CHAITANYA BHARATHI INSTITUTE OF TECHNOLOGY (A)

Department of Bio-Technology

Scheme of Instructions of VII Semester of B. Tech Bio-Technology as per AICTE Model Curriculum 2022-23

B.Tech (Bio-Technology)

SEMESTER VII

S. No.	CourseCode	Title of the Course	Scheme of Instruction			Scheme of Examination			Credits
			Hours Per week			Durationof SEE in Hours	Maximum Marks		
			L	T	P		CIE	SEE	
THEORY									
1		**Professional Elective - III**	3	-	-	3	40	60	3
2		**Professional Elective - IV**	3	-	-	3	40	60	3
3		**Professional Elective - V**	3	-	-	3	40	60	3
4		**Open Elective – II**	3	-	-	3	40	60	3
5	20EGMO4	Gender sensitization	2	-	-	2	-	50	Non-Credit
PRACTICALS									
6	20BTC33	Project Part-I	-	-	4	-	50	-	2
7	20BTI03	Internship	4-6weeks/ 180hours			-	-	50	3
Total			**14**	**0**	**4**				**17**
Clock Hours Per Week – 18									

L: Lecture T: Tutorial P: Practical
CIE – Continuous Internal Evaluation SEE - Semester End Examination

Professional Elective–III (Plant and Animal Biotechnology)	
20BT E10	Tissue Engineering
20BT E11	Genome Editing
20BT E12	Photochemical and Herbal Products
20BT E13	Developmental Biology

Professional Elective–IV (Industrial applications of Biotechnology)	
20BT E14	Food Biotechnology
20BT E15	Nanobiotechnology
20BT E16	Good Manufacturing Laboratory Practice
20BT E17	Regulatory Affairs and Clinical Trials

Professional Elective–V (Computational Biology)	
20BT E18	Rational Drug Discovery
20BT E19	Molecular Modeling and drug design
20BT E20	Structural Biology
20BT E21	Genomics and Proteomics

TISSUE ENGINEERING
(Professional Elective -III)

Instruction	3 L Hours per week
Duration of SEE	3 Hours
SEE	60 Marks
CIE	40 Marks
Credits	3

Course Objectives

1. To provide fundamental principles and elements of tissue engineering.
2. To get an insight into the roles of cells, tissue organization, and matrix in tissue engineering.
3. To learn the tissue culture techniques and scale-up designs.
4. To learn the different biomaterials used for the fabrication of scaffolds.
5. To gain knowledge about the therapeutic applications of tissue engineering.

Course Outcomes:

At the end of the course, students will be able to

1. Outline the concepts of tissue engineering, ethical issues, and future prospects
2. Illustrate the molecular mechanisms at the tissue level and in cell-matrix in tissue engineering.
3. Identify in vitro culturing techniques and scale-up designs.
4. Classify the compatible biomaterials used for the fabrication of scaffolds in Tissue engineering.
5. Summarize the therapeutic applications of tissue engineering.

Mapping of Course Outcomes with Program Outcomes and Program Specific Outcomes:

PO / CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2
CO1	1	1	-	-	1	2	-	3	-	1	1	1	2	2
CO2	1	-	-	2	1	-	-	-	-	1	-	1	3	3
CO3	2	1	1	2	1	2	1	-	-	1	1	2	3	3
CO4	2	1	1	2	2	-	1	-	-	1	1	2	3	3
CO5	1	1	1	2	1	2	1	1	-	1	1	2	3	3

UNIT-I

Introduction to Tissue Engineering: Basic definition of Tissue engineering; origin and history of Tissue Engineering, an overview of its basic steps and its applications; General scientific issues, Ethical issues; Current challenges and future prospective.

UNIT-II

Cells and Tissue Organization: Cells-cell growth and death; cell differentiation; Cells in tissues and organs. Cell to cell interactions; cell adhesion molecules (CAM) Organization of cells into higher ordered structures- Mesenchymal cells; EMT, Molecular mechanisms and control of EMT process. Tissues-Vascularity; angiogenesis; wound healing Extracellular matrix (ECM) –components.

UNIT-III

Biomaterials of Tissue Engineering: Biomaterials Properties, Types of Biomaterials, Biological polymers; Synthetic polymers; a hybrid of synthetic and biological polymers; Scaffolds, 3D scaffolds, Scaffold fabrication conventional techniques: Solvent casting, porogen leaching, freeze drying, electro spinning and 3D bio-printing.

UNIT-IV

Functional Tissue Engineering: Cell and tissue culture- media; culture initiation; transformation and immortalization; validation; differentiation; maintenance of cells in vitro; cryopreservation. Stem cells in tissue engineering Bioreactors for tissue engineering- Bioreactor design requirements; Spinner flask bioreactors. Rotating-wall bioreactors, Compression bioreactors, Strain bioreactors, Hydrostatic pressure bioreactors, Flow perfusion bioreactors and combined bioreactors.

UNIT-V

Applications of Tissue Engineering: Tissue replacement –crucial factors, Skin tissue engineering, Bone tissue engineering; Cardiac tissue engineering; Neural tissue engineering; Vascular tissue engineering; Lab on chip/Organ on chip technology.

Text Books:

1. Robert.P.Lanza, Robert Langer & Vacanti, Principles of tissue engineering. Academic Press. 4th edition 2014.
2. B. Palsson, J.A. Hubbell, R. Plonsey & J.D. Bronzino. Tissue engineering. CRC Taylor & Francis press 2003.
3. B. Palsson & S.N. Bhatia. Tissue engineering. Pearson Education India Education Services Pvt. Ltd. 2016.

Suggested Reading:

1. Atala O.P &Lanza.L, Methods of tissue engineering. Woodhead Publishing Ltd. Cambridge. UK. 2009.

GENOME EDITING
(Professional Elective -III)

Instruction	3 L Hours per week
Duration of SEE	3 Hours
SEE	60 Marks
CIE	40 Marks
Credits	3

Course Objectives:

1. To learn Genome editing and its tools for genome engineering
2. To understand the genome editing strategy and target site
3. To know the genome editing tools applications in plant, animals and industry
4. To understand the emergent challenges for CRISPR technologies

Course Outcomes:

At the end of the course, students will be able to

1. Outline the Genome editing and its tools for genome engineering
2. Describe the genome editing strategy and target site
3. Explain the Genome editing in Plants for crop improvement
4. Discuss the Genome editing in animals and for human welfare
5. Summarize the application genome editing and emergent challenges for CRISPR technologies

Mapping of Course Outcomes with Program Outcomes and Program Specific Outcomes:

PO / CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2
CO1	1	-	-	-	-	2	-	-	-	1	-	1	1	1
CO2	1	-	-	-	-	2	-	-	-	1	-	1	1	1
CO3	1	-	-	-	-	2	-	-	-	1	-	2	1	1
CO4	1	-	-	-	-	2	-	-	-	1	-	2	1	1
CO5	1	-	1	-	-	2	-	3	-	1	-	2	1	1

UNIT-I

Introduction to Genome Editing and its tools: Overview of traditional methods: homologues recombination for gene knockout. RNAi system, Cre-LoxP and Flp-FRT systems. Engineered enzyme systems: Zinc finger nucleases (ZFNs), transcription-activator like effector nucleases (TALEN), meganucleases and the clustered regularly interspaced short palindromic repeats(CRISPR/Cas9) system.

UNIT-II

Genome editing strategy and target site: Gene Knockout with single site targeting, Gene Knockout with double sit targeting, Gene Knockout via sequence insertion and the problem of noncoding RNAs, Inserting or correcting mutations, inserting a gene or other DNA Sequence. Design of sgRNA. Multiplex Automated Genomic Engineering (MAGE).

UNIT-III

Genome editing in Plants for crop improvement: The history of targeted mutations in plants. Use of ZFNs and TALENs as early tools for genome editing. Discovery of CRISPR-Cas system and its applications. GM plants, Recent innovations in the technology and case studies where CRISPRC as has been used for plant improvement. Regulaory approaches for genome edited crops.

UNIT-IV

Genome editing in Animals: Therapeutinc Genome editing – Ex Vivo therapeutic genome and in vivo therapeutic genome editing, creating chromosome rearrangement, Study gene function with stem cells, Transgenic animals, Endogenous gene labeling, targeted transgene addition,

UNIT-V

Genome Editing Applications: Genome editing of Algal species by CRISPR Cas9 for Biofuel production, genome editing its role in bioremediation; Devlopment and use of CRISPR in Industrial applications, Emergent challenges for CRISPR : Ethics, Biosafety and risk of targeted gene editing, Biosecurity, Patenting CRISPR Technologies and products, regulator issues with CRISPR products.

Text Books:

1. CRISPR Gene Editing, Methods and Protocols, Editors: Luo, Yonglun (Ed.)
2. Genome Editing and Engineering, From TALENs, ZFNs and CRISPRs to Molecular Surgery. Edited by Krishnarao Appasani.

Suggested Reading:

1. Progress in Molecular Biology and Translational Science Vol 149-Genome Editing in Plants. Edited by Donald P. Weeks and Bing Yang. Academic Press.
2. Precision Medicine, CRISPR, and Genome Engineering, Moving from Association to Biology and Therapeutics, Editors: Tsang, Stephen H. (Ed.). Springer

20BT E12 **With effect from the Academic year 2023-24**

PHYTOCHEMICALS AND HERBAL PRODUCTS
(Professional Elective -III)

Instruction	3 L Hours per week
Duration of SEE	3 Hours
SEE	60 Marks
CIE	40 Marks
Credits	3

Course Objectives:

1. To impart knowledge on medicinal plants and the extraction of crude drugs.
2. To provide comprehensive knowledge on analysis, types, and detection of phytochemicals and adulterants.
3. To impart knowledge on the applications of various phytochemicals and herbal products.

