Maharashtra Education Society's
Abasaheb Garware College (AUTONOMOUS)

Two Years Post Graduate Program in
Biotechnology

(Faculty of Science & Technology)

Syllabi Under NEP
2020 for

M.Sc II Biotechnology (Level 6.5)

Choice Based Credit System Syllabus

To be implemented from Academic Year 2024-2025

M.Sc. II Biotechnology (NEP 2020)
Sem III

Level	Course Type	Course Code	Course Title	Credits	Remark	Number of hrs
6.5	Major core	BT-601-MJ	Animal Biotechnology	4T		60
	Major core	BT-602-MJ	Bioprocess Engineering	4T		60
	Major core	BT-603-MJ	Bioinformatics	2T		30
	Major core	BT-604-MJP	Practicals in Animal Biotechnology, Bioprocess Engineering and Bioinformatics	4P		120
	Major elective	BT-610-MJ BT-611-MJP	Nano Biotechnology Practicals in Nano Biotechnology	2T 2P	Choose any one combination	30 60
	Major elective	BT-612-MJ BT-613-MJP	Crop Biotechnology Practicals in Crop Biotechnology	2T 2P		30 60
	RP	BT-631-RP	Research project	4		120
			Total Credits			22

Sem IV

Level	Course Type	Course Code	Course Title	Credits	Remark	Number of hrs
6.5	Major core	BT-651-MJ	Genomics and Proteomics	4T		60
	Major core	BT-652-MJ	Advanced Bioanalytical Techniques	4T		60
	Major core	BT-653-MJ	Quality Control, Bioethics and IPR	4T		60
	Major elective	BT-660-MJ	Systems Biology	2T	Choose any two courses	30
	Major elective	BT-661-MJ	Clinical Research and Database management	2T		30
	Major elective	BT-662-MJ	Drug development	2T		30
	Major elective	BT-663-MJ	Molecular mechanisms of Development	2T		30
	RP	BT-681-RP	Research Project	6 P		180
			Total Credits			22

Semester III

Course Code and title: BT-601-MJ Animal Biotechnology
Credits: **04** **Total Lectures: 60**

Course outcomes:
By the end of this course students will able to

1. Understand basic principles in animal tissue culture
2. Understand concept of transgenic animals and different related techniques
3. Know basic information related to stem cells and apply the knowledge

Units	Topics	Number of Lectures
I	**Introduction to tissue culture:** • History, basic concepts in animal tissue culture • Importance of maintenance of sterility and use of antibiotics, different types of contaminants • Detection of cryptic contaminants-Mycoplasma and viruses • Cross contamination, eradication of contaminants • Logic of formulation of tissue culture media: natural, synthetic media, sera and substitutes • Introduction to the balanced salt solutions • Role of carbon dioxide in animal cell culture • Different types of tissue culture vessels used **Various systems of tissue cultures**: Distinguishing features, advantages and limitations. **Methodology**: i. Primary culture, ii. Explant culture, iii. Suspension culture. Concept of Cell senescence, Hayflick's limit, Contact inhibition, anchorage (in) dependence **Cell lines**: Definition, establishment and maintenance, Normal, Transformed/established cell lines: characteristic features, Contact inhibition, anchorage (in) dependence, Cell and tissue response to various factors	15
II	**3-D Cultures** **Organ culture:** Methods, behavior of organ explant, and applications of organ culture. Histotypic and organotypic cultures: methods and applications Tissue engineering, Measurement of viability and cytotoxicity, microscopic examination of cultures, subculture of cells (monolayer and suspension cells), passage number Cryopreservation of cultured cells, cell synchronization Cell cloning and types, Cell sorting, Cell transformation, Scaling up, Cell hybridization **Application of animal cell culture**: For *in vitro* testing of drugs,	15

	Propagation of viruses, Production of viral vaccines and pharmaceutical proteins, monoclonal antibodies.	
III	**Stem cells technology**– • Concept, characteristics of different types of stem cells- adult stem cells, embryonic stem cells, embryonic carcinoma cells, embryonic germ cells, induced pluripotent stem cells, cancer stem cells • Identification, purifications, assessment of potency and proliferation of stem cells • Long term maintenance and characterization of differentiated cells by Fluorescence microscopy, FACS, RNA-sequencing analysis and microarray. • Molecular mechanisms of stem cell self-renewal and pleuripotency, Cell cycle regulation in stem cells • Concept of Stem cell niche with suitable examples • Overview of Neural stem cells, Hematopoietic stem cells, Mesenchymal stem cells • Applications of stem cells in therapeutics- in treatment of diabetes, neurodegenerative diseases, skin burns etc.	15
IV	**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 • Concept of Knockout, knockdown mice- methods and application • Transgenic animals: fish, *Xenopus*, mammals- methods and applications, • Mouse models for neurodegenerative disorders, cancer	10
V	**Artificial Breeding Techniques:** • Semen collection, cryopreservation of semen sample, ova and embryos, Artificial insemination - various methods with advantages and limitations • Estrous cycle, estrous synchronization, *In vitro* fertilization and embryo transfer technology • Animal cloning: concept and application in conservation	5

References:

