

# CHAITANYA BHARATHI INSTITUTE OF

# TECHNOLOGY(A)

Choice Based Credit System (with effect from 2019-20) B.Tech (Biotechnology)

## SEMESTER-VII

			Scheme of Instruction		f Scheme of Examination			
S.No	Course Code	Title of the Course	Hour	rs per eek	Duration of SEE	Maximu	m Marks	Credits
			L/T	P/D	in Hours	CIE	SEE	
		]	THEOR	Y				
1	16BT C41	Down Stream Processing	3	-	3	30	70	3
2	16BT C42	Plant Biotechnology	3	-	3	30	70	3
3	16BT C43	Animal Biotechnology	3	-	3	30	70	3
4	16BT C44	Bioprocess Dynamics & Control	3	-	3	30	70	3
5	16BT C45	Computer Applications in Bioprocess Industries	3	-	3	30	70	3
6	16BT E46 16BT E47 16BT E48	Elective-V (Core) Genomics & Proteomics Cancer Biology Intellectual Property Rights Regulatory Affairs & Clinical Trials	3	-	3	30	70	3
		PR	ACTIC	ALS				
7	16BT C49	Down Stream Processing Lab	-	3	3	25	50	2
8	16BT C50	Tissue Culture Lab	-	3	3	25	50	2
9	16BT C51	Project Seminar	-	3	-	50	-	2
		TOTAL	18	9	24	280	520	24

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L: Lecture T: Tutorial D: Drawing CIE - Continuous Internal Evaluation

P: Practical

SEE - Semester End Examination

#### DOWN STREAM PROCESSING

3 L Hours per week		
3 Hours		
70 Marks		
30 Marks		
3		

#### **Course Objectives:**

- 1. Student is made to understand the role and, importance of downstream processing.
- 2. Students are taught the various techniques of cell disruption and the principles of solid liquid separation processes, filtration and centrifugation
- 3. Students are made to understand the principles of membrane based separations and their applications.
- 4. Students are enlightened about chromatographic separations, types and their importance in product purification.
- 5. Students are made to study the principle of crystallization, drying and lyophilisation.

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

- 1. Explain the key aspects of Downstream Processing from both a technical and economic perspective.
- 2. Learn the various techniques of cell disruption and unit operations for separation of insolubles
- 3. Design mineral water plant
- 4. Design and select chromatographic separation process for different bioproducts and scale up
- 5. Learn various techniques of product polishing and formulation.

# UNIT-I

**Role Of Downstream Processing In Biotechnology:** Role and Importance of Downstream Processing in Biotechnological Processes; Characterization of Biomolecules and fermentation broths; Physico-Chemical basis of Bioseparations; Characteristics of Bio-separations; Process design criteria for bioproducts; Downstream process economics.

# UNIT-II

**Primary Separation And Recovery Processes:** Cell Disruption methods for intracellular products- Mechanical, Chemical and Enzymatic Methods; Removal

of Insolubles, Biomass separation techniques; Flocculation; Sedimentation; Centrifugation; Filtration: Theory, Equipment-Depth filters, Plate and frame filters, Pressure leaf filters, Continuous rotary drum filters, filter media and filter aids, Problems on specific resistance of the cake, time taken for filtration and, compressibility of cake.

# UNIT-III

**Product Enrichment Operations:** Membrane-based separations-Types of membranes, solution diffusion model, capillary flow model; Types of flow-Cross flow, Tangential flow and mixed flow; Types of membrane based separations: Micro-filtration, Ultra-filtration, Dialysis, Electro dialysis, Reverse Osmosis; Theory, design and configuration of membrane separation equipment, Applications; Aqueous Two-phase extraction of proteins; Precipitation of proteins with salts and organic solvents; Adsorption processes.

# UNIT-IV

**Product Purification And Polishing:** Chromatographic separations- Principles, Classification, General description of column chromatography; IMAC, Bioaffinity Chromatography; Design and selection of chromatographic matrices; Design of large-scale chromatographic separation processes

# UNIT-V

**New and Emerging Technologies**: Pervaporation, super critical fluid extraction; Electrophoretic Separations; Final Product Polishing- Crystallization: nucleation, crystal growth, Industrial crystallizers, Drying: drying terminologies, drying curve, Industrial dryers Lyophilization: principles and applications; Formulation Strategies; Case studies (Citric acid / Penicillin and Low volume high value product like recombinant proteins).

## **Text Books:**

- 1. Sivasankar B, J M Asenjo, Separation processes in Biotechnology, Marcel-Dekker, 1993.
- Keith Wilson, John Walker, John M. Walker, Principles and Techniques of Practical Biochemistry 5th edition Cambridge University Press, 2000.

# Suggested Reading:

1. Nooralabettu Krishna Prasad, Downstream Process Technology by PHI publications.

#### **PLANT BIOTECHNOLOGY**

Instruction	3 L Hours per week		
Duration of SEE	3 Hours		
SEE	70 Marks		
CIE	30 Marks		
Credits	3		

#### **Course Objectives:**

- 1. The students should be able to understand explicitly the basic concepts of Plant Tissue culture.
- 2. To understand the developmental pathways of callus induction and plant regeneration.
- 3. To understand the techniques for production of secondary metabolites in *in vitro* using plant cell and tissue culture.
- 4. To understand the methods of gene transfer in plants for production of transgenics.
- 5. To understand the various strategies and sources of trangenes for crop improvement.

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

- 1. Describe the theoretical concepts behind establishment of in vitro techniques.
- 2. Explain the importance and applications of various in vitro techniques
- 3. Exploit plant tissues for production of biologics at commercial scale.
- 4. Interpret the knowledge of how the transgenes are utilized in the production of trangenics resistant to biotic, abiotic stress resistant and improved quality etc.
- 5. Analyse and use the appropriate vectors for production of transgenics

## UNIT-I

**Introduction To Plant Tissue Culture:** Introduction to cell and tissue culture: History, Totipotency, Cell Theory, Tissue culture media (composition, preparation);Sterilization techniques; Callus and cell suspension culture; Organogenesis and Embryogenesis and their applications.