Course Outcomes:

At the end of the course, the students are able to

1. Classify the sources of various crude drugs and their medicinal values.
2. Outline the procedures involved in the detection, extraction, and analysis of crude drugs and adulterants.
3. Interpret the structure, types and extraction procedure of different plant secondary products.
4. Outline the applications of phytochemicals.
5. Discuss the various aspects of herbal products and licensing of herbal drugs

Mapping of Course Outcomes with Program Outcomes and Program Specific Outcomes:

PO / CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2
CO1	-	-	-	-	-	-	-	-	-	1	-	1	1	2
CO2	-	1	-	-	2	-	-	-	-	-	-	1	3	3
CO3	-	1	-	1	2	-	-	-	-	-	-	1	3	3
CO4	-	-	-	-	-	-	-	-	-	-	-	-	1	1
CO5	-	-	-	-	-	2	1	2	-	-	-	-	2	2

UNIT-I

Crude Drugs, Medicinal And Aromatic Plants: Crude Drugs - Scope and Importance, Classification (Taxonomical, Morphological, Chemical, Pharmacological); Collection and processing of Crude Drugs; Utilization of Medicinal and Aromatic Plants in India; Genetics as applied to Medicinal herbs; Biogenesis of Phytopharmaceuticals.

UNIT-II

Analysis Of Phytochemicals: Methods of Drug evaluation (Morphological, Microscopic, Physical and Chemical); Preliminary screening, Assay of Drugs - Biological evaluation/assays, Microbiological methods, Chemical Methods of Analysis and Detection of Adulterants: Chemical estimations; Drug adulteration - Types of adulterants.

UNIT-III

Types Of Phytochemicals: Carbohydrates and its derived products- Structures, types and extraction methods: Glycosides - Digitalis, Aloe, Dioscorea; Volatile Oils - Clove, Mentha; Alkaloids - Taxus, Papaver, Cinchona; Flavonoids-and Resins; Tannins (Hydrolysable and Condensed types).

UNIT-IV

Applications Of Phytochemicals: Application of phytochemicals in industry and healthcare; Biocides, Bio- fungicides, Biopesticides.

UNIT-V

Herbal Products: History, Scope, and Current aspects of herbs and herbal medicines; Classification of active components of therapeutic plant and herbal products; Preparation of standardized extracts of Garcinea, Forskolin, Garlic, Turmeric and Capsicum, issues of licensing of herbal drugs.

Text Books:

1. Kokate CK, Purohit AP and Gokhale SB, "Pharmacognosy", 4th edition, NiraliPrakashan, 1996.
2. Trease and Evans WC Evans, "Pharmacognosy", 14th edition, Harcourt Brace & Company. 1989.
3. Hornok L, "Cultivation & Processing of Medicinal Plants" Chichister, U. K: J. Wiley & Sons.1992.

Suggested Reading:

1. Natural Products in medicine: A Biosynthetic approach Wiley. 1997
2. Chaudhri RD, "Herbal Drugs industry, A practical approach to Industrial Pharmacognosy" Eastern publishers, 2nd reprint, New Delhi. 1999.

DEVELOPMENTAL BIOLOGY
(Professional Elective -III)

Instruction	3 L Hours per week
Duration of SEE	3 Hours
SEE	60 Marks
CIE	40 Marks
Credits	3

Course Objectives:

1. Students are made to understand the basic concepts of developmental biology.
2. Students are taught the structure of gametes, and how they are generated.
3. Students are taught the influence of genes on body axis formation in Drosophila and Mammals.
4. Students are enlightened about the later embryonic developments i.e. Organogenesis.
5. Students are made aware of sex determination in Drosophila and Mammals.

Course Outcomes:

At the end of the course, the students are able to

1. Discuss basic concepts of Developmental Biology.
2. Describe the anatomy of gametes and biochemistry involved in gamete recognition
3. Analyze the role of genes in the body axis formation of drosophila.
4. Outline the importance and differentiation of germinal layers into different organs and compare the role of genes in the sex determination of Drosophila and Mammals.
5. Explain the genetic anomalies that lead to diseases.

Mapping of Course Outcomes with Program Outcomes and Program Specific Outcomes:

PO / CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2
CO1	1	1	-	2	1	2	1	3	-	2	-	3	1	2
CO2	1	-	-	1	1	2	1	3	-	2	-	3	1	2
CO3	1	-	-	1	1	2	1	3	-	2	-	2	1	2
CO4	1	-	-	1	1	2	1	3	-	2	-	2	2	2
CO5	1	1	-	1	1	3	3	3	-	2	-	2	2	2

UNIT-I

Introduction to Developmental Biology: Overview of anatomical approach, Evolutionary Embryology, Medical embryology & teratology, Mathematical modeling for development, Stages of animal development: The Frog life cycle, Development dynamics of cell specification (Autonomous, Conditional, Syncytial and Morphogenetic Gradients), Induction and Competence.

UNIT-II

Gametogenesis and Fertilization in Mammals: Structure of Gametes: Sperm, Egg, Spermatogenesis and oogenesis in Mammals, Recognition of egg and sperm, Mammalian Fertilization (Fusion of Gametes and prevention of Polyspermy).

UNIT-III

Drosophila Embryonic Development: Early Drosophila developments: Fertilization, Cleavage, Gastrulation, Segmentation and the Anterior-Posterior body plan, Segmentation genes (Gap Genes, pair rule genes and segment polarity genes), The Homeotic selector genes, Generating Dorsal-Ventral axis.

UNIT-IV

Organogenesis and Sex Determination: The emergence of Ectoderm-The Central nervous system and Epidermis, Mesoderm – Osteogenesis and Myogenesis, Lateral plate mesoderm and endoderm – the Heart, Blood cells, Endoderm - Digestive tube and Respiratory tube, Sex determination in Drosophila and Mammals.

UNIT-V

Ramifications of Developmental Biology: Medical Implications of Developmental biology: Genetic errors of human development, Infertility, In Vitro fertilization (IVF) and Teratogenesis (disruptors of teratogenesis), Developmental biology and future of medicine.

Text Books:

1. ManjuYadav, "Molecular Developmental Biology" Discovery Publishing, September, 2008.
2. Scott F Gilbert, Michael JF Barresi. "Developmental Biology", 11th edition, Sinauer Associates, Inc, 2013.

Suggested Reading:

1. Snustad P, Simmons and Jenkins, "Principles of Genetics", 2nd Edition, John Wiley Publications, 1999.
2. P.C.Jain , "Elements of Developmental Biology" International Publications, 2013.

FOOD BIOTECHNOLOGY

(Professional Elective -IV)

Instruction	3 L Hours per week
Duration of SEE	3 Hours
SEE	60 Marks
CIE	40 Marks
Credits	3

Course Objectives:

1. Student is made to understand the importance of food biotechnology and its nutritive value.
2. Students are taught the types of food available in the nature and its consumption value.
3. Students made to understand the food spoilage.
4. Students are enlightened about the importance of food processing.
5. Students are made aware of chemical and physical methods of food processing.

Course Outcomes: At the end of the course the students are able to

1. Apply the fundamentals of food biotechnology to their real-life situation
2. Differentiate types of food and explain their nutritive value
3. Examine the types of pathogens and their effect on food
4. Demonstrate the physical and chemical methods of food processing.
5. Apply the techniques to preserve the food material to avoid food spoilage.

Mapping of Course Outcomes with Program Outcomes and Program Specific Outcomes:

PO / CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2
CO1	1	1	0	0	1	2	2	0	0	0	0	1	3	2
CO2	1	0	1	0	0	2	0	0	0	0	0	0	3	2
CO3	1	0	0	0	1	0	1	0	0	0	0	0	3	2
CO4	2	1	0	1	1	2	2	0	0	1	0	2	3	2
CO5	2	1	1	0	1	2	2	0	0	1	0	2	3	2

UNIT-I

Introduction To Food Biotechnology: Introduction to scope and importance of food biotechnology, Nutritive value of the food; Shelf life of food. Water relationships in foods: water activity and its relevance to deteriorative processes in foods (chemical, enzymic, physical and microbial changes). Lipids of biological importance like cholesterol and phospholipids. Food Pigments &Flavoring Agents: Importance, types and sources

UNIT- II

Food Products: Introduction to Probiotics, Nutraceuticals and GM foods; Processing and post-harvest technology of various food products (High Fructose Corn syrup, Single Cell Protein and Bakery Products, Milk Products). Fermented food: origin, scope and development, sourkraut, youghurt, cheese, miso, tempeh.

UNIT- III

Food Spoilage And Food Microbiology: Shelf life of food. Microbes found in raw materials and foods that are detrimental to quality, Factors that influence the development of microbes in food, Food spoilage by bacterial agents (Clostridium, Salmonella, Vibrio and Shigella), Non-bacterial agents (Protozoa, Algae, Fungi and Viruses)

UNIT- IV

Food Processing Applications: Principles and methods of food processing (freezing, heating, dehydration, canning, additives, fermentation, irradiation, extrusion cooking, dielectric heating). Enzymes and chemicals used in food processing for flavor development; Processing of meat, fisheries, vegetables, and dairy products. Food adulteration and food safety.

UNIT- V

Food Preservation: Application of sugar and salt, antimicrobial agents, biological agents, non-ionizing and ionizing radiations in preservation of foods. Basic concepts in thermal destruction of microorganisms D, Z, F values. Blanching, Pasteurization and Sterilization of foods. Controlled and Modified atmosphere storage of foods. Intelligent packaging concept.

Text Books:

1. Roger Angold, Gordon Beech & Taggart, Food Biotechnology1st edition, Cambridge End Press, 1989.
2. Frazier, William, C.Westhoff, Dennisc, Food Microbiology, 2nd Edition TATA Mcgraw Hill Publishers, 1989.

Suggested Reading:

1. Ashok Pandey, Biotechnology:Food Fermentation, Asia Tech Publishers Inc,New Delhi,1999.
2. J.M.Jay, M.J.Loessner and D.A.Golden, Modern food microbiology, 7th edition, Springer, 2006.
3. Romeo T. Toledo, Fundamentals of Food Process Engineering, 3rd edition, Springer, February, 2007.