1. R. Ian Freshney. Culture of Animal cells, 8th Edition, (2021). A John Wiley & Sons, Inc., Publications, USA
2. Robert Lanza et al. *Essentials of Stem Cell Biology*,3rdedition, Academic Press, 2014.USA
3. G.C. Banerjee - Text book of Animal Husbandry, 8th edition, (2018), Oxford and IBH Publishing co. Pvt. Ltd. India
4. Glick B.R., Pasternak J.J., Patten C. L- Molecular Biotechnology: 6thedition. (2022), ASM press, USA

Course Code and title: BT-602-MJ Bioprocess Engineering
Credits:04 **Total Lectures: 60**

Course outcomes:
After the end of course student will

1. Student will able to describe the fermentation and control system
2. Will able to summarize the prerequisite for fermentation.
3. Able to predict the mass transfer in fermentation
4. Able to comply the DSP
5. Learn to summarize the production and economics

Units	Topic	No. of Lectures
1	An introduction to fermentation processes Range of fermentation processes Chronological development of fermentation industry Components of fermentation processes Types of Fermentations : Solid state fermentation, Dual/Multiple, Aerobic, Anaerobic, batch, fed-batch, continuous Microbial growth kinetics: Batch, Fed batch and Continuous culture Comparison of batch and continuous culture in industrial processes Example of the use of fed batch culture 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	15
2	Isolation of industrially important microorganisms, primary screening, secondary screening, general methods for secondary screening Inoculum Development: Inoculum Development for bacterial, yeast and mycelial processes, aseptic method of inoculation, achievement and maintenance of aseptic conditions. Criterion for choice of microorganisms to be used as an production strain Reoxidation of NADH during fermentation Various fate of Glucose with respect to microbial fermentation Strickland reaction Relevance of strain improvement with world war I Improvement of Production strain, Linear and branched pathway control, various mechanisms of overproduction of compound, isolation and recovery of auxotroph, Strain improvement by genetic engineering Medium formulation (Statistical design) of optimal growth and product formation, **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,	15
3	**Mass transfer**: Concept of mass transfer, Molecular diffusion and	10

	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 NonNewtonian 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.	
4	**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 ultrafiltration; Drying; Crystallization, Whole Broth Processing	10
5	**Industrial production and recovery** Antibiotics (ampicillin), enzyme (one extracellular and intracellular), Vitamin C, Glutamic acid, lactic acid, cheese Fermentation economics, market potential Quality control and Quality assurance of fermentation product	10

References

1. Pauline Doran, (2012), Bioprocess Engineering Principles - Academic Press, second Edition
2. Stanbury, P. F., Whittaker, A. and Hall, S., (2016) Principles of Fermentation technology, Springer, Third edition
3. Dr. Prasanna V Dharani Aiyer Basics of Fermentation Technology (2018)

Course Code and title: BT-603-MJ Bioinformatics
Credits: 02 **Total Lectures: 30**

Course outcomes:
After the end of course students will

1. Learn to describe the biological database
2. Able to summarize the data entry format and alignment method
3. Interpret the information in sequence alignment and SPDBV
4. Relate the chemical structure with database structure of ligand
5. Develop the knowledge of molecular docking

Units	Topic	No. of Lectures
1	Introduction to bioinformatics Application of bioinformatics in various fields Biological databases: Nucleotide sequence database, NCBI, EBI, DDBJ Redundant and non-redundant databases Concept of INSDC Protein Databases: PDB, SCOP and CATH, Uniprot, PIR Literature databases: PubMed, PMC	6
2	Submission of sequences to databases Flat file format of Genbank, EBML, Swissprot Flat file format of PDB Introduction to global search engine ENTREZ Concept of Sequence analysis and alignment Methods of PSA: Dot matrix, Dynamic programming approach, word based (k-tuple) BLAST and FASTA Different parameter for BLAST and FASTA algorithm	6
3	Scoring matrices for Protein and Nucleotide sequences (PAM series and BLOSUM series), Gap Penalty and Penalty Scheme Multiple sequence alignment algorithms, Methods of MSA (Progressive, Iterative, Block-Based Alignment) (CLUSTALW and CLUSTALX,T-Coffee). Application of Multiple sequence alignment	6
4	Basic structure visualization of protein by using SPDBV Basics of RNA structure prediction Methods for prediction of RNA secondary structure Minimum free energy method and sequence covariation Tertiary structure prediction (Homology modelling and Fold Recognition, ab initio methods). Ramachandran Plot.	6
5	Pharmacophore and Chemoinformatics Pharmacophores introduction and different classes Identification of pharmacophore features Chemical Structure representation: 1D, 2D and 3D structures Computer representation of molecules Molecular file format , SMILE, MOL and WLN Compound library formatting and filtering	3
6	Introduction to modelling protein ligand interactions Pose Prediction Strategies in molecular Docking: Rigid body docking	3

	flexible ligand docking (Conformational search method, Fragmentation method, Database method) Scoring Functions: Force field-based, Empirical, Knowledge based Application in Structure Based Drug Designing Molecular dynamics and simulations	