## UNIT-II

**Tissue Culture In Crop Improvement:** Micropropagation of virus-free plants; Somaclonal variation; Haploids in plant breeding; Germplasm conservation (Cryopreservation). Protoplast isolation, culture and fusion: Somatic hybridization.

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## UNIT-III

**Molecular Farming & Industrial Products:** in vitro production of short chain and long chain fatty acids; Industrial enzymes; Edible vaccines. Production of secondary metabolites from plant cell cultures using Cell suspension cultures, Immobilized cell systems, Precursor feeding (elicitation) and hairy roots. Bioreactor systems and models for mass cultivation of plant cells.

## UNIT-IV

**Plant Genetic Engineering –I Techniques:** Agrobacterium mediated gene transfer; Plant vectors and their use in genetic manipulation; Direct gene transfer methods; electroporation, microinjection, particle bombardment and chemical methods.

## UNIT-V

**Plant Genetic Engineering –Ii Productivity And Safety Regulations:** Transgenics in crop improvement: Biotic Stress resistance: Herbicide,Insect, Disease, virus etc., Abiotic stress tolerance: Drought, Temperature, Salt. Transgenics for improved nutrional quality, storage, longer shelf life. Environmental impact and gene flow.

## **Text Books:**

- 1. Bhojwani SS and Razdan, Plant Tissue Culture Theory and Practice, Elsevier Science, 2004
- 2. Chawla HS, Introduction to Plant Biotechnology, 4th edition, Oxford and IBH publishers, 2002

## Suggested Reading:

- 1. Nigel G Halford, Plant Biotechnology: Current and future applications of genetically modified crops, edited John Wiley & Sons Ld. 2006.
- 2. Surabh Bhatia, Kiran Sharma, Randhir Dahiya and, Tanmoy Bera, Modern applications of Plant Biotechnology in Pharmaceutical Sciences, Elsevier publication, Academic press, 2015

#### ANIMAL BIOTECHNOLOGY

Instruction	3 L Hours per week		
Duration of SEE	3 Hours		
SEE	70 Marks		
CIE	30 Marks		
Credits	3		

#### **Course Objectives:**

- 1. Students are expected to understand the technical procedure involved to culture animal cells.
- 2. Students will learn various steps involved in the establishment of primary culture and their maintenance.
- 3. Students will know about cell viability and cytotoxicity, cell death.
- 4. Students are expected to know about stem cells and their applications.
- 5. Students will describe IVF and embryo transfer, cloning and gene transfer methods for generation of transgenic animals and its applications.

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

- 1. Explain the animal cell culture requirements and procedure.
- 2. Outline the establishment and maintenance of animal cell culture.
- 3. Discuss about Stem cells and their applications and describe the procedure for measurement of cell viability and cytotoxicity, cell death.
- 4. Explain various methods for IVF and embryo transfer, cloning and generation of transgenic animals and their applications.
- 5. Outline various applications of animal biotechnology.

## UNIT-I

Animal Cell Tissue Culture: History and scope of animal cell tissue culture, advantages and disadvantages of tissue culture; Laboratory facilities for animal tissue culture; Aseptic techniques; The substrate on which cells grow; Treatment of substrate surfaces; Culture media for cells and tissues.

## UNIT-II

**Primary Culture and Cell Lines:** Disaggregation (Enzymatic and Mechanical) of tissue and Primary culture. Culture cells and evolution of cell lines. Maintenance of cultures- Cell lines, Cell separation, Cell synchronization; Cloning of cell lines; Cell transformation; Bioreactors for animal cell culture; Scaling-up of animal cell culture.

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## UNIT-III

**Stem Cells, Cell Viability and Toxicity:** Stem cells, types of stem cells, embryonic stem cells and their applications; Measurement of cell viability and cytotoxicity, Measurement of cell death; Senescence, Apoptosis, Necrosis.

# UNIT-IV

**Embryo Transfer, Cloning and Transgenic Animals:** Artificial insemination, *in vitro* fertilization and embryo transfer; Cloning of animals - Reproductive cloning, Therapeutic cloning; Gene transfer or Transfection methods; Transgenic animals-Mice, Sheep, Pig, Rabbit, Goat, Cow and fish.

## UNIT-V

**Applications of Animal Biotechnology:** Application of animal cell culture; Mammalian cell products; Viral vaccines produced from animal cell cultures. Three dimensional culture; Tissue engineering.

# Text Books:

- 1. Ian Freshney, R., "Culture of Animal Cells: A manual of basic technique and specialized applications" Seventh edition, John Wiley and Sons, 2016.
- 2. John Masters, "Animal Cell culture: A practical approach" OUP Oxford, 2000.
- 3. Gupta P.K., "Biotechnology and Genomics" Rastogi Publications, 1<sup>st</sup> edition, 6<sup>th</sup> reprint, 2013

# Suggested Reading:

- 1. Srivastava, A.K., Singh, R.K., Yadav, M.P., "Animal Biotechnology" Oxford & IBH Publishing Co. Pvt. Ltd., 2005.
- 2. Ranga, M.M., "Animal Biotechnology", 3 reprint, Agrobios, India, 2010.

#### **BIOPROCESS DYNAMICS & CONTROL**

3 L Hours per week		
3 Hours		
70 Marks		
30 Marks		
3		

## **Course Objectives:**

- 1. The course aims at providing dynamics of system process, flow, level and temperature etc.
- 2. The course aims at incorporating with concepts of response of first order system for non interacting and interacting systems.
- 3. The course aims at providing knowledge the design of control system for open and close loop control.
- 4. The course aims at inculcating concepts of the control of pH of process and biochemical reactions.

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

- 1. Use the knowledge of Process dynamics to control level, temperature, flow variable etc in bioprocess industries.
- 2. Devise simple feedback control strategy for a bioprocess
- 3. Incorporate the knowledge of closed loop and open loop tuning methods to fine tune the control parameters.
- 4. Use the knowledge of control valve sizing in the design of control valve system in bioprocess units.
- 5. Apply the knowledge of process control to regulate the pH of bioreactors and apply the knowledge of process control to regulate the pH of bioreactors.