NANO BIOTECHNOLOGY

(Professional Elective -IV)

Instruction	3 L Hours per week
Duration of SEE	3 Hours
SEE	60 Marks
CIE	40 Marks
Credits	3

Course Objectives

1. To introduce the concept of nanotechnology and nano-size
2. To gain knowledge on the synthesis and characterization of nanomaterials
3. To have awareness about different types of Nanostructures
4. To get familiarize with applications of nanobiotechnology in different fields

Course Outcomes

1. Discuss the multidisciplinary nature of nanotechnology and nanoscale paradigm in terms of properties at the nano scale dimension.
2. Describe different methods used for the synthesis and characterization of nanomaterials.
3. Interpret various types of nanostructures.
4. Summarize general applications of nanobiotechnology.
5. Outline the current applications of nanobiotechnology.

Mapping of Course Outcomes with Program Outcomes and Program Specific Outcomes:

PO / CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2
CO1	0	0	0	0	1	0	0	0	0	0	0	1	2	1
CO2	0	1	1	1	1	0	0	0	0	0	0	0	3	3
CO3	0	0	0	0	0	0	0	0	0	0	0	1	1	2
CO4	0	0	0	0	0	0	1	0	0	0	0	0	3	1
CO5	0	0	0	0	0	2	1	2	0	0	0	1	3	1

UNIT-I

Introduction and Significance of Nano Domain: Nanotechnology - A Historical Perspective, definition of nanoscale with special reference to biosystems, scope and future prospects of Nanotechnology, Nanobiotechnology and Bionanotechnology, Opportunities and Challenges in Bionanotechnology; Limitations of micron size, need for nano-size—surface volume ratio significance, significance and key feasstures of nano-size, comparison of particle behaviour at nano-size to Macro Size: Gold and Titania, advantages of scaling down—nano-size.

UNIT-II

Synthesis and Characterization of Nanomaterials: Synthesis of Nanomaterials – Top-down and bottom up approaches with examples, physical, chemical and biological methods, characterization of nanomaterials- Optical (UV-Visible/fluorescence), X-ray diffraction, Imaging and size- (Electron Microscopy- SEM, TEM), Atomic force microscopy, Scanning tunneling microscopy, Spectroscopy- NMR, Raman FT-IR and Plasma Resonance

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UNIT-III

Nanostructures: Smart materials, nanoscale biostructures, carbon nanotubes, nanowires, nanoflakes, nanoshells, quantum dots, dendrimers, micelles, nanosomes, liposomes, virosomes, polymersomes.

UNIT-IV.

General Applications of Nanobiotechology: Application of nanotechnology in medical diagnosis, drug discovery, drug development, drug delivery, Photodynamic Therapy.

UNIT-V

Current applications of Nanobiotechology: Application of nanotechnology in Protein Engineering, Tissue engineering, Agriculture, Environment, food processing, Nanotechnology and Nanoparticles: Clinical, Ethical, and Regulatory Issues.

Text Books:

1. Christof M. Niemeyer and Chad A. Mirkin, “Nanobiotechnology: Concepts, Applications and Perspectives” Wiley Publishers, April 2004.
2. Mark Ratner and Daniel Ratner, “ Nanotechnology: A Gentle Introduction to Next Big Idea”, Low Price edition, Third Impression, Pearson Education.

Suggested Reading:

1. David S Goodsell, “Bionanotechnology”, John Wiley & Sons, 2004.
2. DebasisBagchi, ManashiBagchi, Hiroyoshi Moriyama, Fereidoon S hahidi, “Bio-Nanotechnology: A Revolution in Food, Biomedical and Health Sciences” Wiley -Blackwell, 2013.
3. Elisabeth S P, Aravind P, “Bionanotechnology”, Morgan & Claypool publishers, 2007.

GOOD MANUFACTURING LABORATORY PRACTICE
(Professional Elective -IV)

Instruction	3 L Hours per week
Duration of SEE	3 Hours
SEE	60 Marks
CIE	40 Marks
Credits	3

Course Objective(s):

1. Basic understanding of the regulatory requirement of cGMP
2. To know about drug development approval process and regulations related to clinical trials
3. To safely practice laboratory protocols

Course Outcomes:

After studying this course, students will be able to:

1. Learn and adopt quickly in a GMP environment and understand the principles and applications of the GMP.
2. Evaluate the criteria for drug approval related documentation and quality systems Importance of GMP and GLP for drug regulation
3. Describe quality assurance, design of quality systems, risk analysis and risk assessment
4. Able to apply knowledge of laws related to drug development approval process and regulations related to clinical trials
5. Safely practice basic laboratory procedures and protocols, maintain laboratory records compliant with current industry standards.

Mapping of Course Outcomes with Program Outcomes and Program Specific Outcomes:

PO / CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2
CO1	1	1	1	0	1	2	1	2	1	2	1	1	3	1
CO2	1	1	1	1	1	0	1	2	0	1	1	1	3	
CO3	1	1	1	1	1	3	1	1	1	1	1	1	3	
CO4	1	1	0	1	1	3	1	1	1	0	1	1	3	
CO5	1	1	1	1	1	3	1	2	1	1	1	1	3	2

UNIT-I

Introduction to GMP and GLP: Introduction to Good Manufacturing Laboratory Practice, Definitions, History, Requirement of GLP and GMP compliance for regulatory approval. Role of FDA in CGMP, recent milestones in FDA.

UNIT-II

Ethics and design of experiments in GMP: Ethics in manufacturing and control, Principles of quality by design (QBD), Introduction to the concept of Design of Experiment (DOE) Application of QBD principles in Biotech product development.

UNIT-III

Case studies in GMP: Example of QBD and DOE in Process Development, Example of DOE in analytical development, Introduction to ICH guidelines and their usage. National and international regulatory authorities and their function. Risk management methods and tools; FMEA, HACCP.

UNIT-IV

A**pproval and regulation process in GMP:** Pharmaceutical Jurisprudence and Laws related to Product design, Drug Development & Approval Process, Regulation of Clinical and Preclinical Studies State level (DCA) and central level (DCGI/CDSCO**)**

UNIT-V

General measures in GLP practices General Rules/Protocols for Lab Safety measures, Precaution and Safety in handling of chemicals, Laboratory tools, Glassware's and instruments. Internal and External Audit. Basic SOP for instrument handling and maintenance.

Text Books:

1. Sarwar Beg and Md Saquib Hasnain, Pharmaceutical Quality by design: Principles andapplication, Academic press, March 2019.(QBD).
2. cGMP starter guide: Principles in Good Manufacturing Practices for Beginners,Emmet P. Tobin, Create space Independent Publishing Platform, April 2016.
3. Good Manufacturing Practices for Pharmaceuticals: GMP in Practice, B Cooper,Createspace Independent Publishing Platform, July 2017.

Reference Books:

1. Good manufacturing practices for pharmaceuticals . Edited by Graham P. Bunn. Seventh edition. Boca Raton, Florida, DRUGS AND THE PHARMACEUTICAL SCIENCES A Series of Textbooks and Monographs Series Executive Editor James Swarbrick, CRC Press Taylor & Francis Group. 2019.
2. ICH guidelines available in the official website “https://www.ich.org”.
3. Handbook Good Laboratory Practices-World health organization(WHO)

REGULATORY AFFAIRS AND CLINICAL TRIALS
(Professional Elective–IV)

Instruction	3 L Hours per week
Duration of SEE	3 Hours
SEE	60 Marks
CIE	40 Marks
Credits	3

Course Objectives:.

1. To make the students understand about Intellectual property rights and their importance, National and
2. International regulatory affairs, GCP & ICH guidelines.
3. To introduce and provide a comprehensive introduction to Regulatory Affairs as typically practiced by Regulatory Affairs professionals in medical device and biopharma companies.
4. To enable students to follow the Current trends in Clinical research and regulations.

Course Outcomes:

At the end of the course, the students are able to

1. Classify the role of regulatory committees in controlling the risk and information on ethical issues linked to research on animal models, transgenics.
2. Summarize the Government of India rules and regulations about the ICH, GCP, FDA guidelines.
3. Discuss the role of regulatory affairs and their significance globally.
4. Outline the criteria for drug approval related documentation.
5. Discuss the various phases of clinical trials and the basis of approval of new drugs, their outcome in new drug discovery.

Mapping of Course Outcomes with Program Outcomes and Program Specific Outcomes:

PO / CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2
CO1	0	0	2	0	0	3	2	2	1	2	1	1	2	3
CO2	1	2	2	0	0	3	2	1	0	1	0	1	1	2
CO3	1	1	0	1	0	2	1	3	1	0	1	1	1	2
CO4	2	1	0	1	1	2	2	2	0	1	1	1	2	2
CO5	2	1	0	1	1	2	2	2	0	1	1	1	2	3

UNIT-I

Regulatory affairs: Definitions of ACT, regulation, guidance, responsibilities of RA professional. Investigational New drug, applications. Regulatory framework in India governing GMOs-Recombinant DNA Advisory Committee (RDAC), Institutional Biosafety Committee (IBSC), Review Committee on Genetic Manipulation, Genetic Engineering Approval Committee (GEAC), Recombinant DNA Guidelines (1990),

UNIT-II

Regulatory Affairs- India: Indian contest- requirements and guidelines of GMP, understanding of Drugs and Cosmetic Act 1940 and rules 1945 with reference schedule M, U & Y. The Narcotics Drugs and Psychotropic Substances Act Medicinal and Toilet Preparations (Excise Duties) Act, 1955 The Pharmacy Act, 1948 Types of ANDA filing (Para I, II, III, IV filing) Clinical trial approval by Drug Controller General of India (DCGI, CDSCO) Exclusivities (NCE, NS, NP, NDF, PED, ODE, PC). ADR : definition and classification

UNIT-III

Regulatory Affairs- Global: Introduction to FDA, WHO, Code of federal Regulations, ICH guidelines in Pharma covigilance. Related quality systems- objectives and guidelines of USFDA, WHO & European Medicines Agency and its responsibility, EU clinical trial directive. Requirement of GLP: Guidance and recommendation on Dissolution and Bio-equivalence requirement. Hatch Waxmann Act.

UNIT-IV

Documentation And Protocols: Documentation: Types related to pharmaceuticals industry, protocols, harmonizing formulation development for global fillings, NDA, ANDA, IND, BLA, CTD, DMF, Dealing with post approval changes-SUPAC, handling and maintenance including electronic documentation, 510K device application.