References

1. Mount David W. Bioinformatics: Sequence and Genome Analysis. Publisher: Cold Spring Harbor Laboratory Press; 2004.
2. Teresa Attwood, Parry-Smith David J. Introduction to Bioinformatics. Publisher: Pearson Education (Singapore) Pte. Ltd., 1999.
3. Orpita Bosu, Simminder Kaur Thukral. Bioinformatics: Experiments, Tools, Databases, and Algorithms (Oxford Higher Education) 2007

Course Code and title: BT-604-MJP Practicals in Animal Biotechnology, Bioprocess Engineering and Bioinformatics

Credits: 4 **Total Practicals: 30**

Course Outcomes:

On completion of course students will be able to,

1. To study the techniques of establishment, maintenance and preservation of cell lines
2. Learn to identify the different isolates for antibiotic and enzyme production as well as their maintenance
3. Able to optimize the parameter for fermentation process
4. Able to search, retrieve information from databases and perform sequence similarity
5. Apply the similarity search for phylogenetic analysis
6. Evaluate the model and perform docking

	Title of Experiment	**No. of Practicals**
Sr. No.	**Animal Biotechnology Practicals**	
1	Preparation, sterilization of Animal Tissue Culture Media	1
2	Establishment of primary cell culture from chick embryos	2
3	Viable cell counting (trypan blue and MTT assay)	2
4	Subculturing of adherent cells and maintenance of cell line	2
5	Growth curve studies of animal cells	2
6	Demonstration of cryopreservation	1
	Bioprocess Engineering Practicals	
1	Screening and identification (Genus Level) of a production strain (enzyme /antibiotic) from soil samples.	3
2	Maintenance of the isolated production organism (Agar slants/ glycerol stocks /soil culture/ lyophilisation) at least two methods.	1
3	Medium optimization for laboratory scale production of enzyme/antibiotics.	2
4	Study of Working of lab bench fermenter/bioreactor with production of enzyme or antibiotic using screened organism	1
5	Recovery and Assay of product formed (Bioassay or Enzyme assay).	1
6	Solid state fermentation: Lab scale production of a product.	1
7	Visit to fermentation industry and Report writing	1
	Bioinformatics Practicals	
1.	Database searching and retrieval of information a. Nucleotide sequence database b. Protein database c. Literature searching	2
2.	Sequence similarity searching using a. BLAST b. FASTA	1

3.	Multiple sequence alignment using bioedit/clustal	1
4.	Phylogenetic analysis using Phylip or Mega	1
5.	Basic Structure visualization using DeepView (Performing basic tasks like Selecting and Displaying structures, Colouring, Measuring distances and labeling)	2
6.	Prediction of protein tertiary structure using any method (MODELLER/ SWISS Model)	1
7.	Molecular Docking using AutoDock and Molecular visualization of docked complexes (using Pymol or Chimera)	2

References:

1. R. Ian Freshney. Culture of Animal cells, 7th Edition, (2015). A John Wiley & Sons, Inc., Publications, USA
2. Butter worth, Heinemann, Operational Modes of Bioreactors, BIOTOL series - 1992
3. Butter worth Heinemann, Bioreactor Design & Product Yield, BIOTOL series - 1992
4. Baxevanis Andreas D. Bioinformatics: A Practical Guide to the Analysis of Genes and Proteins, Latest Edition. Publisher: New York, John Wiley & Sons, Inc.
5. Bourne Philip E., Weissig Helge. Structural Bioinformatics (Methods of Biochemical Analysis, V. 44), 2003. Publisher: Wiley-Liss. ISBN: 0471202002.
6. Sternberg Michael J. E. Protein Structure Prediction: A Practical Approach. Publisher: USA, Oxford University Press. 1997. ISBN: 0199634953

Course Code and title: BT-610-MJ Nanobiotechnology
Credits: **02** **Total Lectures: 30**
Course outcome:
Students will learn basics of nanotechnology, synthesis of nanoparticles, characterization of nanoparticles and applications of Nanobiotechnology

Units	Topic	Lectures (30)
I	**Introduction to Nanobiotechnology:** • History of nanotechnology and its emergence, Concept of Nano-biotechnology, • Types of nanoparticles and Their Properties: Quantum dots, Polymeric nanoparticles, • Metal nanoparticles, metal oxide nanoparticles, Dendrimers, Composites.	05
II	**Methods for synthesis of Nanomaterials:** Physical method: • Introduction • Mechanical method • Sputter deposition • Electric arc deposition • Methods based on evaporation Chemical method: • Introduction • Colloids and colloids in solutions • Microemulsion • Sol- Gel Method Biological method: • Introduction • Synthesis using microorganisms • Synthesis using plant Extracts • Use of Proteins and DNA Templates	10
III	**Physiochemical characterization of Nanomaterials:** • Optical (UV-Vis/Fluorescence) • X-ray diffraction, Imaging and size • FTIR • Electron microscopy- TEM, SEM, • light scattering- DLS, NTA; Zeta potential	08
IV	**Applications of Nanobiotechnology:** • Nanomedicines(Health and disease - infectious and chronic) • Nanoparticles for diagnostics and imaging • Food Science (Food Processing, Food Packaging, detection of pathogens) • Nanosensors • Nanotechnology for water remediation and purification • Nanotechnology in agriculture.	06
V	Fate of nanomaterials, environmental and health impact of	01

	nanomaterials, Genotoxicity and cytotoxicity evaluation of Nanomaterials ,eco-toxicology	