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## NIT-I

**Process Dynamics:** Laplace transform of simple functions, transforms of derivatives, solutions of differential equations, inversion by partial fractions, Partial fractions. Process variables, Dynamics of simple processes – Flow, level, Temperature, Pressure and Concentration; Transfer function – Properties, response of simple processes for Step, Impulse and Sinusoidal Forcing functions. Concept of Time Constant, Linearization, Response of first order systems in series - Non-interacting and Interacting systems. Physical examples of second order system

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## UNIT-II

**Control Actions And Controllers:** Controller and Control system – measuring device and final control elements, Open and Closed loop control, Negative and Positive feedback control, Servo and Regulatory problems. Ideal transfer functions –Control valve, Controllers, Proportional, Integral and derivative actions – PI. PD and PID controls. Block diagram- Development of block diagram, Over all Transfer function for single loop system, overall transfer function for change in set point and load, transportation lag.

## UNIT-III

**Optimum Controller settings:** Controller Tuning – Evaluation criteria with l/ 4th decay ratio, Criteria for good control- IAE. ISE, ITAE. Controller Tuning – Ziegler –Nicholas and Cohen Coon methods .Continuous cycling method, Control of processes with a time delay.

# UNIT-IV

**Final Control Element:** I/P Converter– pneumatic, electric and hydraulic actuators. Control valves – Construction, valve sizing, valve characteristics, valve positioner. Control of Globe, Butterfly and Diaphragm valves.

## UNIT-V

Advanced Control Strategies: Brief description of Cascade control. Feed forward control, Ratio control, with a simple example. Dynamics and Control of pH of a process and Biochemical reactor.

## **Text Books:**

- 1. Donald R.Coughanowr, Process Systems Analysis and Control, 2nd ed., McGraw Hill Inc., 1991.
- 2. George Stephanpoulos,"Chemical process control", Pearson Prentice Hall, 1984.
- 3. Seborg, Edgar, Mellichamp, Doyle, "Process Dynamics and Control", 3rd edition John Weily and Sons, 2010.
- 4. Harriott P, "Process control", Tata McGraw-Hill publishing Co., New Delhi, Reprint 1991.

## Suggested Reading:

- 1. Patranabis D, Principles of Process Control by 2nd ed., Tata McGraw-Hill publishing Co., New Delhi, Reprint 1997.
- 2. Eckman D.P., Automatic process control, Wiley Eastern Ltd., New Delhi, 1993.

# COMPUTER APPLICATIONS IN BIOPROCESS INDUSTRIES

Instruction 3 L He	3 L Hours per week		
Duration of SEE 3 Hour	rs –		
SEE 70 Mai	rks		
CIE 30 Mar	rks		
Credits 3			

## **Course Objectives:**

- 1. This course aims at providing knowledge on basic concepts in software development processes, Algorithm design and Process Models.
- 2. The course is designed to give an understanding on obtaining. solutions of differential equations by Euler's, Modified Euler's, Runge-Kutta methods
- 3. This course aims at providing an insight into the solution of set of simultaneous equations by Gauss elimination, Gauss Jordan and Gauss Seidel methods.
- 4. The aim of the course is also to give the students an understanding of obtaining solutions of numerical methods.

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

- 1. Distinguish between different process models
- 2. Formulate process models leading to set of ordinary differential equations and solution procedures numerical methods.
- 3. Formulate process models leading to set of linear simultaneous equations and solution procedures.
- 4. Formulate process models leading to transcendental and polynomial equations and solution procedures.
- 5. Understand the steps involved in optimization that are a prerequisite for the development of process flow sheets and optimize biochemical process.

# The Programs are to be written in "C" only UNIT-I

**Computers and Software:** Computing environments, the software development processes, Algorithm design, Program composition, Quality Control, Documentation, Storage and •Maintenance, Software strategy. Process Models: Uses, Distributed & Lumped parameter models, Linear and Nonlinear models, Steady state and Dynamic models, Continuous and Discrete models, Empirical

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models. Formulation of Process Models: Momentum, mass and energy balances, constitutive rate equations, transport rate equations, biochemical kinetic rate expressions, thermodynamic relations. Review on "C" Language Fundamentals.

# UNIT-II

**Function Approximation:** Function Approximations by Linear and nonlinear least square analysis, Formulation Process Models leading to set of ordinary differential equations and solution procedures by Eulers, Modified Eulers and Runge Kutta methods.

## UNIT-III

**Formulation of Process Models :** Formulation of Process Models leading to set of linear simultaneous equations and solution procedures by Method of determinants, Gauss Elimination, Gauss Jordan, Jacobi and Gauss-Seidel methods.

# UNIT-IV

## Process Models Leading to Transcendental and Polynomial Equations:

Formulation of Process Models leading to transcendental and polynomial equations and solution procedures by Bisection, Reguli-falsi, Newton Raphson, Richmond, Muller's and Bairstow methods.

## UNIT-V

**Process Optimization :**Nature and organization, basic concepts and elements of Optimization, Scope and hierarchy of optimization, Essential features and general procedure of optimization problems and applications of optimization, single variable functions, direct, indirect and random search methods – with and without acceleration Elimination methods for unrestricted and exhaustive search, Fibonacci search, Dichotomous search, Golden-section (gradient) search methods.

## Text Books:

- 1. DR. B.S. Grewal, Higher engineering mathematics Khanna publishers, 1998.
- 2. Steven C. Chapra and Raymond P Canale, Numerical methods for Engineers 2nd edition, MCGraw Hill International edition, 1988.

## Suggested books:

- 1. Henry R. Bungay Computer Applications in Bioprocessing Volume 70 Springer, 2000.
- 2. Edger T.E., and Himmelbau D.M., "Optimization of chemical processes", McGraw Hill international edition, 1988 3. Bioprocess engineering Enrique Galindo and Octavio T. Ramírez Volume 16, Issue 7, 1998.