UNIT-V

Introduction To Clinical Research: History, Importance, Phases, Scope and stake holders in clinical research, Declaration of Helenski, 2000 amendment, Principles of GCP, Roles and responsibilities in clinical research according to ICH GCP, Sponsor, Investigator, Essential documentation, Confidentiality issues. Clinical data management system, Double data entry.

Text Books:

1. Good Clinical Practices, Central Drugs Standard Control Organization, Govt. of India Drugs and Cosmetics Act, 1940.
2. Dominique PB and Gerhardt Nahler, "International Clinical Trial", Volume 1&2, ,Interpharm Press, Denver, Colorado.

Suggested Reading:

1. Code of Federal Regulations by USFDA-Download
2. ICH-GCP Guidelines-Download.
3. Fleming DA, Hunt DL, "Biological Safety Principles and Practices", 3rd edition, ASMPress, Washington, 2000.

RATIONAL DRUG DISCOVERY

(Professional Elective-V)

Instruction	3 L Hours per week
Duration of SEE	3 Hours
SEE	60 Marks
CIE	40 Marks
Credits	3

Course Objectives:

1. The student is made to understand the fundamentals of molecular modeling and drug discovery
2. Students are made to understand quantum Mechanics and molecular mechanism
3. Students are enlightened about molecular dynamics simulation methods.
4. Students are enlightened about the methods for Molecular Docking and lead optimization, ADMET properties of the drug.
5. Students are made to understand the basics of Pharmacophore and QSAR

Course Outcomes:

At the end of the course, the students are able to

1. Describe drug discovery process, CADD, molecular modeling etc.
2. Explain the quantum Mechanics and molecular mechanism.
3. Identify various molecular dynamics simulation methods.
4. Discuss the methods for Molecular Docking and lead optimization, ADMET properties of the drug.
5. Summarize about the Pharmacophore and QSAR.

Mapping of Course Outcomes with Program Outcomes and Program Specific Outcomes:

PO / CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2
CO1	1	1	1	0	1	2	1	0	0	2	0	2	3	1
CO2	1	1	0	0	1	0	1	0	0	1	0	2	3	2
CO3	1	1	0	1	1	2	1	0	0	2	0	2	3	2
CO4	1	1	0	0	1	2	1	1	0	2	0	2	3	2
CO5	1	1	1	0	1	2	1	0	0	2	1	1	2	1

UNIT-I

Molecular Modeling in Drug Discovery: Drug discovery process, Role of Bioinformatics in drug design, Methods of computer aided drug design, ligand design methods, drug design approaches, Target identification and validation, lead optimization and validation, Structure and ligand based drug design, modeling of target-small molecule interactions, Molecular simulations. Protein Modeling.

UNIT-II

Quantum Mechanics and Molecular Mechanics: Features of molecular mechanics force fields; Bond structure and bending angles –electrostatic, van der Waals and non – bonded interactions, hydrogen bonding in molecular mechanics; Derivatives of molecular mechanics energy function; Application of energy minimization.

UNIT-III

Molecular Dynamics simulation methods: Molecular Dynamics using simple models; Molecular Dynamics with continuous potentials and at constant temperature and pressure; Time – dependent properties; Solvent effects in Molecular Dynamics; Conformational changes from Molecular Dynamics simulation and application.

UNIT-IV

Molecular Docking and lead optimization: Molecular Docking; Types of Molecular Docking, docking algorithms and programs, Structure-based methods to identify lead compounds; de novo ligand design; Applications of 3D Databases Searching and virtual Screening; Strategy for target identification and Validation, lead identification, optimization and validation. Combinatorial chemistry and library design, virtual screening, drug likeness and compound filtering, Absorption, distribution, metabolism, excretion and toxicity (ADMET) property prediction, computer based tools for drug design.

UNIT-V

Pharmacophore and QSAR: Pharmacophore derivation, 3D pharmacophore prediction and application in drug discovery; QSARs and QSPRs, QSAR Methodology, Various Descriptors used in QSARs: Electronic; Topology; Quantum Chemical based Descriptors. Use of Genetic Algorithms, Neural Networks and Principal Components Analysis in the QSAR equations.

Text Books:

1. Computational methods in drug design Fred E. Cohen, Walter Hamilton Moos Publisher: ESCOM Science, 1993.
2. Molecular Modelling for Beginners - Alan Hinchliffe Publisher: John Wiley & Sons Inc, 2008. ISBN: 978-0470513149.
3. Combinatorial Library Design and Evaluation: Principles, Software, Tools, Applications in Drug Discovery – Arup Ghose, VellarkadViswanadhan Publisher: CRC Press, 2001. ISBN: 0-8247-0487-8.

Suggested Reading:

1. Molecular Modeling Basics - Jan H. Jensen Publisher: CRC Press, 2010. ISBN 978- 1420075267.
2. 3D QSAR in Drug Design: Recent Advances – Hugo Kubinyi, GerdFolkers, Yvonne C. Martin Publisher: Springer Science & Business Media. ISBN: 0-306-46858-1.
3. Computational Chemistry and Molecular Modeling - K. I. Ramachandran, GopakumarDeepa, Krishnan Namboori Publisher: Springer – Verlag Berlin Heidelberg. ISBN: 978 3540773023.

MOLECULAR MODELING & DRUG DESIGN
(Professional Elective -V)

Instruction	3L Periods per week
Duration of university Examination	3 Hours
University Examination	60 Marks
Sessional	40 Marks
Credits	3

Course Objectives:

1. Empirical force fields and Hydrogen bonding in different molecules.
2. Simulation methods to calculate Thermodynamic properties of molecules.
3. Molecular dynamics simulation of molecules by simple and continuous potential.
4. Practical aspects in setting and running the molecular dynamics simulation.
5. Montecarlo simulation method for rigid and flexible molecules.
6. QSAR between different protein-ligand interactions.

Course Outcomes:

After completion of the course students gain knowledge in the following concepts:

1. Calculate the total energy of the molecule by using force field potentials.
2. Calculate Internal energy, Heat capacity, Temperature, and pressure.
3. Hard sphere potential, Continuous potential by Finite differential method.
4. Choosing the initial configuration and analyzing the results of computer simulation.
5. Simulation of polymers by Random walk method, Self-avoiding walk method.
6. Classification of Drug Design. CADD to treat Alzheimer's and Tuberculosis diseases

Mapping of Course Outcomes with Program Outcomes and Program Specific Outcomes:

PO / CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2
CO1	1	0	0	1	1	0	0	0	0	1	0	0	1	0
CO2	1	2	1	2	2	2	0	0	0	1	0	1	2	3
CO3	1	2	1	2	2	2	0	0	0	1	0	1	2	3
CO4	1	2	1	2	2	2	0	0	0	1	0	1	2	3
CO5	1	1	0	2	1	2	1	0	0	1	0	1	3	2

UNIT-I

Empirical Force Fields And Molecular Mechanics: Introduction to Molecular Mechanics, Coordinate system, Molecular graphics, Force fields, Bond stretching, Angle bending, Torsions, Out of plane bending motions, Electrostatic interactions, Vanderwalis interactions , Effective pair potentials, Hydrogen bonding.

UNIT-II

Computer Simulation Methods: Calculation of Thermodynamic properties, Phase space, Practical aspects of computer simulation, Periodic boundary condition, Boundaries monitoring Equilibrium, Truncating the potential and minimum image convention, Long-range process, Analyzing results of simulation and estimating errors**.**

UNIT-III

Molecular Dynamics Simulation Methods: Molecular Dynamics using simple modules, Molecular Dynamics with continuous potentials: Finite difference methods and Predictor corrector integration method, Constraint Dynamics, Transport properties, Time-dependent properties, Molecular Dynamics at Constant Temperature and Pressure.

UNIT-IV

Monte Carlo Simulation Methods: Metropolis methods, Importance of Hamiltonian equation, Monte Carlo simulation of Rigid and Flexible molecules, Monte Carlo simulation of Polymers: Lattice model & continuous polymer model, calculating chemical potential, Differences between Molecular dynamics & Monte Carlo simulation method.

UNIT-V

Applications Of Molecular Modeling And Drug Design: Production of Drugs in Pharmaceutical companies, CADD: Structure-Based Drug Design and Ligand Based Drug Design, Quantitative Structural Activity Relationship (QSAR) studies in Protein-Ligand interactions, Case studies of Alzheimer's disease, Tuberculosis, and Cancer, etc.

Text Books:

1. Molecular modeling principles and Applications AR Leach, Longman, (1996).
2. Molecular Dynamics simulation -Elementary Methods- John Wiley and Sons, (1997).

Suggested Reading:

1. Protein Engineering - Moody PCE and AJ Wilkinson. IRL Press.
2. Introduction to protein structure by C. Brandon and J. Tooze, Garland, 2nd edition, (1998).
3. Essentials of Drug Designing V. Kothakar, Dhruv publications

STRUCTURAL BIOLOGY
(Professional Elective -V)

Instruction	3 L Hours per week
Duration of SEE	3 Hours
SEE	60 Marks
CIE	40 Marks
Credits	3

Course Objectives:

This course focuses on

1. To provide the foundation for understanding, the basic structural biology of macromolecules such as Proteins, DNA, and RNA.
2. To give an understanding of the energetics and kinetics of proteins that will facilitate application to current and future research problems.
3. To provide knowledge about various biophysical techniques for protein structure determination.
4. To give an understanding of various bioinformatics tools in structural biology.

Course Outcomes:

At the end of the course, the students are able to

1. Demonstrates the hierarchy in protein organization and structure-function relationship
2. Outlines the mechanisms, dynamics, and physical interactions that maintain protein structure.
3. Demonstrate the basic techniques involved in determining the structure of a biomolecules
4. Assess conceptual basics of structural dynamics of other macromolecules DNA, RNA & enzyme
5. Illustrates the computer-based visualizations and molecular simulations

Mapping of Course Outcomes with Program Outcomes and Program Specific Outcomes:

PO / CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2
CO1	3	2	2	2	1	2	2	1	2	2	2	2	3	3
CO2	3	2	2	2	1	2	1	1	2	1	1	2	3	2
CO3	3	2	2	2	1	2	1	1	2	2	2	2	3	2
CO4	3	2	2	2	1	2	2	1	2	2	1	2	3	3
CO5	2	2	1	2	1	1	1	1	2	1	1	2	2	2

UNIT-I

Protein structural biology: Conformational effect of amino acid on protein structure, basic polypeptide stereochemistry, hierarchy in protein folds: secondary structure, tertiary structure, quaternary structure. Motifs and domains of protein structures. Structure Conformational analysis.