Reference Books:

1. The Chemistry of Nanomaterials: Synthesis, Properties and Applications, 2 Volume Set
2. C. N. R. Rao (Editor), Achim Müller (Editor), Anthony K. Cheetham (Editor), 2004. Wiley Publisher.
3. Nanobiotechnology: Concepts, Applications and Perspectives, Christof M. Niemeyer (Editor), Chad A. Mirkin (Editor) , Wiley Publishers, April 2004.
4. Nanoparticles: From theory to applications – G. Schmidt, Wiley Weinheim , 2004
5. Nanochemistry: A Chemical Approach to Nanomaterials – Royal Society of Chemistry, Cambridge UK 2005.
6. Wang, Y., Zhang, Y., & Zhang, Y. (2023). Green synthesis of metal nanoparticles using plant extracts: A review. Trends in Green Chemistry, 5, 45-59.
7. Kumar, A., Sharma, G., & Sharma, S. (2023). Recent advancements in the synthesis of metal oxide nanoparticles: A comprehensive review. Materials Science and Engineering: C, 132, 112345.
8. Zhu, H., Li, S., & Yang, X. (2023). Advances in the synthesis of carbon-based nanoparticles for biomedical applications. Carbon, 184, 498-512.
9. Tran, H. D., Le, Q. T., & Vu, T. H. (2023). Recent developments in the synthesis of semiconductor nanoparticles for photocatalytic applications. Journal of Photochemistry and Photobiology C: Photochemistry Reviews, 52, 100487.
10. Singh, P., Shukla, A., & Sharma, S. (2023). Biosynthesis of metal nanoparticles using microorganisms: A comprehensive review. Biotechnology Advances, 52, 107898.

Course Code and title: **BT-611-MJP Practicals in Nanobiotechnology**
Credits: **02** **Total practicals: 15**

Sr. No.	Laboratory Course- Nanobiotechnology	No. of Practical
1	**Synthesis of metal/metal oxide Nanoparticles by:** a. Chemical b. Microbial and c. Plant based method	**5**
2	**Characterization of nano-materials by spectroscopic method**: i. Analysis of absorption spectra of thin films of Nanomaterials ii. Determination of absorption coefficient for different wavelength	**5**
3	**Biological activities of nanoparticles:** 1. Antimicrobial activities of synthesized nanoparticles (MIC/MBC determination) 2. Cytotoxicity testing of nanoparticles using MTT/Tryphan blue assay	**5**

Reference Books:

1. Wang, Y., Zhang, Y., & Zhang, Y. (2023). Green synthesis of metal nanoparticles using plant extracts: A review. Trends in Green Chemistry, 5, 45-59.
2. Kumar, A., Sharma, G., & Sharma, S. (2023). Recent advancements in the synthesis of metal oxide nanoparticles: A comprehensive review. Materials Science and Engineering: C, 132, 112345.
3. Zhu, H., Li, S., & Yang, X. (2023). Advances in the synthesis of carbon-based nanoparticles for biomedical applications. Carbon, 184, 498-512.
4. Tran, H. D., Le, Q. T., & Vu, T. H. (2023). Recent developments in the synthesis of semiconductor nanoparticles for photocatalytic applications. Journal of Photochemistry and Photobiology C: Photochemistry Reviews, 52, 100487.
5. Singh, P., Shukla, A., & Sharma, S. (2023). Biosynthesis of metal nanoparticles using microorganisms: A comprehensive review. Biotechnology Advances, 52, 107898.

Course Code and title: BT-612-MJ Crop Biotechnology

Credits: 2 **Total Lectures: 30**

Course outcomes:

On completion of course students will be able to,

1. Generate awareness to various biotechnological methods used in the field of agriculture.
2. Learn and applyknowledge of molecular assays for characterizing and improvement of crops.
3. Know future opportunities in this important sector of national economy.

Units	Topics	Number of Lectures
I	**Introduction to Crop Biotechnology** • Importance of Agriculture at national economy • Advantages of biotechnological methods over conventional methods of crop improvement. • *In-Vitro* Plant propagation- Success stories a) Virus indexing, virus free plants by Meristem tip culture b) Diplodization of haploids for generating homozygous lines c) Synthetic seed production d) Endosperm culture & production of triploids for production of seedless plant varieties e) Somatic hybrids for overcoming sexual barriers f) Commercial micro propagation of horticulturally important crops • Use of bioreactors for secondary metabolite production and Scale-up for Commercialization • Beneficial microorganisms in Agriculture: Bio fertilizer (Bacterial, Cyanobacterial and Fungal), microbial Bio insecticides • Major pest and diseases of horticultural crops and their control by Biotechnological 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** • 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	9
IV	**Development and formulation (with various carrier materials) of bioinoculants, for better Agricultural productivity, using:** • Growth promoting substances • Nitrogen fixation • Phosphate solubilization	8

	• Metal chelation, (siderophores) • Growth hormone producing microorganisms **Agricultural biotechnology and agribusiness** **Opportunities in the Agriculture Biotechnology**	