3 Hours

70 Marks

30 Marks

3

3 L Hours per week

# GENOMICS & PROTEOMICS

Elective-V (Core)

Instruction	
Duration of SEE	
SEE	
CIE	
Credits	

#### Course Objectives:

- 1. 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 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. Be able to know about genomes, types of genomes and the advanced techniques used for analysing genome.
- 2. Be able to construct cDNA libraries and explain the importance of cDNA libraries in the identification of functional genes in the genome.
- 3. Understanding the advancements in the field of modern genomics from classical genomics.
- 4. To have basics of how proteins are determined and about the function of proteins
- 5. Be able to design personalized medicines and explain their uptake, action and metabolism.

## 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, YAC, BAC, Hybrid mapping strategies, microarrays, Sequence specific tags(SST),Sequence tagged sites(STS), FISH, RFLP and RAPD.

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## UNIT-II

**Functional Genomics:** Construction and screening of cDNA libraries; cDNA microarrays(DNA micro array, protein micro array), Gene disruptions, Serial analysis of gene expression (SAGE), SAGE Adaptation for Downsized Extracts (SADE); Applications of DNA arrays.

## UNIT-III

**Next Generation Sequencing:** Next generation sequencing- importance; Different sequencer platforms available; Methods of Sequencing; File formats; Data generation tools; Preprocessing of data; Genome wide association studies; Chip-Seq; RNA-Seq; Metagenomics.

## UNIT-IV

**Proteomics And Tools Used For Proteomics:** Protein structure, Protein databases, data mining, Sequence alignment, Algorithms in proteomics, Applications of proteomics: proteome mining, protein expression profiling, protein-protein interactions, protein modifications; Protein digestion techniques; Mass spectrometry: MALDI-TOF, Mass analyzers, peptide Mass Fingerprinting, Protein arrays.

## UNIT-V

**Metabolomics And Pharmacogenomics:** Metabolomis-Basics; Pharmacogenomics-Basics, Diseased genes and their identification; Drug uptake an 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. Cendric Gondro, "Primer to Analysis of Genomic Data Using R", Springer, 2015.

With effect from the Academic Year 2019-20

3 L Hours per week

3 Hours

70 Marks

30 Marks

#### 16BT E47

## **CANCER BIOLOGY**

Elective-V (Core)

Instruction	
Duration of SEE	
SEE	
CIE	
Credits	

#### **Course Objectives:**

- 1. Student is made to understand the role of cell cycle and diet in cancer.
- 2. Students are taught the Molecular aspects of cell cycle control.
- 3. Importance of physical and chemical carcinogens taught by showing effects of mutagens on cell cycle.
- 4. Students are enlightened about discovery of proto-oncogenes and their activation.
- 5. Students are made to understand the diagnosis and treatment of cancer.

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

- 1. Apply to real life situations, the concept of diet and cell cycle.
- 2. Incorporate the fundamentals of cell biology and Molecular biology to understand how they are responsible for cancer.
- 3. Explain the types of carcinogens and the effect of mutagens on cell cycle.
- 4. Describe the structure of retrovirus and how they led to discover the oncogens.
- 5. Outline the No. of stages of cancer, detection of cancer and treatment of cancer and explain the ADME properties of anti cancer drugs.

## UNIT-I

**Fundamentals Of Cancer Biology:** Definition and hall marks of cancer, Cell cycle control, regulation of the cell cycle by cyclins, cyclin-dependent kinases, cdk inhibitors, Mutations that cause changes in signal molecules, Effects on receptor, Signal switches, Tumor suppressor genes, Different forms of cancer(Case studies for carcinoma ex: breast cancer and stomach cancer), Diet and cancer.

# UNIT-II

**Principles Of Carcinogenesis:** Natural History of Carcinogenesis, Types of Carcinogenesis, Chemical Carcinogenesis, Metabolism of Carcinogenesis, Targets

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of Chemical Carcinogenesis, Principles of Physical Carcinogenesis, Ionizing radiation and UV radiation mechanism of Carcinogenesis.

# UNIT-III

**Principles Of Molecular Cell Biology Of Cancer:** Oncogenes, Identification of Oncogenes, Retroviruses and Oncogenes, Detection of Oncogenes, Growth factor and Growth factor receptors that are Oncogenes, Activation of protooncogens to oncogens. Growth factors related to transformations.

## UNIT-IV

**Cancer Metastasis And Treatement:** What is Metastasis, Classic theory of tumor Metastasis, Clinical significance of invasion, Heterogeneity of metastatic phenotype, Three-step theory of invasion (Basement Membrane disruption, role of Proteinases in tumor invasion and tumor cell locomotion).Diagnosis of cancers, Advances in Cancer detection(Biomarkers technology and nanotechnology), Different forms of therapy- Chemotherapy, Radiation therapy and immunotherapy.

# UNIT-V

**Principles Of Cancer Pharmacology:** Pharmacokinetics and pharmacodynamics of antineoplastic drugs. Metabolism of anticancer drugs, inter individual differences in response to anticancer drugs, mechanisms of anticancer drug resistance. Molecular targets for drug development, mechanism of gene silencing (antisense, ribozymes, RNAi) and chemoprevention studies.

## **Text Books:**

- 1. Franks LM and N.M.Teich, "Introduction to Cellular and Molecular Biology of Cancer", 2<sup>nd</sup> edition, Oxford Medical Publications, 1991.
- 2. Raymond W. Ruddon "Cancer Biology", 3<sup>rd</sup> edition, Oxford University Press, USA 1995.
- 3. King, Roger J B, Robins, Mike W, "Cancer Biology", 3<sup>rd</sup> edition, Prentice Hall, USA.2003.

## **Suggested Reading:**

- 1. Fiona Macdonald, Christopher Ford, Alan Casson, "Molecular Biology of Cancer", 2<sup>nd</sup> Edition, Taylor & Francis, 2004.
- 2. Robert A. Weinberg, "The Biology of Cancer", 5<sup>th</sup> edition, Garland Science.2006.
- 3. Robin Hesketh, "Introduction to Cancer Biology" Cambridge University Publishers, Jan, 2013.