UNIT-II

Protein Kinetics and Energetics: Mechanism of Protein folding- kinetics intermediates- transition states. Thermodynamics of protein stability: Driving forces in protein folding - Estimation of solvation free energies. Bonds and energies in macromolecules- Covalent, Ionic, coordinate, hydrophobic and Vander walls interactions. Phase problem and methods of phase separation

UNIT-III

Methods for structure determination: Basics of Crystallization, methods of protein crystallization, Macromolecular crystallography: X-ray crystallography, Bragg equation, scattering factor, Nuclear Magnetic Resonance (NMR), Single particle Cryo Electron Microscopy, FRET advantages and disadvantages of all the processes.

UNIT-IV

DNA, RNA, and Enzyme structures: DNA and RNA secondary structures (duplex, triplex, quadruplexes and aptamers), RNA secondary structure prediction. Structural dynamics: Dynamics of Protein-RNA complexes, Enzyme-ligand interaction, Structure-function relationship.

UNIT-V

Computational Structure Biology: Protein Structure visualization tools, Protein fold-function relationships, best practices on the use of protein structures from protein data bank: Protein Data Bank (PDB) and EM Data Bank, BioMagResBank (BMRB).Introduction to molecular dynamics simulation, the need for simulation in studying biology, case studies on structure-based drug designing and protein engineering.

Text Books:

1. Liljas L, Nissen P, Lindblom G, Textbook of Structural Biology, Volume 8 of Series in structural biology, World Scientific, 2016.
2. Introduction to Protein Architecture: The Structural Biology of Proteins, 2014, Lesk A. M., Oxford University Press; 4threvised Edition.
3. Schwede T, Computational Structural Biology: Methods and Applications, World Scientific, 2008.

References:

1. Principles of nucleic acid structure, by Stephen Neidle.
2. K.P.Murphy. Protein structure, stability and folding (2001) Humana press. ISBN 0-89603682-0
3. Arthur M.Lesk Introduction to protein architechcture (2001) Oxford University Press. ISBN0198504748
4. The Art of Molecular Dynamics Simulation by D. C. Rapaport Cambridge University Press; 2nd edition 2004.
5. Biochemistry, Berg J, M., Stryer L., Tymoczko J, Gatto G. WH Freeman & Co, 2019, 9th Edition

GENOMICS AND PROTEOMICS
(Professional Elective -V)

Instruction	3 L Hours per week
Duration of SEE	3 Hours
SEE	60 Marks
CIE	40 Marks
Credits	3

Course Objectives:

1. The student is made to understand the fundamentals of genome
2. Students are made to understand DNA sequencing and various DNA sequencing methods.
3. Students are enlightened about the construction and screening of cDNA libraries.
4. Students are enlightened about the current methods existing in the field of genomics.
5. Students are made to understand the basics of proteomics, tools for proteomics and protein modifications

Course Outcomes:

At the end of the course, the students are able to

1. Describe genomes, types of genomes and the advanced techniques used for analyzing the genome.
2. Explain the methods of functional genomics.
3. Discuss the various sequencing technology in genomics.
4. Describe the tools used for the characterization of proteins
5. Explain about personalized medicines their uptake, action and metabolism.

Mapping of Course Outcomes with Program Outcomes and Program Specific Outcomes:

PO / CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2
CO1	1	0	0	0	1	0	0	0	0	0	0	2	1	1
CO2	1	0	0	0	1	0	0	0	0	0	0	2	1	1
CO3	1	0	0	0	1	0	0	0	0	0	0	2	1	1
CO4	1	0	0	0	1	0	0	0	0	0	0	2	1	1
CO5	1	0	0	0	1	0	0	0	0	0	0	2	1	1

UNIT-I

Structural Genomics: Overview of Genome - Types, analysis of genomes; comparative homologies; evolutionary changes; Genetic analysis: Linkage mapping and analysis, High resolution chromosome maps, Physical mapping, Hybrid mapping strategies, Sequence specific tags(SST), Sequence tagged sites(STS), FISH.

UNIT-II

Functional Genomics: Gene disruption and methods; DNA microarray and its Applications; Serial analysis of gene expression (SAGE); Genome wide association studies; Chip-Seq; RNA-Seq; Metagenomics.

UNIT-III

Next Generation Sequencing: Next generation sequencing - importance; Different sequencer platforms available; Methods of Sequencing; File formats; Data generation tools; Pre-processing of data and analysis; Introduction to rRNA sequencing and Single-cell sequencing

UNIT-IV

Proteomics: Protein arrays: basic principles. Computational methods for identification of polypeptides from mass spectrometry. Protein arrays: bioinformatics-based tools for analysis of proteomics data (Tools available at ExPASy Proteomics server); databases (such as Inter Pro) and analysis tools. Protein-protein interactions: databases such as DIP, PPI server and tools for analysis of protein-protein interactions

UNIT-V

Metabolomics And Pharmacogenomics: Metabolomics - Basics; Pharmacogenomics - Basics, Diseased genes and their identification; Drug uptake and metabolism; Drug targets; Designer medicine; Genomics perspective of bioterrorism; Ethical and legal implications.

Text Books:

1. Sahai S, "Genomics and Proteomics-Functional and Computational Aspects", Plenum Publications,1999.
2. Rastogi SC, Mendiratta N, Rastogi P, "Bioinformatics-Methods and Application, Genomics, Proteomics,and drug discovery", 2nd edition, Prentice Hall of India, New Delhi,2003.
3. Hunt SP, Levessy FJ, "Functional genomics" Oxford University Press, UK,2000.

Suggested Reading:

1. Lieber DC, "Introduction to Proteomics, Tools for the new biology", Humana Press, UK,2000.
2. CendricGondro, "Primer to Analysis of Genomic Data Using R", Springer,2015.

GENDER SENSITIZATION

Instruction	2 L Hours per week
Duration of SEE	2 Hours
SEE	50 Marks
CIE	0 Marks
Credits	No Credit

Course Objectives:
This course will introduce the students to:
1. Sensibility regarding issues of gender in contemporary India.
2. A critical perspective on the socialization of men and women.
3. Popular debates on the politics and economics of work while helping them reflect critically on gender violence.

Course Outcomes:
After successful completion of the course the students will be able to:
1. Understand the difference between "Sex" and "Gender" and be able to explain socially constructed theories of identity.
2. Recognize shifting definitions of "Man" and "Women" in relation to evolving notions of "Masculinity" and "Femininity".
3. Appreciate women's contributions to society historically, culturally and politically.
4. Analyze the contemporary system of privilege and oppressions, with special attention to the ways gender intersects with race, class, sexuality, ethnicity, ability, religion, and nationality.
5. Demonstrate an understanding of personal life, the workplace, the community and active civic engagement through classroom learning.

UNIT – I
Understanding Gender:
Gender: Why Should We Study It? (Towards a World of Equals: Unit -1)
Socialization: Making Women, Making Men (Towards a World of Equals: Unit -2)
Introduction. Preparing for Womanhood. Growing up Male. First lessons in Caste. Different Masculinities.

UNIT – II
Gender and Biology:
Missing Women: Sex Selection and Its Consequences (Towards a World of Equals: Unit -4) Declining Sex Ratio. Demographic Consequences.
Gender Spectrum: Beyond the Binary (Towards a World of Equals: Unit -10) Two or Many? Struggles with Discrimination.

UNIT – III
Gender and Labour:
Housework: the Invisible Labour (Towards a World of Equals: Unit -3) "My Mother doesn't Work." "Share the Load."
Women's Work: Its Politics and Economics (Towards a World of Equals: Unit -7) Fact and Fiction. Unrecognized and Unaccounted work. Additional Reading: Wages and Conditions of Work.

UNIT-IV
Issues Of Violence
Sexual Harassment: Say No! (Towards a World of Equals: Unit -6) Sexual Harassment, not Eve-teasing- Coping with Everyday Harassment- Further Reading:"Chupulu".

Domestic Violence: Speaking Out (Towards a World of Equals: Unit -8) Is Home a Safe Place? -When Women Unite [Film]. Rebuilding Lives. Additional Reading:New Forums for Justice.

Thinking about Sexual Violence (Towards a World of Equals: Unit -11) Blaming the Victim-"I Fought for my Life…." - Additional Reading: The Caste Face of Violence.

UNIT – V
Gender: Co - Existence
Just Relationships: Being Together as Equals (Towards a World of Equals: Unit -12) Mary Kom and Onler. Love and Acid just do not Mix. Love Letters. Mothers and Fathers.Additional Reading: Rosa Parks-The Brave Heart.

Text Book:

1. A. Suneetha, Uma Bhrugubanda, DuggiralaVasanta, Rama Melkote,VasudhaNagaraj, AsmaRasheed, GoguShyamala, DeepaSreenivas and Susie Tharu "Towards a World of Equals: A Bilingual Textbook on Gender" published by Telugu Akademi, Hyderabad, Telangana State, **2015**.

Suggested Reading:

1. Menon, Nivedita. Seeing like a Feminist. New Delhi: Zubaan-Penguin Books, 2012
2. AbdulaliSohaila. "I Fought For My Life…and Won."Available online at:
    2. http://www.thealternative.in/lifestyle/i-fought-for-my-lifeand-won-sohaila-abdulal/

Web Resources:

1. https://aifs.gov.au/publications/gender-equality-and-violence-against-women/introduction
2. https://theconversation.com/achieving-gender-equality-in-india

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Note: Since it is an Interdisciplinary Course, Resource Persons can be drawn from the fields of English Literature or Sociology or Political Science or any other qualified faculty who has expertise in this field from engineering departments.