References:

1. Newbury HJ, Plant molecular breeding, (2009), , John Wiley and Sons., USA.
2. Ashwani Kumar, Plant tissue culture and molecular a. Markers: their role in improving crop productivity, 2009, , Shekhawat NS – (IK International)
3. H K Das, Biotechnology, 4th edition, (2010), Wiley India Pvt. Limited, India
4. , Slater A,Scott, Plant Biotechnology: the genetic manipulation of plants, 2008 NW,(Oxford Press)
5. Grierson D, Plant Genetic Engineering, 2012, Springer Netherlands.
6. Primose SB & Twyman RM, Principles of Gene Manipulation and Genomics, 2006, 7th Ed. Blackwell Publishing.
7. Arie Altman and Paul Hasegawa, Plant Biotechnology and Agriculture, 2011, Elsevier Publications (1st Ed)
8. Nag and Ahindra Textbook of Agricultural Biotechnology, 2008,

Course Code and title: BT-613-MJP Practicals in Crop Biotechnology

Credits: 2 **Total Practicals: 15**

Course Outcomes:

On completion of coursestudents will be able to,

1. Plan and execute tissue culture techniques for improvement of crop species
2. Get hands on training on conducting pot trials of bioinoculants
3. Get accustomed to web resources for use in plant genotyping and CRISPR-CAS technology

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

References:

1. Ashwani Kumar, Shekhawat NS, Plant tissue culture and molecular a. Markers: their role in improving crop productivity, 2009, IK International
2. H K Das, Biotechnology, 4th edition, 2010, Wiley India Pvt. Limited, India
3. Slater A, Scott NW, Plant Biotechnology: the genetic manipulation of plants, 2008, (Oxford Press)
4. Fowler MR Green MR &Sambrook J, Molecular Cloning: A Laboratory Manual. 4th Ed. Vol. I, II & III, 2014, Cold Spring Harbor Laboratory Press.

Course Code and Title: BT-631-RP Research Project

Credits: **4**

Course outcome:

1) Learners will gain knowledge on research and will gain hands on experience on any selected topics in the field of Biotechnology.

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 Third 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.

References:

1. Best Approach to Thesis and Scientific Writing; Methodology and Results Presentation, Philip Walters, 2018.
2. Scientific thesis writing and paper presentation, Gurumani N. MJP Publisher, 2021.

Semester IV

Course Code and title: BT-651-MJ Genomics & Proteomics
Credits: **4** **Total Lectures: 60**

Course outcome:
1. Students will learn various genomics approaches with appropriate examples.
2.Gain knowledge about different types of microarrays and their applications.
3. Get exposure about various proteomics approaches with explanatory examples.
2. Acquire knowledge about different types of techniques used in proteomics.

	Genomics	
Units	**Topics**	**Number of Lectures**
1	Genomics and Proteomics overview, omes and omics. Concepts and applications of 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.	14
2	**Transcriptomics and Microarray** Introduction to transcriptomics and expression profiling. DNA and RNA Microarray –Preparation, working and analysis Microarray databases and bioinformatics tools. Investigative techniques –EST, SAGE, SNP, MPRAs.	10
3	**Applications of genomics** Metagenomics. Toxicogenomics. Pharmacogenomics. Basic research Medical Genetics.	6
	Proteomics	
4	Introduction & concept of proteomics, Protein structure-function relationship. **Types of Proteomics**: Expression proteomics, Structural Proteomics, Functional Proteomics.	5
5	**Techniques in Proteomics** Protein Isolation and Separation techniques. Structural analysis of proteins- X-ray crystallography and NMR spectroscopy. 2 D electrophoresis. Peptide mapping & sequencing.	12

	Protein structure prediction- homology modelling. Mass Spectrometry: MALDI_TOF, ESI Tandem, Ion Trap, Peptide mass fingerprinting. LC-MS, (SILAC) - Radio-labelling, Chemical tagging.	
6	**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
7	**Applications** Health care**,** Biomarkers in disease diagnosis, Biomarker-drug development and their target identification. Identification and characterization of novel proteins.	5

Reference Books:

1. Aastha Sobti, Manishi Mukesh, RC Sobti- Genomics, Proteomics, and Biotechnology, 2022
2. Jonathan Pevsner- Bioinformatics and functional genomics, 3rd Edition, 2022
3. AnnekeLucassen, Tom Strachan- Genetics and Genomics in Medicine, 2nd Edition, 2022
4. P.K. Gupta- Biotechnology and genomics, 2019
5. George Wright- Fundamentals of Proteomics, 2022
6. SudheerAwasthi- Introduction to Proteomics, 2022
7. Belinda Pitman- Proteomics: Technology, Analysis and Applications, 2019
8. Steven Tiff- Advanced Principles of Proteomics, 2019

Course Code and title: BT-652-MJ Advanced Bioanalytical Techniques
Credits: **04** **Total Lectures: 60**

Course Outcomes:

1. Students will understand the Principles of various Bioanalytical techniques, their working and instrumentation.
2. Students can use Bioanalytical techniques in research work to study biomolecules.