#### 16BT E48

# INTELLECTUAL PROPERTY RIGHTS REGULATORY AFFAIRS AND CLINICAL TRIALS

Elective-V (Core)

Instruction
Duration of SEE
SEE
CIE
Credits

3 Hours 70 Marks 30 Marks 3

3 L Hours per week

#### Course Objectives:

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

#### **Course Outcomes:**

The students at the end of the course will

- 1. The Students will apply the knowledge gained about IPR and to demonstrate the process of patent filing.
- 2. To create awareness to the Students about the ICH, GCP, FDA guidelines.
- 3. To discuss and explain the role of regulatory affairs and their significance.
- 4. Evaluate the criteria for drug approval related documentation.
- 5. To evaluate, assess, compare and interpret various phases of clinical trials and the basis of approval of new drugs, their outcome in new drug discovery.

## UNIT-I

**Intellectual Property Rights:** Intellectual property rights, and intellectual property protection, patents and methods of application of patents, trade secret, copy rights, trade marks, legal implication, trade related aspects (TRIPS), farmers rights, plant breeder's rights.

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## 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) Exclusivities (NCE, NS, NP, NDF, PED, ODE, PC).

#### UNIT-III

**Regulatory Affairs- Global:** Introduction to FDA, WHO, Code of federal Regulations, ICH Guidelines, Related quality systems- objectives and guidelines of USFDA, WHO & ICH, 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 and Scope, stake holders in clinical research, Framework of clinical research, Declaration of Helenski, 2000 amendment, medical and clinical research terminology, Principles of GCP, Roles and responsibilities in clinical research according to ICH GCP, Sponsor, Investigator, IRB/IEC, Essential documentation, Confidentiality issues. Clinical data management system, Double data entry.

## **Text Books:**

- Fleming DA, Hunt DL, "Biological Safety Principles and Practices", 3<sup>rd</sup> edition, ASM Press, Washington, 2000.
- 2. Dominique PB and Gerhardt Nahler, International Clinical Trial, Volume 1&2,, Interpharm Press, Denver, Colorado.

## **Suggested Reading:**

1. Good Clinical Practices, Central Drugs Standard Control Organization, Govt. of India Drugs and Cosmetics Act, 1940.

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2. Code of Federal Regulations by USFDA-Download

#### DOWN STREAM PROCESSING LAB

3 P Hours per week		
3 Hours		
50 Marks		
25 Marks		
2		

#### **Course Objectives:**

- 1. To provide an opportunity to experimentally verify the theoretical concepts studied.
- 2. To give extensive exposure to various unit operations of downstream processing.
- 3. Students are explained how to design protocol for separation of bioproduct based on characteristics

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

- 1. Understand the fundamentals of downstream processing for biochemical product recovery.
- 2. Calculate operating parameters for a given downstream processing unit operation.
- 3. Develop their skills in the purification of bioproducts from fermentation broths.
- 4. Design chromatographic separation process for a given compound.
- 5. Arrange unit operations into an appropriate sequence for the purification of a given type of biological product.

## List of Experiments:

- 1. Cell Disruption of microorganism using sonicator.
- 2. Cell Disruption of plant cells / animal cells.
- 3. Homogenization of microbes / plant material using pestle and mortar.
- 4. Liquid-liquid extraction.
- 5. Separation of solids from liquid by Sedimentation
- 6. Separation of micro organisms from fermentation broth by Microfiltration.
- 7. Separation of solute particles by Dialysis.
- 8. Separation of alpha amylase by Ammonium Sulphate Precipitation.
- 9. Isolation and quantification of casein from milk by Isoelectric Precipitation.
- 10. Separation of biomolecules by Gel Exclusion Chromatography.

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- 11. Purification of lysozyme from chicken egg white extract by Ion Exchange Chromatography.
- 12. Purification of proteins by Affinity Chromatography.
- 13. Determination of purity and molecular weight of proteins by SDS-PAGE.
- 14. Simple distillation- vapor liquid equilibrium.
- 15. Solid liquid extraction.

## Text books:

- 1. David Plummer, "An introduction to Practical Biochemistry" 3<sup>rd</sup> edition, John Wiley & Sons, 1998.
- 2. Keith John Walker John <u>Walker</u> Principles and Techniques of Biochemistry and Molecular Biology by,Cambridge University Press; 6 edition, 2005.

#### TISSUE CULTURE LAB

Instruction	3 P Hours per week		
Duration of SEE	3 Hours		
SEE	50 Marks		
CIE	25 Marks		
Credits	2		

#### **Course Objectives:**

- 1. The students should be able to understand explicitly the concepts of Plant Tissue culture and Animal tissue culture.
- 2. Develop their skills in plant tissues culture techniques.
- 3. Get extensive exposure to various techniques of plant cell and tissue culture.
- 4. To develop a protocol for genetic transformation using Agrobacterium strains.
- 5. The students will handle animal cell culture.

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

- 1. Provides an opportunity to experimentally verify the theoretical concepts studied.
- 2. Gain hands on training in developing protocols for various in *in vitro* techniques: callus cultures, cell and suspension cultures etc.
- 3. Establish *in vitro* techniques of micropropagation of crop/horticulture and medicinal plants.
- 4. Establish a system of genetic transformation using Agrobacterium strains.
- 5. Handle and experience the Protoplast isolation and culture that helps them to produce somatic hybrids.

## List of Experiments

- 1. Preparation of Plant tissue Culture Media
  - i) Preparation of MS stock solutions
  - ii) Preparation of MS callus induction media
- 2. Surface sterilization
- 3. Callus induction: Embryo Culture.
- 4. Meristem tip culture
- 5. Micro propagation of horticultural/medicinally important plants

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- 6. Cell suspension cultures initiation and establishment.
- 7. Organogenesis and Embryogenesis.