20BT C33 **With effect from the Academic year 2023-24**

PROJECT PART-I

Instruction	4P Hours per week
SEE	0 Marks
CIE	50 Marks
Credits	2

The objective of Project Part -1 is to enable the student take up investigative study in the broad field of Engineering / Technology, either fully theoretical/practical or involving both theoretical and practical work to be assigned by the Department on an individual basis or two/three students in a group, under the guidance of a supervisor. This is expected to provide a good initiation for the student(s) towards R&D.

The work shall include:

1. Survey and study of published literature on the assigned topic;
2. Working out a preliminary Approach to the Problem relating to the assigned topic;
3. Conducting preliminary Analysis/Modelling/Simulation/Experiment/Design/Feasibility;
4. Preparing a Written Report on the Study conducted for Presentation to the Department;
5. Final Seminar, as oral Presentation before a departmental Committee.

Mapping of Course Outcomes with Program Outcomes and Program Specific Outcomes:

PO / CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2
CO1	0	0	0	0	0	0	0	0	0	0	0	1	1	1
CO2	0	1	0	0	0	0	0	0	0	0	0	1	3	3
CO3	3	1	0	1	1	0	0	0	0	0	0	0	2	3
CO4	0	0	0	1	0	0	0	0	0	0	0	0	1	1
CO5	0	0	0	0	0	0	0	0	0	2	0	0	2	2
CO6	0	0	0	0	0	0	0	0	2	0	0	0	1	1

Guidelines for the award of Marks: Max. Marks: 50

Evaluation by	Max .Marks	Evaluation Criteria / Parameter
Supervisor	20	Project Status / Review
	5	Report
Department Committee	5	Relevance of the Topic
	5	PPT Preparation
	5	Presentation
	5	Question and Answers
	5	Report Preparation

GUIDELINES:

These guidelines assure consistency in the quality and components of project to be taken in VIIth Semester within the Department and they are segregated into 3 sections

A) Section 1 describes guidelines and procedures for allotment, submission, and acceptance of the project

1. Students will be allotted with a faculty supervisor based on their topic/ area of interest.
2. There will be a maximum of 3 students attached to each of the staff for each research project
3. Students are encouraged to select a topic that has scope to be continued as major project in VIIIth Semester
4. Tentative area of research, title and objectives along with novelty statement have to be surveyed with proper discussion and guidance of internal guide
5. All the above mentioned should be finalized in consultation with the faculty supervisor
6. Care should be taken that no two project problems should be same. Care should be taken that the problem should not be same as done in the department over last three years
7. No change in project or group after the department research committee and HoD finalizes the list
8. Soft bound project reports (3 Nos) duly certified by internal guide, DRC and the HOD should be submitted at the time of final review
9. The students should record the observations, impressions, information gathered and suggestions given, if any. It should contain the sketches & drawings related to the observations made by the students. Students shall be ready to show the diary to the internal guide or DRC or HoD at any point of time.
10. Responsibilities of students include
    a. Schedule meetings as needed with the guide, or others as needed.
    b. Meet the deadlines as specified in the departmental curriculum.
    c. Submit working drafts to the project guide during the writing process.
    d. The student is responsible for making all arrangements for preparation of the report

B) Section 2 provides an overview of the structure and content of the project report and minimal formatting requirements for preparation of the report.

1. The report consists of three general sections: The preliminary pages, text and references.
    - ✓ Title page (mention the guide's name-both internal and external also)
    - ✓ Certificates (INTERNAL AND EXTERNAL)
    - ✓ Declaration
    - ✓ Acknowledgements
    - ✓ Contents
    - ✓ Abbreviations
    - ✓ List of Tables
    - ✓ List of Figures
    - ✓ Abstract (in 250 words) and Keywords
    - ✓ Novelty statement
    - ✓ Aim and objectives
    - ✓ Introduction
    - ✓ Review of literature
    - ✓ Materials and Methods (if any)
    - ✓ Results and Discussion (if any)
    - ✓ Expected Conclusions (200 words)
    - ✓ References
    - ✓ Appendix (if any)
    - ✓ Published research papers (if any)
2. The report should be written in Times New Roman (12 size), 1.5 or double spacing, headings and side headings in bold, well defined margins, pagination, etc.
3. Students are instructed to prepare a comprehensive PowerPoint presentation with all findings to present before DRC during final review

C) Section 3 suggests the time schedule.

Students should attend all the reviews and follow the deadlines as per the almanac will be allotted with a faculty supervisor

Suggested schedule:

Starting Date	Day 1 (As per almanac)
Literature review / survey	End of 4 Weeks
Tentative aim and objectives	End of 8 Weeks
Process Manuscript submission	End of 10 Weeks
Material and microbes procurement (if any)	End of 12 Weeks
Results and Analysis (if any)	End of 14 Weeks
Approval of printout draft and Manuscript	End of 16 Weeks
Submission of bound copies	Last Day (As per almanac)

The project would be evaluated on a regular basis by the DRC by conducting periodical reviews and marks will be awarded following the rubrics

The students have to fill the checklist provided by the DRC in order to evaluate the project's feasibility to be carried out in department

FEASIBILITY CHECK LIST

S. No	Detail	Response
1	Tentative title of the project	
2	Tentative objectives	
3	Novelty statement/Gaps identified	
4	No. of papers referred to identify the gaps and frame the objectives	
5	No. of days required for literature survey	
6	Time required to complete the project in 8^{th} semester	
7	Chemicals/Materials required for the project	
8	Equipment/Software required	
9	If equipment/software not available, identification of any alternatives	
10	Microorganisms required	
11	Planning to do project internally/external	
12	If external, the topic should be related to the ones in 8^{th} semester	
13	Expertise available in CBIT	
14	Any ethical approvals required (animal/human testing)	

INTERNSHIP

Instruction	4-6 week
Duration of Internship	135 Hours
SEE	50 Marks
Credits	3

Schedule for the internship schedules will be given in a flexible manner according to the availability opportunities. The minimum and maximum requirement regarding Internship duration and credits is given in Table-1

Table 2: Internship Frame work

Schedule	Activities	Duration	Credits
Summer / Winter vacation after (6th Semester)	Industrial / Govt. /NGO / MSME/ Rural Internship/ Innovation/ Entrepreneurship/ NSQF level 3, 4,5	4-6 weeks	Summer / Winter vacation after (6th Semester)

INTERNSHIP GUIDELINES:

a) Student's Diary/Daily Log: The students should record the observations, impressions, information gathered and suggestions given, if any. It should contain the sketches & drawings related to the observations made by the students. Students shall be ready to show the diary to the Industry supervisor or the Faculty Mentor at any point of time. Failing to produce the same, Intern may be debarred for the remaining period of his/her internship. Daily diary needs to be submitted to Faculty Mentor at the end of Internship along with the attendance record and an evaluation sheet duly signed and stamped by the industry. Daily diary is evaluated on the basis of the following criteria:

- Regularity in maintenance of the diary/log
- Adequacy & quality of information recorded
- Drawing, sketches, and data recorded.
- Thought process and recording techniques used
- Organization of the information

b) Internship Report: At the end of the internship, each student should prepare a comprehensive report to indicate what he/she observed and learned in the training/internship period. It should be signed by the internship supervisor. The report will be evaluated by the Industry Supervisor on the basis of the following criteria:

- Originality
- Adequacy and purposeful write-up
- Organization, format, drawings, sketches, style, language etc.
- Variety and relevance of learning experience
- Practical applications, relationships with basic theory and concepts taught in the course

EVALUATION OF INTERNSHIP:

The industrial training/internship of the students will be evaluated in three stages:

1. Evaluation by the Industry (in the range of 1 to 10 where 1-Unsatisfactory; 10-Excellent)
2. Evaluation by faculty supervisor on the basis of site visit(s) or periodic communication (15 marks)
3. Evaluation through seminar presentation/Viva-Voce at the Institute(This can be reflected through marks assigned by Faculty Mentor (25 marks))

Evaluation through Seminar presentation/Viva-Voce at the institute: Students will give a seminar based on his/her training report, before an Expert Committee constituted by the concerned department as per the norms of the institute. The evaluation will be based on the following criteria:

- Quality of content presented
- Proper planning for presentation
- Effectiveness of presentation
- Depth of knowledge and skills
- Attendance record, daily diary, departmental reports shall be analyzed along with the internship Report

CHAITANYA BHARATHI INSTITUTE OF TECHNOLOGY (A)

Department of Bio-Technology
Scheme of Instructions of VIII Semester of B. Tech Bio-Technology as per AICTE Model Curriculum 2023-24
B.Tech (Bio-Technology)

SEMESTER VIII

S.No.	Course Code	Title of the Course	Scheme of Instruction			Scheme of Examination			Credits
			Hours Per week			Duration of SEE in Hours	Maximum Marks		
			L	T	P		CIE	SEE	
THEORY									
1		**Professional elective-VI**	3	-	-	3	40	60	3
2		**Open Elective –III**	3	-	-	3	40	60	3
PRACTICALS									
3	20BTC34	Technical Seminar	-	-	2	-	50	-	1
4	20BTC35	Project Part-II	4-6 weeks of industry Internship (180 hours)/12 hours			-	100	100	4
Total			**6**	**0**	**14**				**11**
Clock Hours Per Week –20									

L: Lecture T: Tutorial P: Practical

CIE – Continuous Internal Evaluation SEE - Semester End Examination

Professional elective-VI (Advanced applications of Biotechnology)	
20BT E22	Immunodiagnostics
20BT E23	Biomaterials
20BT E24	Metabolic Engineering
20BT E25	Biosimilar Technology

20BT E22 **With effect from the Academic year 2023-24**

IMMUNODIAGNOSTICS
(Professional Elective -VI)

Instruction	3 L Hours per week
Duration of SEE	3 Hours
SEE	60 Marks
CIE	40 Marks
Credits	3

Course Objectives:

1. To learn the basic principles, procedures, and applications of immunodiagnostic tests.
2. To understand the principles and applications of immunodiagnostic tests.
3. To learn the steps involved in the production, diagnosis, and applications of monoclonal antibodies.
4. To learn the development of prophylactic agents such as vaccines.
5. To learn the novel methods used for immunodiagnostics.

