit Course (Total Lectures: 60)

Units	Topic	No. of Lectures 60
I	**Introduction :** • Introduction to Pharmaceutical Biotechnology and Drug discovery. • Drug targets: Structure and functions; Physiochemical properties of drugs; drugs from natural sources. • Pharmacodynamics, pharmacokinetics and drug metabolism, Drug tolerance & intolerance, drug allergy, drug induced side effects with examples. • Screening and isolation of bioactive compounds	8
II	**Drug action and Resistance** • Mechanism of action of anti-diabetic, anticancer, anti-inflammatory and antibiotics (any two drugs of each) • Mechanisms of drug resistance to antibiotics and anticancer drugs with examples • MDR, XDR or PDR • Assay of drug potency- bioassay and immunoassay	8
III	**Process of Drug Development** • Target identification and validation. • Pre-clinical studies- -Toxicity (Cytotoxicity, Genotoxicity, Reproductive toxicity, Carcinogenicity, Mutagenicity, and other tests) • Animal models for *in vivo* activity of drugs testing	7
IV	**Clinical Research in Drug Development:** **Protocol Designing:** • Definition of protocol, its importance and purpose • Protocol format: broad contents of protocol • Protocol writing team and role of each member • Clinical trial design: Types of study designs • Sampling, sample size, randomization, Inclusion & Exclusion criteria • Phases of clinical trial & Types of trials **Good Clinical Practice (GCP)-ICH :** • Ethics in clinical research: Principles and origin • ICH: Purpose, regulations & guidelines • Ethics committees: Roles & responsibility of IEC and IRB • Responsibilities of Sponsors, Investigators & Regulators • Clinical trial Monitoring and responsibilities of monitors • Informed consent and Informed consent form	18

	• Essential Documents **Clinical Safety & Pharmacovigilance:** • Definition, recording & reporting of AE, ADR, SAE • Pharmacovigilance: International procedures • Pharmacovigilance in India	
VI	**Computer aided drug design** (CADD) • Importance of CADD • Drug discovery- issues • Target and lead identification • Drug and databases • Drug- Properties / Simplified Molecular Input Line Entry System (SMILES) • Drug- ADMET • Molecular Modeling	10
VI	**Role of Regulatory Authorities in Drug Approvals:** • The Food and Drug Administration (FDA), Investigational new drug application, New drug application; • European regulations National regulatory, authorities, European medicines agency and the new EU drug approval system, Centralized procedure, Mutual • Regulatory Authority in India (DCGI & CDSCO) • Schedule Y of Drugs & Cosmetics Act • Pharmacopeia • Drug patenting and licensing in Pharma industry	10

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2. Vyas and Dixit Pharmaceutical Biotechnology, 1 st CBS Publisher New Delhi, 1991
3. P. K. Gupta, Elements Of Biotechnology, Rastogi Publication, 10 th edition, 2004
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M.Sc.II Biotechnology (CBCS Semester Pattern) Semester-IV
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Subject Code: 2 3 MBT – 406T Subject: Research Methodology & Scientific Communication
2 Credit Course (Total Lectures: 30)

Sr No	Topic	No. of Lectures 30
1.	**Introduction to Research Methods:** • Types of research philosophies (positivist, interpretivist, pragmatist and realistic), various steps in scientific research, Scientific temper andattitude, Experimental Design, Defining Controls, deductive and inductive reasoning; reductionist and holistic approaches of scientificresearch.	3
2	**Scientific Methodology:** • Problem identification, Critical thinking, hypothesis formulation and hypothesis testing (Power analysis) • Difference between hypothesis, reasoning, theory and scientific law	3
3	**Data Collection and analysis**: • Types of Data, Methods and Techniques of data collection • Methods of primary data collection (observation/ experimentation/ questionnaire/ interviewing/ case/ pilot study) Methods of secondary data collection (internal/ external), schedule method **Research data organization:** • Creating, Analyzing, Formatting Data & Content using Spreadsheets Insert, View, Edit etc. • Managing Lab Work books, Data tabulation, Calculations, Equations and analyzing biological Data using statistical tools. **Data Analysis:** • Data distributions, Statistical tests for comparison of sample means and sample variance-t-test, non-parametric tests, Correlation and Regression, F, t and Z distribution; goodness of fit, chi-square. • Introduction to multivariate analysis Mathematical models Simulation as a tool to test these models. • Software for data processing: Multidimensional Use of Excel; Sigmastat; GraphPad Prism; SPSS, SAS, R software.	10
4	**Research in Practice:** • Literature review, Journals, Conference Proceedings, Journal Impactfactor, Citation Index, h, g, h-g index	3
5	**Research Ethics:** • Social implications of research, bio-safety issues Animal experimentation ethics, wild-life ethics and human experimentation ethics • Data fudging and plagiarism: Use of URKUND, Turnitin and iThenticate software	3
6	**Scientific Communication:** • Importance of scientific communication, Types of scientificcommunications, Logical organization of	8

	scientific data and documentation.	
	Different modes of scientific communication: • **Scientific Writing:** Characteristic of good scientific writing, Structure and content, Style, Literature references • **Report Writing**: Types of research reports, guidelines for writing a report, report format, Details of research Proposal writing, Research paper writing, Thesis writing(Introduction, Literature review, Materials and Methods, Results, Discussion, Conclusion and Implications, conflict of interest) • **Oral forms of scientific Communication**-Popular and Scientific talks, Poster presentations, Organizing Presentation Material, Use of audio visual aids in presentation elements of presentation preparation: objective, subject, audience, Length of talk Managing & Delivering Presentations • **Legal forms of communication in science**: Plagiarism and scientific misconduct, Ethics in scientific communication, patent submissions. • **Internal examination of scientific communication**	