Units	Topics	Number of Lectures
1	**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, phase contrast microscopy, confocal microscopy, fluorescence microscopy Single cell imaging.	15
2	**Histochemical and Immunotechniques** • Antibody generation, Detection of antigen using ELISA, RIA, Western blot • Immunoprecipitation, Flowcytometry and FACS • Detection of antigens in living cells (Stem Cell Markers) • *insitu* localization by techniques such as FISH and GISH.	15
3	**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 surface plasma resonance methods.	15
4	**Advanced Chromatography and Electrophoretic technique:** • Introduction, principle and applications of HPTLC, HPLC, UHPLC GLC, GC-MS • Affinity chromatography: Principle, types, Application, • IF and 2 D electrophoresis, Capillary Electrophoresis, DGGE (Denaturing gradient gel electrophoresis)	15

References:

1. Wilson and Walker's Principles and Techniques of Biochemistry and Molecular Biology, 8th edition, 2018
2. Biophysical chemistry by Upadhyay, Upadhyay and Nath, Himalaya publication house, 4th edition, January 2020
3. Willard and Merrit, Instrumental Methods and Analysis, 7th edition 2004
4. Vogel's, Text Book of Quantitative Chemical Analysis, 6th Edition, 2004.
5.Raymond P. W. Scott, Techniques and Practice of Chromatography, 1st edition –e BooK March 2020

6. Steven R.,Ordoukhanian, Phillip, Salomon, Daniel R- Next Generation Sequencing Methods and Protocols, 2018.
7. Xinkun Wang- Next-Generation Sequencing Data Analysis 1st Edition CRC Press 2020.

Subject code and Title: BT-653-MJ Quality Control, Bioethics and IPR

Credits: **4** **Total Lectures: 60**

Course outcome:

By the end of this course students will be able;

1. To gain knowledge of quality control and documentation required in industry
2. To understand ethical aspects of work in biotechnology
3. Learn forms of IP and the importance of IPR guidelines to be followed in biotechnology and in-general

Unit	Topics	Number of Lectures
	Quality control	
I	**Quality Standard & Quality assurances:** • Concept of Quality Assurance & Quality Control their function and advantage, quality assurance and quality management in Biotech Industry • Critical quality point in different stages of production including raw materials & processing material • Types of validation in pharma industry, Importance of validation, Elements of validation (Q, OQ, PQ, DQ) • Toxicity, clinical trials studies, clinical research & clinical data management	10
II	**Risk Assessment and Management:** • Risk assessments to identify potential hazards associated with QA and QC activities and implementing appropriate risk management measures to mitigate these risks. • Implementation of containment strategies, • Establishment of emergency response protocols, and • Development of contingency plans for dealing with accidents or incidents.	5
III	**Essential Documents & Regulatory Submission, Compliance and Audits**– • Preparation, production and quality control of regulatory documents, creating editorial time lines 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 art work used in regulatory document • Regulatory requirements for biotech/pharma product development	10

	Bioethics	
IV	**Introduction** • Introduction to Ethics and Bioethics, Framework for ethical decision making • National Ethical Guidelines for biomedical and health research • Bioethical issues related to healthcare & medicine, food & agriculture, genetic engineering	10
V	**Ethical Issues:** • Animal 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 in India - Blue cross society, Society for prevention of cruelty against Animals. • CPCSEA committee, Ethical limits of animal use • Publication ethics and regulations • Biodiversity	10
	Intellectual Property Rights (IPR)	
VI	**Intellectual property rights (IPR):** • Introduction to intellectual property rights. • Forms of IP- Patent, Copyright, Trademark, Geographical Indications, Industrial Design, Trade Secrets • Farmers Rights, Animal and Plant breeders rights • WIPO, WTO agreement, TRIPS, Patent Cooperation treaty. • Patent system in India • Basic requirements of patentability, patentable subject matter, novelty, the Public Domain, Non-obviousness, compulsory licensing, Patent infringements and revocation. • Special issues in Biotechnology Patents: Disclosure Requirements, Collaborative research, competitive research, Patent Litigation: Recent Development in Patent System; Patentability of biotechnology invention and its commercialization • Budapest Treaty on international recognition of the deposit of microorganisms	15

Reference Books:

1. CVS Subramanyam and J Thimmasetty, (2013), Pharmaceutical

Regulatory Affairs - Selected Topics, Vallabh Prakashan Delhi
2. Deepa Goel & Shomni Parashar, (2013), IPR, Biosafety and Bioethics, published by Pearson Education India
3. Alexander I. Poltorak; Paul J. Lerner Wiley, 2011 (2nd edition) Essentials of Intellectual Property: Law, Economics, and Strategy
4. Deepa Goel and Shomini Parashar, Pearson; 1st edition (1stJanuary2013), IPR, Biosafety and Bioethics,
5. Kshitij Kumar Singh, Biotechnology and Intellectual Property Rights : Legal and Social Implications Springer (India) (2014)
6. M.K. Sateesh, 2008, Bioethics and Biosafety, International Publishing House Pvt. Ltd.
7. Matthew Rimmer, 2008, Intellectual Property and Biotechnology: Biological Inventions
8. Rajmohan Joshi (Ed.), 2006, Biosafety and Bioethics. Isha Books, Delhi.
9. Sasson A, Biotechnologies and Development, UNESCO Publications.
10. Wadehra,B.L., (2011), Law Relating To Intellectual Property, Fifth Edition, Universal Law Publishing Co. Pvt. Ltd.