Course Outcomes:

At the end of the course, students will be able to

1. Outline the principle, importance, scope, classification of immunodiagnostic tests and antigen-antibody reaction
2. Explain the principles and application of immunodiagnostics tests for diagnosing various diseases
3. Discuss the production of monoclonal antibodies for diagnosis, treatment, and prevention of disease.
4. Describe various methods used for vaccine development.
5. Summarize the various novel techniques used in immunodiagnostics.

Mapping of Course Outcomes with Program Outcomes and Program Specific Outcomes:

PO / CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2
CO1	1	-	-	1	-	2	-	1	-	1	-	1	1	1
CO2	1	-	-	1	-	2	1	1	-	1	-	1	1	1
CO3	1	-	-	1	-	2	1	1	-	1	-	1	1	1
CO4	1	-	-	1	-	2	1	1	-	1	-	1	1	1
CO5	1	-	-	1	-	2	1	1	-	1	-	1	1	1

UNIT-I

Introduction to Immunodiagnostics: Principles of immunodiagnostic tests and their development; classification of immunodiagnostic tests; Immunodiagnostics importance and scope; the antigen-antibody reaction; Selection and preparation of reagents; Assay design; Antibody engineering; Catalytic antibodies.

UNIT-II

Immunodiagnostics Techniques: Immunodiagnostics techniques – Precipitation, Immunoelectrophoresis, Agglutination, RIA, ELISA, Fluoroimmunoassay, Luminescent immunoassay, Immunofluorescence, Cell separation techniques, Western blotting.

UNIT-III

Hybridoma Technology: Hybridoma technique - choice of host for immunization and myeloma cells, choice of immunogen, preparation of antigen for immunization, growth of myeloma cell lines, preparation of cells for fusion, cell fusion, selection and screening of hybridoma, purification and application (biochemical research, clinical diagnosis and treatment) of monoclonal antibodies.

UNIT-IV

Vaccines: Whole organism Vaccines; Subunit vaccines - Herpes Simplex virus, Foot and Mouth disease; Peptide vaccines - Foot and Mouth disease, Malaria; Live recombinant vaccines- Cholera, Salmonella; Vector vaccines - directed against viruses and bacteria; Purified vaccines, Conjugate polysaccharide vaccines; DNA vaccines; Antifertility vaccines.

UNIT-V

Novel Techniques in Immunodiagnostics: Imaging as an Immunodiagnostic Tool; Multicolor Flow Cytometry; Immunoglobulin and Free-light Chain Detection; Methods for Autoantibody Detection; Immunodiagnostic of Allergy; Multiplex Analysis of Cytokines; Immuno monitoring of Clinical Trials; Immunological Assays Used in Vaccine Clinical Trials.

Text Books:

1. Edwards R, “Immunodiagnostics: A practical approach” Oxford University Press, 1999.
2. Rastogi SC, “Immunodiagnostics Principles and Practice” New Age Publishers, 1996.

Suggested Reading:

1. Shepherd, P., Dean C., “Monoclonal Antibodies: A Practical Approach” Oxford University Press, 2000.
2. Jenni Punt, Sharon Stanford, Patricia Jones, Judith A Owen., “Kuby Immunology” 8th edition, Macmillan learning, 2018.
3. Ralph M Aloisi Lea, Principles of Immunology and Immunodiagnostics, Lea &Febiger, 1988.

BIOMATERIALS
(Professional Elective–VI)

Instruction	3LHoursperweek
Duration of SEE	3Hours
SEE	60Marks
CIE	40Marks
Credits	3

Course Objectives:

Students are made to understand the following concepts during their course of time:

1. To learn the types and trends of Biomaterials.
2. To recognize the procedures for manufacturing of Metallic Biomaterials.
3. To be aware of the types of ceramic Biomaterials.
4. To elaborate the detailed features of polymer and composite Biomaterials.
5. To learn the applications of Biomaterials.

Course outcomes:

By the end of the course the students are able to

1. Explain types and properties of Biomaterials.
2. Compare the techniques for manufacture of metallic Biomaterials and their use in health care industry.
3. Outline the physiological properties and various techniques for manufacture of ceramic biomaterials.
4. Illustrate the preparation of polymer and composite Biomaterials.
5. Apply the different type of Biomaterials in health industry.

Mapping of Course Outcomes with Program Outcomes and Program Specific Outcomes:

PO / CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2
CO1	1	2	1	2	2	3	2	2	0	1	0	3	3	3
CO2	1	1	1	2	3	3	1	2	0	1	0	3	3	3
CO3	1	1	1	2	2	3	2	1	0	1	0	3	3	3
CO4	2	1	2	2	2	2	2	2	0	1	0	3	3	3
CO5	2	1	1	2	2	2	2	1	0	1	0	3	3	3

UNIT-I

Introduction to Biomaterials: Introduction and importance of biomaterials; Types of biomaterials: metallic, ceramic, polymeric and composite biomaterials; Future trends in biomaterials.

UNIT-II

Metallic Biomaterials: Properties of metallic biomaterials; Stainless steels; CoCr alloys; Ti alloys; Corrosion of metallic implants; Manufacturing of implants. Case study for manufacturing of Cardiac implants, Dental implant and their biocompatibility and hemocompatibility.

UNIT-III

Ceramic Biomaterials: Properties of ceramic biomaterials; Classification according to physiological response of ceramic biomaterials: bioinert, bioactive and bioresorbable ceramics; Deterioration of ceramics; Bio ceramic manufacturing techniques (ex; Manufacturing of orthopaedic implants and their biocompatibility and hemocompatibility.

UNIT-IV

Polymeric and composite biomaterials: Polymerization and basic structure; Polymers used as biomaterials; Properties of polymeric and composite biomaterials; Sterilization; Surface modifications for improving biocompatibility; Surface-protein interactions.

UNIT-V

Applications of Biomaterials: Applications of biomaterials in tissue engineering; Drug delivery; Biosensing; Diagnostics.

Text Books:

1. Buddy D. Ratner, Allan S. Hoffman, Frederick J. Schoen, Jack E An Introduction to Materials in Medicine, (Elsevier Academic Press, ISBN: 0-12-582463-7),2002.
2. J.B. Park and J.D. Bronzino. Biomaterials: Principles and Applications. CRC Press. 2002. ISBN: 0849314917
3. K.C. Dee, D.A. Puleo and R. Bizios. An Introduction to Tissue-Biomaterial Interactions. Wiley 2002. ISBN: 0-471-25394-4.

Reference Books

1. T.S. Hin (Ed.) Engineering Materials for Biomedical Applications. World Scientific. 2004. ISBN 981-256-061-0
2. B. Rolando (Ed.) Integrated Biomaterials Science. Springer. 2002. ISBN: 0-306-46678-3.

20BT E24 **With effect from the Academic year 2023-24**

METABOLIC ENGINEERING
(Professional Elective-VI)

Instruction	3LHoursperweek
Duration of SEE	3Hours
SEE	60 Marks
CIE	40 Marks
Credits	3

Course Objectives:

1. To identify the different metabolic regulations.
2. To outline various pathways of Biosynthesis of secondary metabolic and their applications.
3. To identify factors and criteria for bioconversions
4. To learn the concept of metabolic flux and its application.
5. To compute metabolic pathways and algorithms.

Course Outcomes:

At the end of the course the students are able to

3. Summarize the basic concepts of metabolic engineering.
4. Describe the various biosynthesis of secondary metabolites & their applications in various fields.
5. Discuss the factors influence the bioconversions and genetic manipulations of metabolic pathways.
6. Explain the analysis & applications of metabolic flux.
7. Outline the metabolic pathway modeling synthesis using bioinformatics tools and its applications.

Mapping of Course Outcomes with Program Outcomes and Program Specific Outcomes:

PO / CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2
CO1	2	1	2	3	2	2	2	2	1	2	1	3	3	3
CO2	1	1	1	2	2	2	2	2	1	2	1	3	3	3
CO3	1	1	1	2	2	2	2	2	1	1	1	3	3	3
CO4	2	1	2	2	3	2	2	2	1	1	1	0	3	3
CO5	1	1	1	2	3	2	2	2	1	1	0	3	3	2

UNIT- I

Introduction: Identification of metabolic regulation: a key point in Metabolic Engineering. Basic concepts of Metabolic Engineering- Overview of cellular metabolism, Different models for cellular reaction, induction, Jacob monad model & its regulation, Different regulation by Isoenzymes, feedback regulation. Amino acid synthesis, pathways with regulation at enzyme & cell level.

UNIT-II:

Biosynthesis Of Secondary Metabolites: Regulation of secondary metabolic pathways, precursor effect, prophase, Idiophase –relationships. Catabolite regulation bypassing control of secondary metabolism, producers of secondary metabolites and their applications.

UNIT-III

Bioconversions: Factors affecting bioconversions, Specificity, Yields, Co metabolism, Product inhibition, mixed or sequential bioconversions, Conversion of insoluble substances. Applications of Bioconversions.Strain selection, Genetic improvement of strains, Gene dosage, metabolic pathway manipulations to improve fermentation.The modification of existing or the introduction of entirely new metabolic pathways.

UNIT-IV

Metabolic Flux: Metabolic flux distribution analysis, Experiments determination method of flux distribution, Metabolic flux analysis and its applications. Experimental determination of metabolic fluxes C13 labeling, NMR and GC-MS based methods for flux determination.

UNIT-V

Metabolomics & Applications of Metabolic Engineering: Metabolic pathway modeling, Analysis of metabolic control and the structure metabolic networks, metabolic pathway synthesis algorithms. Application in pharmaceuticals, chemical bioprocess, food biotechnology, agriculture environmental bioremediation and biomass conversion.

Text Books:

1. Stephanopoulos GN, Aristidou AA and Nielsen J, “Metabolic Engineering Principles &Methodologies”, Academic Press-Elsevier,1998.
2. Wand. D.I.C Cooney C.L., Demain A.L., Dunnil.P. Humphrey A.E. Lilly M.D. “Fermentation and Enzyme Technology, John Wiley and sons, 1980.
3. Metabolic engineering SangyYuplee and E.T. Pa poutsakis Marcel DekkerInc.

Suggested Reading:

1. Zubay G., Biochemistry, Macmillan Publishers, 1989.
2. Stanbury P.F., and Whitaker A., Principles of Fermentation Technology Pergamon Press, 1984.