References:

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9. John D'Angelo, Ethics in Science: Ethical Misconduct in Scientific Research (2012),CRC Press, USA
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M.Sc. II Biotechnology (CBCS Semester Pattern) Semester III
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Subject Code: 2 3 MBT – 406P
Subject: Research Methodology & Scientific Communication (2 Credit Practical Course)

S. No.	Practical	No. of Practical
1	Using the tools for literature survey (PubMed/ INFLIBNET/ Delnet/ JGate/ Google Scholar)	1
2	Writing hypothesis and designing the research question	2
3	Designing the biological/biotechnological experiment	1
4	Handling/utilizing different types of statistical analysis software (GraphPad Prism/ Origin/ SigmaPlot) for given biological datasets (Chi-square/ t-test/ DMRT/ ANOVA)	2
5	Presenting scientific photographs/ diagrams/ tables and preparation of captions / legends thereof	1
6	Using a web-based reference manager tool like Mendeley, Zotero	1
7	Scientific presentation (writing or constructing abstract/ graphical abstract/ work-flow/ concept notes, etc.) from the provided experimental study	2
8	Study of data fudging and plagiarism using online tools (iThenticate/URKUND/Turnitin)	1
9	Submission of manuscript to a peer-reviewed indexed research journal – key pre-requisites and the process involved	1

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M.Sc.II Biotechnology (CBCS Semester Pattern) Semester-IV
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Subject Code: 2 3 MBT - 407 Subject: Clinical Research, Data Management and IPR
4 Credit Course (Total Lectures: 60)

Unit	Topic	No. of Lectures 60
CLINICAL RESEARCH AND DATA MANAGEMENT		
I	**Introduction to Clinical Research** **Drug Development Process** • Overview of Drug Development Process including clinical trials phases	1
II	**Protocol Designing:** • Definition of protocol, its importance and purpose • Protocol format: Chapters (Headings) and broad contents of protocol • Important scientific and administrative aspect included in protocol • Protocol writing team and role of each member • Clinical trial design: Types of study designs • Sampling, sample size, randomization, Inclusion &Exclusion criteria • Phases of clinical trial & Types of trials	5
III	**Good Clinical Practice (GCP)-ICH E6:** • Ethical Principles and their origin • Ethics in clinical research: As per ICMR & GCP • Ethics committees: Roles & responsibility of IEC and IRB • Ethics in relation to vulnerable groups & special situations • Responsibilities of Sponsors, Investigators & Regulators • ICH: Purpose, regulations & guidelines • Informed consent and Informed consent form • Essential Documents	5
IV	**Drug Regulatory Affairs (Clinical Trial)** • Regulatory Authority in India (DCGI & CDSCO) • Schedule Y of Drugs & Cosmetics Act • International Scenario of Regulatory Aspects: FDA, CFR,	4

V	**Clinical Safety &Pharmacovigilance:** • Definitions of AE, ADR, SAE, • Recording & reporting: Objectives & Importance • Pharmacovigilance: International procedures • Pharmacovigilance in India	3
VI	**Monitoring of Clinical Trials** • Monitoring and its role in clinical trials • CRF and other source documents relevant to monitoring	2
VII	**Concept of Database and Clinical Data Management** • Concept and designing of Database, • Data management & IT in clinical research • CRF designing • Query raising and query resolution • EDC System and 21 CFR Part 11 compliance • **Practical for Protocol Design, CRF Design and source documentation**	10
INTELLECTUAL PROPERTY RIGHTS		
VIII	• General Regime of Intellectual Property Rights: Overview and Historical Perspectives; • Intellectual Property as an Instrument of Development; • Need for Protecting Intellectual Property- PolicyConsideration-National Perspectives and Internationaldemands; • TRIPS (Trade Related Intellectual Property Rights) Agreement and International Treaties related to IPR	6
IX	• Patents: Criteria of Patentability; types of patent applications: provisional and complete specifications. • Procedure for Filing Patent Applications, Patent Granting Procedure; • Revocation, Patent Infringement and Remedies; • Relevant Provisions of the Biological Diversity Act, 2002; • Commercialization of patented innovations; licensing –outright sale, licensing, royalty;	8

X	• Copyright and Neighboring Rights - Conceptual Framework, Copyright works, Ownership, transfer and duration of Copyright, Renewal and Termination of Copyright, Neighbouring Rights, Infringement of copyrights and remedies; Examples and Case study; • Protection of Plant Varieties and Plant Breeders' Rights - Protection of Plant Varieties and Farmers' Rights, Authority and Registry, Registration of Plant Varieties and Essentially derived variety, Duration, Effect of Registration and Benefit Sharing; Examples and Case study;	12
XI	Patent Specification Drafting Exercise	4

Reference Books:

1. Katzung, B.G. Basic and Clinical Pharmacology, (2010) Prentice hall,International
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