Subject Code and title: BT-660-MJ Systems Biology
Credits: 2 **Total Lectures: 30**

Course Outcomes:
On completion of course students will be able to,

1. know key ideas and tools of Systems Biology
2. understand genome, transcriptome, proteome, metabolome and interactome level information.
3. comprehensively understand physiology, metabolic and gene regulatory networks and work with them

Units	Topics	Number of Lectures
I	**Systems Biology – Fundamentals** Systems Biology-Introduction. Overview of genome, transcriptome, proteome, metabolome and interactome. Gene Control- Mechanisms at Transcriptional and Translational Levels. Genetic Switches. Biochemical, Genetics and Systems Biology Paradigms.	5
II	**Systems Microbiology and Developmental Systems Biology** Quorum Sensing – The Language of Bacteria, Quorum Sensing in Gram Negative and Gram Positive Bacteria. Hybrid Quorum Sensing in Vibrio harveyi – Two Component Signaling. Programmed Population Control by Cell –Cell Communication and Regulated Killing. Drosophila melanogaster – Life Cycle, Morphogen Gradient. Establishment of Developmental Precision and Proportions in the Early Drosophila Embryo.	8
III	**Gene Expression Networks** Transcription Networks. Networks in Biology - Network Motifs. Feed Forward Loops in Biological Systems. Coherent Feed Forward Loops. Kinetics of Coherent FFLs-Sign sensitive delay circuits. Noise in Gene Expression, Quantifying Noise in Gene Expression, Noise in Gene Regulatory Networks, Noise based Switches and Amplifiers for Gene Expression.	12
IV	**Tools for Systems Biology** Pathway Mapping through KEGG. Cytoscape. Virtual Cell. Other relevant bioinformatics tools.	5

References:

1. Alon, Uri. An Introduction to Systems Biology-Design Principles of Biological Circuits. CRC Press, 2nd edition 2020.
2. Junker, Bjorn H.; Schreiber, Falk (ed).Analysis of Biological Networks. John Wiley & Sons, 2008.
3. Ingalls, Brian P. Mathematical Modeling in Systems Biology: An Introduction (1st edition). MIT Press, 2013.

Subject code and Title: BT-661-MJ Clinical Research and Database Management
Credits: **2T**

Total Lectures: 30

Course Outcomes:

On completion of course students will be able to,

1) Understand the fundamental concepts and phases of clinical trials.
2) Learn about the regulatory framework governing clinical research.
3) Gain insights into ethical considerations and patient safety in clinical trials.
4) Develop skills in designing clinical trial protocols and selecting appropriate endpoints.
5) Learn about data collection, management, and analysis techniques.
6) Understand the principles of Good Clinical Practice (GCP) and quality assurance in clinical trials.

Units	Topics	Number of Lectures
	Clinical Research	
I	**Introduction to Clinical Trials** Overview of clinical research Historical perspective and evolution of clinical trials Phases of clinical trials Importance of clinical trials in biotechnology **Regulatory aspects in Clinical Trials** Regulatory agencies and their roles (FDA, EMA, etc.) Regulatory requirements for clinical trials Investigational New Drug (IND) application process Institutional Review Boards (IRBs) and ethics committees	5
II	**Ethical Considerations and Patient Safety** Principles of bioethics in clinical research Informed consent process Protection of human subjects Monitoring and reporting adverse events Trial Design and Endpoints Types of clinical trial designs (randomized controlled trials, observational studies, etc.) Selection of study endpoints (primary, secondary, surrogate) Sample size calculation and power analysis Randomization and blinding Protocol Development Components of a clinical trial protocol Writing clear and concise study objectives and hypotheses Selection and recruitment of study participants Study procedures and interventions	5

III	**Good Clinical Practice (GCP) and Quality Assurance** Principles of GCP Responsibilities of investigators, sponsors, and monitors Site selection, initiation, and monitoring visits Audits and inspections	2
	Database management	
IV	**Concept of Database and Clinical Data Management** Data Collection and Management, Concept and designing of Database, Case report form (CRF) design Data collection methods (electronic data capture, paper-based) Quality control and data validation Data management & IT in clinical research Data management systems and software Data Analysis and Interpretation Statistical methods for analyzing clinical trial data Interpreting study results Publication and dissemination of trial findings Dealing with missing data and biases Query raising and query resolution EDC System and 21 CFR Part 11 compliance Practical for Protocol Design, CRF Design and source documentation	13
V	**Clinical data management systems** Electronic data capture systems, Choosing vendor products, Implementing new systems, Clinical data analysis, Importing data from Excel to SAS, Statistical analysis of SAS datasets. Standard operating procedures and guidelines for data Management.	5

References:

1. Shein-Chung Chow, Jen-Pei Liu, and Hansheng Wang, 2004, Design and Analysis of Clinical Trials: Concepts and Methodologies
2. Duolao Wang, Ameet Bakhai, and Shein-Chung Chow, 2006, Clinical Trials: A Practical Guide to Design, Analysis, and Reporting
3. Good Clinical Practice: A Question & Answer Reference Guide by NCURA (National Council of University Research Administrators) 2021.
4. Regulatory guidelines and documents from FDA, EMA, and ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) 2023.
5. Katzung, B.G., 2010, Basic and Clinical Pharmacology, Prentice hall International
6. National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017)
7. E6 Good Clinical Practice. Code, Document Title, Previously coded. E6(R2) Good Clinical Practice(GCP). Finalised Integrated Addendum: November 2016.
8. New Drugs and Clinical Trials Rules 2019

Subject code and Title: BT-662-MJ Drug Development

Credits:**2** **Total Lectures: 30**

Course outcome:

By the end of this course students will be able.

1. To understand the fundamental concepts and principles of drug development in the context of biotechnology.
2. To know the stages of drug development, including target identification, lead discovery, preclinical testing, clinical trials, and regulatory approval.
3. To explore various biotechnological techniques and platforms used in drug discovery and development.
4. To analyze the challenges and ethical considerations associated with drug development.
5. To develop critical thinking and problem-solving skills through case studies and practical exercises.

Unit	Topics	Number of Lectures
I	**Introduction to Drug Development** • Overview of drug development process • Historical perspective and current trends in biotechnology-based drug development	2
II	**Target Identification and Validation** • Molecular targets in drug discovery • Techniques for target identification and validation • Biomarkers and their role in target validation **Lead Discovery and Optimization** • High-throughput screening techniques • Rational drug design approaches • Lead optimization strategies	8
III	**Preclinical Development** • In vitro and in vivo preclinical testing • Pharmacokinetics and pharmacodynamics studies • Safety assessment and toxicology studies **Clinical Development: Phase I and Phase II Trials** • Overview of clinical trial phases • Design and implementation of Phase I and Phase II trials • Biomarker development and patient stratification **Clinical Development: Phase III Trials and Regulatory Approval** • Design and execution of Phase III trials • Regulatory submission process and approval pathways • Post-marketing surveillance and pharmacovigilance	10
IV	**Biotechnology in Personalized Medicine** • Precision medicine approaches in drug development • Companion diagnostics and targeted therapies **Commercialization and Market Access**	10

	• Market analysis and commercialization strategies • Health economics and market access considerations • Intellectual property protection and technology transfer **Ethical and Regulatory Considerations** • Ethical issues in drug development • Regulatory compliance and Good Clinical Practice (GCP) • Patient rights and informed consent	

References :

1. Kewal K. Jain Principles of Drug Development in Transplantation and Autoimmunity 2017
2. SA Dugger Drug development in the era of precision medicine 2018.
3. Rodney J. Y. Ho and Milo Gibaldi Biotechnology and Biopharmaceuticals: Transforming Proteins and Genes into Drugs 25 Oct 2013
4. Steven Piantadosi Clinical Trials: A Methodologic Perspective 9 Oct 2017.

Course Code and title: BT-663-MJ Molecular Mechanisms of Development
Credits: 02 **Total Lectures: 30**

Course Outcome:
On completion of course students will be able to,

1. Understand fundamental concepts of animal growth and development
2. Realize the importance of molecular tools to decode the developmental processes
3. Acquire knowledge of various genes during the course of development and apply it during experimentation

Units	Topics	Number of Lectures
I	**Introduction** • Principles of growth and development in animals • Roles of molecular tools to decipher developmental processes • Use of *invitro* methods to study development • Gametogenesis and Fertilization in Sea urchin and mammals • Activation of egg metabolism- Release of $Ca^{++}$and its role • Fusion of genetic material • Cytoplasmic rearrangement and its significance **Cleavage and Gastrulation mechanisms in vertebrate and invertebrate model systems with regulation of various genes:** frog, chick, mouse, Drosophila embryos Cell signaling pathways for embryonic development	15
II	**Pattern formation during embryonic development in following model organisms: (dorsal-ventral, anterior-posterior and left- right axes specifications)** • Drosophila– detailed studies on Maternal effect and zygotic genes including gap genes, pair rule genes, segment polarity genes and homeotic genes • Frog • Chick • Mouse • Concept of Primary embryonic induction- Role of BMP and its antagonists Post-embryonic developmental events – metamorphosis, Regeneration	15

References:

1. Barresi M.J.F. and Gilbert S.F. Development Biology, 13th edition, (2023), (Sinauer Associates, USA)
2. Wolpert L, Tickle C, A. M. Arias Principles of Development, 6th edition (2019),. Oxford University Press, USA.
3. B. I. Balinsky, B.C. Fabian An introduction to embryology, 5th edition, (2012) Cengage Learning India

Course Code and Title: BT-681-RP Research Project

Credits: **6**

Course outcome:

1) Learners will gain knowledge on research and will gain hands on experience on any selected topics in the field of Biotechnology.

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 project 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.

References:

1. Philip Walters Best Approach to Thesis and Scientific Writing; Methodology and Results Presentation, , 2018.
2. Gurumani N. Scientific thesis writing and paper presentation, MJP Publisher, 2021.