BIOSIMILAR TECHNOLOGY
(**Professional Elective -VI**)

Instruction	3 L Hours per week
Duration of SEE	3 Hours
SEE	60 Marks
CIE	40 Marks
Credits	3

Course Objectives:

1. Student is made to understand about the design and development of different kinds of biologics, biomimetics, and biosimilars.
2. Students are taught about different biotechnological applications of biologics, biomimetics, and biosimilars.
3. Students are made to study the regulatory framework about the biosimilars.

Course Outcomes:

At the end of the course the students are able to

1. Outline the biologics, biosimilars and super biologics.
2. Distinguish the various biosimilar drugs
3. Compare and contrast various biosimilar characterization methods.
4. Interpret various bioequivalence studies.
5. Analyze various case studies of biosimilar products of Indian companies

Mapping of Course Outcomes with Program Outcomes and Program Specific Outcomes:

PO / CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2
CO1	1	1	1	0	0	3	1	0	0	2	0	2	3	1
CO2	1	1	0	0	0	2	0	0	0	2	0	1	3	2
CO3	1	0	0	0	1	2	0	0	0	2	0	3	3	2
CO4	1	1	0	0	1	2	2	1	0	2	0	3	3	2
CO5	0	1	0	0	0	2	2	1	0	2	1	2	2	1

UNIT-I

Introduction to Biopharma: Generics in Biopharma, definition of biologics, biosimilars, super biologics, differences between chemical genetics and biosimilars, The developmental and regulatory challenges in biosimilar development, Prerequisites for Biosimilar development, Biosimilar market potential.

UNIT-II

Types of Biosimilar drugs: Peptides, proteins, antibodies, Enzymes, Vaccines, Nucleic acid based therapies (DNA, NA, etc), Cell based therapies (including stem cells)

UNIT-III

Characterization methods: Aggregation- precipitation, floccule strength, precipitate ageing & kinetics, adsorption of proteins & peptides on surfaces, effect of temperature on protein structure, hydration & thermal stability of proteins - solid powders, suspension on non-aqueous solvents, reversed micelles, aqueous solution of polyols, analytical and spectrophotometric characterization of proteins.

UNIT-IV

Bioequivalence studies: Immunogenicity &allergenicity of biosimilars; factors affecting immunogenicity - structural, post-translational modifications, formulations, impurities, manufacturing and formulation methods for biosimilars; types of bioequivalence (average, population, individual).

UNIT-V

Case studies: Indian companies working in this space & their product pipeline (Biocon, Intas, Dr Reddy's, Reliance, Bharat Biotech, Lupin, Cipla, Sanofietc); products -Insulin analog, Erythropoietin, growth hormone, granulocyte stimulating factors, interferons, streptokinase, monoclonal antibodies.

Text Books:

1. Laszlo Endrenyi, Paul Declerck and Shein-Chung Chow, Biosimilar Drug Development, Drugs and Pharmaceutical Sciences, Vol 216, CRC Press.
2. Cheng Liu and K. John Morrow Jr., Biosimilars of Monoclonal Antibodies: A Practical Guide to Manufacturing, Preclinical and Clinical Development, Wiley, Dec 2016.

Reference Material:

1. https://www.drugs.com/medical-answers/many-biosimilars-approved-unitedstates-3463281/

TECHNICAL SEMINAR

Instruction	2P Hours per week
SEE	0 Marks
CIE	50 Marks
Credits	1

The goal of a seminar is to introduce students to critical reading, understanding, summarizing, explaining and preparing report on state of the art topics in a broad area of his/her specialization. Seminar topics may be chosen by the students with advice from the faculty members and the student shall read further relevant articles in the domain.

The seminar must be clearly structured and the power point presentation shall include followingaspects:

1. Introduction to the field
2. Literature survey
3. Consolidation of available information
4. Summary and Conclusions
5. References

Each student is required to:

1. Submit a one page synopsis of the seminar talk for display on the notice board.
2. Deliver the seminar for a maximum duration of 30 minutes, where the presentation should be for20 minutes in PowerPoint, followed by Question and Answers session for 10minutes.
3. Submit the detailed report of the seminar in spiral bound in a précised format as suggested by the department.

Seminars are to be scheduled from 3rd week to the last week of the semester and any change in scheduleshall be discouraged.

For the award of sessional marks students are judged by three (3) faculty members and are based on oral andwritten presentations as well as their involvement in the discussions during the oral presentation.

Note: Topic of the seminar shall be preferably from any peer reviewed recent journal publications

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Guidelines for awarding marks		
Sl No.	Description	Max Marks
1.	Contents and relevance	10
2.	Presentation skills	10
3.	Preparation of PPT slides	05
4.	Questions and answers	05
5.	Report in a prescribed format	20

PROJECT PART-II

Instruction	12 L Hours per week
SEE	100 Marks
CIE	100 Marks
Credits	4

The object of 'Project: Part-2' is to enable the student extend further the investigative study taken up, either fully theoretical/practical or involving both theoretical and practical work, under the guidance of a Supervisor from the Department alone or jointly with a Supervisor drawn from R&D laboratory/Industry. This is expected to provide a good training for the student(s) in R&D work and technical leadership. The assignment to normally include:

1. In depth study of the topic assigned;
2. Review and finalization of the Approach to the Problem relating to the assigned topic;
3. Preparing an Action Plan for conducting the investigation, including teamwork;
4. Detailed Analysis/Modeling/Simulation/Design/Problem Solving/Experiment as needed;
5. Final development of product/process, testing, results, conclusions and future directions;
6. Preparing a paper for Conference presentation/ Publication in Journals, if possible;
7. Preparing a Dissertation in the standard format for being evaluated by the Department.
8. Final Seminar presentation before Departmental Committee.

Mapping of Course Outcomes with Program Outcomes and Program Specific Outcomes:

PO / CO	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PO10	PO11	PO12	PSO1	PSO2
CO1	1	1	0	0	0	0	0	0	0	0	1	2	1	1
CO2	1	2	0	1	2	0	0	0	0	0	1	0	3	3
CO3	1	2	0	1	3	0	1	0	0	0	0	1	2	3
CO4	0	0	0	0	1	0	0	0	1	2	0	0	1	1
CO5	1	0	0	1	0	2	0	2	1	0	0	1	2	2
CO6	0	0	1	0	2	0	2	1	0	0	1	0	1	1

Guidelines for the award of marks in CIE: (Max. Marks: 100)

Evaluation by	Max .Marks	Evaluation Criteria / Parameter
Department Review Committee	10	Review 1
	15	Review 2
	25	Submission
Supervisor	10	Regularity and Punctuality
	10	Work Progress
	10	Quality of the work which may lead to publications
	10	Report Preparation
	10	Analytical / Programming / Experimental Skills

Guidelines for awarding marks in SEE: (Max. Marks: 100)

Evaluation by	MaxMarks	Evaluation Criteria / Parameter
External and Internal Examinerstogether	20	Power Point Presentation
	40	Thesis Evaluation
	20	Quality of the project • Innovations • Applications • Live Research Projects • Scope for future study • Application to society
	20	Viva-Voce

PROJECT PART II GUIDELINES:

These guidelines assure consistency in the quality and components of project within the Department and they are segregated into 3 sections

A) Section 1 describes guidelines and procedures for allotment, submission, and acceptance of the project

1. Students will be allotted with a faculty supervisor based on their topic/ area of interest.
2. There will be a maximum of 3 students attached to each of the staff for each research project
3. Students are encouraged to continue the topic of Project Part I in their previous semester
4. Project problem statement and topic should be finalized in consultation with the faculty supervisor
5. Care should be taken that no two project problems should be same. Care should be taken that the problem should not be same as done in the department over last three years
6. No change in project or group after the department research committee and HoD finalizes the list
7. Hard bound project thesis (4 Nos) duly certified by internal guide, external guide (if any), DRC and the HOD should be submitted at the time of external viva-voce examination
8. The students should record the observations, impressions, information gathered and suggestions given, if any. It should contain the sketches & drawings related to the observations made by the students. Students shall be ready to show the diary to the internal guide or DRC or HoD at any point of time.
9. Responsibilities of students include
    - Schedule meetings as needed with the guide, or others as needed.
    - Meet the deadlines as specified in the departmental curriculum.
    - Submit working drafts to the project guide during the writing process.
    - The student is responsible for making all arrangements for preparation of the thesis

B) Section 2 provides an overview of the structure and content of the project thesis and minimal formatting requirements for preparation of the thesis.

1. The thesis consists of three general sections: The preliminary pages, text and references.
    - ✓ Title page (mention the guide's name-both internal and external also)
    - ✓ Certificates (INTERNAL AND EXTERNAL)
    - ✓ Declaration
    - ✓ Acknowledgements
    - ✓ Contents
    - ✓ Abbreviations
    - ✓ List of Tables
    - ✓ List of Figures
    - ✓ Graphical Abstract or comprehensive overview of work
    - ✓ Abstract (in 250 words) and Keywords
    - ✓ Novelty statement
    - ✓ Introduction
    - ✓ Review of literature
    - ✓ Materials and Methods
    - ✓ Results and Discussion
    - ✓ Conclusions(200 words)
    - ✓ References
    - ✓ Appendix (if any)
    - ✓ Published research papers (if any)
2. The thesis should be written in Times New Roman (12 size), 1.5 or double spacing, headings and side headings in bold, well defined margins, pagination, etc.
3. Students are instructed to prepare a comprehensive PowerPoint presentation with all findings to present before external examiner

C) Section 3 suggests the time schedule.

Students should attend all the reviews and follow the deadlines as per the almanac will be allotted with a faculty supervisor

Suggested schedule:

Starting Date	Day 1 (As per almanac)
Literature review / survey	End of 1 Weeks
Process Manuscript submission	End of 2 Weeks
Material and microbes procurement	End of 4 Weeks
Results and Analysis	End of 12 Weeks
Approval of printout draft and Manuscript	End of 15 Weeks
Submission of bound copies	Last Day (As per almanac)

The project would be evaluated on a regular basis by the DRC by conducting periodical reviews and marks will be awarded following the rubrics