- 8. Production of synthetic seeds.
- 9. Protoplast isolation (demo)
- 10. Agrobacterium mediated gene transfer: induction of Hairy roots
- 11. Preparation of Animal cell culture media
- 12. Preparation of cheek epithelium cells
- 13. Preparation of Primary cell lines
- 14. Cell counting and viability
- 15. Staining of animal cells

# **Text Books:**

- 1. H. Jones and John M. Walker, Plant Gene Transfer and Expression Protocols: Methods in Molecular Biology, 49, Humana Press, 1996.
- 2. J. G. Chirikjian, Biotechnology: Theory and Techniques (Plant Biotechnology, Animal Cell Culture and Immunobiotechnology), Jones & Bartlett Publishers, U.K., 1996.

#### PROJECT SEMINAR

Instruction		
CIE		
Credits		

16BT C51

3 Hours per week 50 Marks 2

The objective of 'Project Seminar' 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.

Guidelines for the award of Marks:

Max. Marks: 50	
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Evaluation by	Max. Marks	Evaluation Criteria / parameter
	20	Project Status / Review
Supervisor	5	Report
	5	Relevance of the Topic
Department Committee	5	PPT Preparation
	5	Presentation
	5	Question and Answers
	5	Report Preparation

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## CHAITANYABHARATHI INSTITUTE OF TECHNOLOGY (A) Choice Based Credit System (with effect from 2019-20) B.Tech (Biotechnology)

#### SEMESTER-VIII

			Schen Instru	ne of ction	Scheme	of Exami	nation	
S.No	Course Code	Title of the Course	Hours	s per ek	Duration of SEE	Maxi Ma	imum Irks	Credits
			L/T	P/D	in Hours	CIE	SEE	
			THEORY	7			-	-
1	16BT E52 16BT E53 16BT E54	Elective-VII (Core) Tissue Engineering Immunodiagnostics Molecular Modeling & Drug Design	3	-	3	30	70	3
2	16ME 006 16EC 002 16EG 001	Elective-VIII (Open) Research Methodologies Biomedical Instrumentation Technical Writing Skills	3	-	3	30	70	3
3	16CS O03 16CS O04 16ME O01	Elective- IX (Open) IOT and Applications Basics of Data Science Using R Entrepreneurship	3	-	3	30	70	3
4	16BT C55	Seminar	3	-	3	50	-	2
5	16BT C56	Project	6	-	3	50	100	6

L: Lecture	T: Tutorial	D: Drawing	P: Practical
CIE - Contin	uous Internal l	Evaluation	SEE - Semester End Examination

#### TISSUEENGINEERING

Elective-VII (Core)

Instruction	3 L Hours per week
Duration of SEE	3 Hours
SEE	70 Marks
CIE	30 Marks
Credits	3

#### **Course Objectives**

- 1. To provide fundamental principles and elements of tissue engineering.
- 2. To get insight into the roles of cells, tissue organization and matrix in tissue engineering.
- 3. To learn the practical approach of carrying out tissue culture.
- 4. To learn about the Stem cells and different materials to use as biomaterials.
- 5. To gain knowledge about the medical applications of tissue engineering

Course Outcomes: At the end of the course students will be able to

- 1. Recognize the upcoming concepts of tissue engineering, ethical issues, and future prospects
- 2. Illustrate the molecular mechanisms at tissue level and in cell matrix in tissue engineering.
- 3. Identify *in vitro* culturing techniques and scale up designs.
- 4. Classify and identifies the need of compatible biomaterials as scaffolds for Tissue engineering.
- 5. Identify and interpret the knowledge, of tissue engineering in producing organs for therapeutic applications.

#### UNIT-I

**Introduction To Tissue Engineering:** Basic definition of Tissue engineering; origin and history of Tissue Engineering, overview of its basic steps and its applications; General scientific issues, Ethical issues; current challenges and future prospectives.

## 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;

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EMT, Molecular mechanisms and control of EMT process. Tissues- Vascularity; angiogenesis; wound healing. Extra cellular matrix (ECM) –components.

## UNIT-III

**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, combined bioreactors

## UNIT-IV

**Biomaterials of Tissue Engineering:** Scaffolds- fabrication; 3D scaffolds Biodegradable polymers; synthetic polymers; hybrid of synthetic and biological polymers; prosthetic devices. Engineering biomaterials for tissue engineering.

#### UNIT-V

**Applications of Tissue Engineering:** Tissue replacement –crucial factors Skin grafting Bone tissue engineering; Cardiac tissue engineering; Neural tissue engineering; Vascular tissue engineering;

#### **Text Books:**

- 1. Robert.P.Lanza, Robert Langer & Vacanti, Principles of tissue engineering.. Academic Press. 2nd edition 2000.
- 2. B. Palsson, J.A. Hubbell, R. Plonsey & J.D. Bronzino. Tissue engineering. CRC Taylor & Francis 2000.

## **Suggested Reading:**

- 1. Bernard prish, Tissue engineering- Design, practice & reporting, Woodhead Publishing Ltd. Cambridge. UK 2009.
- 2. Atala O.P & Lanza.L , Methods of tissue engineering.. Woodhead Publishing Ltd. Cambridge. UK. 2009.

3 Hours

70 Marks

30 Marks

3

3 L Hours per week

## IMMUNODIAGNOSTICS

Elective-VII (Core)

Instruction	
Duration of SEE	
SEE	
CIE	
Credits	

#### **Course Objectives:**

- 1. The students will learn the basic principles, procedures and applications of immunodiagnostic tests.
- 2. The students are introduced to engineer antibody by using rDNA technology
- 3. The students are illustrated to the steps involved in the develop, production and applications of monoclonal antibody technology
- 4. The students will learn the development of preventive agents such as vaccines
- 5. The students also 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, and classification of immunodiagnostic tests.
- 2. Demonstrate the antigen antibody reaction and its application in immunodiagnostics for diagnosing various diseases by using different types of immunodiagnostic tests
- 3. Discuss about the development of monoclonal antibodies for diagnosis, treatment and prevention of disease.
- 4. Explain the new methods of treating various diseases are being explored by vaccine development.
- 5. Describe the novel techniques used in immunodiagnostics.

## 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.

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## UNIT-II

**Immunodiagnostics Techniques:** Immunodiagnostics techniques – Precipitation, Immunoelctrophoresis, 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; Immunomonitoring 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 Stranford, Patricia Jones, Judith A Owen., "Kuby Immunology" 8<sup>th</sup> edition, Macillan learning, 2018.
- 3. Ralph M Aloisi Lea, Principles of Immunology and Immunodiagnostics, Lea & Febiger, 1988.

#### 16BT E54

#### **MOLECULAR MODELING & DRUG DESIGN**

Elective-VII (Core)

Instruction	
Duration of SEE	
SEE	
CIE	
Credits	

3 L Hours per week 3 Hours 70 Marks 30 Marks 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.

Course Outcomes: At the end of the course students will be able to

- 1. Calculate Total energy of molecule by using force field potentials.
- 2. Calculate Internal energy, Heat capacity, Temperature, 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 and classify the CADD to treat Alzheimers and TB diseases.

## UNIT-I

**Empirical Force Fields And Molecular Mechanics:** Introduction to Molecular Mechanics, Coordinate system, Molecular graphics, Force fields, Bond stretching, Angle bending, Torsions, polarizable force fields 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

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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, QMM simulations.

## UNIT-IV

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

## UNIT-V

**Applications of Molecular Modeling and Drug Design:** Production of Drugs in Pharmaceutical companies, CADD: Strucure Based Drug Design and Ligand Based Drug Design, Quantiative Structural Activity Relationship (QSAR) studies in Protein- Ligand interactions, Case studies of Alzheimers disease, Tuberculosis and Cancer etc.

## Text books:

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

## Suggested Reading:

- 1. C. Brandon and J. Tooze, Introduction to protein structure by Garland, 2nd edition, 1998.
- 2. V. Kothakar, Essentials of Drug Designing Dhruv publications, 1998.

18ME 006

## **RESEARCH METHODOLOGIES**

(Elective-VIII) Open

Instruction Duration of SEE SEE CIE Credits	3 L Hours per week 3 Hours 70 Marks 30 Marks 3	<b>UNIT-IV</b> <b>Data Collection:</b> Collection of primary data, Secondary data, Measures of central tendency-mean, mode, median, Measures of dispersion- Range, Mean deviation, Standard deviation, Measures of asymmetry (skewness), Important parametric tests -z, t, F, Chi-Square, ANOVA significance
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#### **Course Objectives:**

- 1. To make the students to formulate the research problem
- 2. To identify various sources for literature review and data collection.
- 3. To prepare the research design
- 4. To equip the students with good methods to analyze the collected data
- 5. To explain how to interpret the results and report writing

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

- 1. Define research problem
- 2. Review and asses the quality of literature from various sources.
- 3. Understand and develop various research designs.
- 4. Analyze problem by statistical techniques: ANOVA, F-test, Chi-square
- 5. Improve the style and format of writing a report for technical paper/ Journal report

## UNIT-I

**Research Methodology**: Objectives and Motivation of Research, Types of Research-Descriptive vs. Analytical, Applied vs. Fundamental, Quantitative vs. Qualitative, Conceptual vs. Empirical, Research Approaches, Significance of Research, Research Methods verses Methodology, Research process, Criteria of Good Research, Problems Encountered by Researchers in India, Technique involved in defining a problem.

# UNIT-II

**Literature Survey:** Importance of Literature Survey, Sources of Informationprimary, secondary, tertiary, Assessment of Quality of Journals and Articles, Information through Internet.

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## UNIT-V

UNIT-III

sample design

**Research Report Writing:** Format of the Research report, Synopsis, Dissertation, Thesis its Differentiation, References/Bibliography/Webliography, Technical paper writing/Journal report writing, making presentation, Use of visual aids. Research Proposal Preparation- Writing a Research Proposal and Research Report, Writing Research Grant Proposal.

Research Design: Meaning of Research Design, Need of Research Design,

Feature of a Good Design Important Concepts Related to Research Design,

Different Research Designs, Basic Principles of Experimental Design, Steps in

## **Text Books:**

- 1. C.R Kothari, "Research Methodology, Methods & Technique", New Age International Publishers, 2004.
- 2. R. Ganesan, "Research Methodology for Engineers", MJP Publishers, 2011

## Suggested Reading:

- 1. Vijay Upagade and Aravind Shende, "Research Methodology", S. Chand & Company Ltd., New Delhi, 2009
- 2. G. Nageswara Rao, "Research Methodology and Quantitative methods", BS Publications, Hyderabad, 2012.
- 3. Naval Bajjai, "Business Research Methods", Pearson 2011.
- 4. Ratan Khananabis and Suvasis Saha, "Research Methodology", Universities Press, Hyderabad, 2015.

3 Hours

70 Marks

30 Marks

3

3 L Hours per week

#### **BIOMEDICAL INSTRUMENTATION**

(Elective-VIII) Open

Instruction	
Duration of SEE	
SEE	
CIE	
Credits	

#### **Course Objectives:**

- 1. To understand the physiological systems present in the human body.
- 2. To understand the application of electronic systems used in modern health care.
- 3. To acquire, process and analyse Bio medical signals.

Course Outcomes: At the end of the course students will be able to

- 1. Know the functionality of the human body.
- 2. Know the practical limitations of electronic gadgets used for human systems.
- 3. Measure various physiological parameters.
- 4. Know the functionality of Bio medical recorders.
- 5. Learn the concepts of Brain- computer interface.

## UNIT-I

**Introduction to Bio Medical Instrumentation:** Components of the Man-Instrument system, Physiological systems of the body, Problems encountered in measuring a living system.Sources of Bio electric potentials: Resting and action potentials, propagation of action potentials, Bio electric potentials.

## UNIT-II

**Basic Transducer Principles:** Transducer principles, active and passive transducers, their bio medical applications.

Electrodes: Electrode theory, bio potential electrodes, bio chemical transducers.

## UNIT-III

**Cardiovascular System:** The heart and cardiovascular system, the heart, blood pressure, blood flow, heart sounds, ECG, Measurement of blood pressure, blood flow, cardiac output, and heart sounds and PCG. Patient care and monitoring systems: Elements of Intensive care systems, patient monitoring systems, other instruments, organisation of the hospital for patient care monitoring, pace makers, defibrillators.

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# UNIT-IV

**Bio Medical Amplifiers:** Basic requirements, differential amplifier, carrier amplifier, chopper amplifier, phase sensitive detector. EEG: Signal sources, EEG recording, applications of EEG. EMG: Surface and needle electrodes, EMG, measurement of conduction velocity, ERG, EOG. Respiration: mechanism, spirometer, and pneumotachograph.

# UNIT-V

**Bio telemetry:** Introduction, physiological parameters adaptable to biotelemetry, components of telemetry system, implantable units, applications of telemetry in patient care. Computer in Biomedical instrumentation: digital computer, micro processor, Interfacing computer with other medical equipment, Biomedical computer applications, Introduction to CAT scanner. X-Ray: X-ray unit, radiation therapy, Introduction to MRI and nuclear imaging.

## **Suggested Reading:**

- 1. Leslie Cromwell, Fred J Weibell and Erich A Pfeiffer, BioMedical Instrumentation and Measurements, PHI, 2<sup>nd</sup> edition, 2003.
- 2. C Raja Rao and SK Guha, "Principles of Medical Electronics and BioMedical Instrumentation", Universities press, 2013.

#### 16EG 001

#### TECHNICAL WRITING

(Elective-VIII) Open

#### Instruction Duration of SEE SEE CIE Credits

#### 3 L Hours per week 3 Hours 70 Marks 30 Marks 3

#### **Course Objectives:**

The course will introduce the students to:

- 1. Process of communication and channels of communication in general writing and technical writing in particular.
- 2. Learn Technical Writing including sentence structure and be able to understand and use technology specific words.
- 3. Write business letters and technical articles.
- 4. Write technical reports and technical proposals.
- 5. Learn to write agenda, record minutes of a meeting, draft memos. Understand how to make technical presentations.

Course Outcomes: At the end of the course students will be able to

- 1. Communicate effectively, without barriers and understand aspects of technical communication.
- 2. Differentiate between general writing and technical writing and write error free sentences using technology specific words
- 3. Apply techniques of writing in business correspondence and in writing articles.
- 4. Draft technical reports and technical proposals.
- 5. Prepare agenda and minutes of a meeting and demonstrate effective technical presentation skills.

## Unit-I

**Communication** – Nature and process.

**Channels of Communication** – Downward, upward and horizontal communication. Barriers to communication.

**Technical Communication** – Definition, oral and written communication. Importance and need for Technical communication. Nature of Technical Communication. Aspects and forms of Technical communication. Technical communication Skills – Listening, Speaking, Reading & Writing.

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#### Unit-II

**Technical Writing** – Techniques of writing. Selection of words and phrases in technical writing. Differences between technical writing and general writing. Abstract and specific words. Sentence structure and requisites of sentence construction. Paragraph length and structure.

## Unit-III

**Business correspondence** – Sales letters, letters of Quotation, Claim and Adjustment letters.

**Technical Articles**: Nature and significance, types. Journal articles and Conference papers, elements of technical articles.

## Unit-IV

**Technical Reports**: Types, significance, structure, style and writing of reports. Routine reports, Project reports.

**Technical Proposals**: Definition, types, characteristics, structure and significance.

## Unit-V

**Mechanics of Meetings:** Preparation of agenda, participation, chairing and writing minutes of a meeting. Memorandum. Seminars, workshops and conferences.

**Technical Presentations**: Defining purpose, audience and locale, organizing content, preparing an outline, use of Audio Visual Aids, nuances of delivery, importance of body language and voice dynamics.

## **Text Book :**

- 1. Meenakshi Raman & Sangeeta Sharma, "TechnicalCommunications-Principles and Practice", Oxford University Press, Second Edition, 2012.
- 2. 1.M Ashraf Rizvi, "Effective Technical Communication", Tata McGraw Hill Education Pvt Ltd, 2012.

## Suggested Reading :

- 1. Kavita Tyagi & Padma Misra, "Basic Technical Communication", PHI Learning Pvt Ltd, 2012.
- 2. R.C Sharma & Krishna Mohan, "Business Correspondence and Report Writing", Tata McGraw Hill, 2003

## Web Resources:

- 1. https://onlinecourses.nptel.ac.in/noc18\_mg13/preview
- 2. https://www.technical-writing-training-and-certification.com/
- 3. https://academy.whatfix.com/technical-writing-skills



16CS 003

3 L Hours per week

3 Hours

3

70 Marks 30 Marks

## **IOTANDAPPLICATIONS**

(Elective-IX) Open

Instruction	
Duration of SEE	
SEE	
CIE	
Credits	

## Pre-requisites: Programming Basics.

#### **Course Objectives:**

- 1. Impart necessary and practical knowledge of components of Internet of Things.
- 2. Develop skills required to build IoT based systems in the field of biotechnology.

Course Outcomes: At the end of the course students will be able to

- 1. Understand Internet of Things and its hardware and software components.
- 2. Interface I/O devices, sensors & communication module.
- 3. Remotely monitor data and control devices.
- 4. Develop real time IoT based projects.
- 5. Advance towards research based IoT in the field of biotechnology.

## Unit- I

**Introduction to IoT:** Sensors, Types of sensors and Transducers, Actuators and Types of Actuators.

## UNIT-II

**Basics of Networking :** Functional Components of IoT, IoT interdependencies, IoT Service oriented architecture, IoT categories, IoT gateways, IoT and associated technologies, Key technologies for IoT, IoT challenges.

# Unit-III

**IoT Hardware Components:** Computing (Arduino/Raspberry Pi), Communication, Sensors, Actuators, I/0 interfaces, Programming API's (for Arduino/ Raspberry Pi).

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## Unit-IV

**Generic IoT Systems:** Home Automation: Smart Lighting, Environment: Weather Monitoring System, Weather Reporting Bot, Forest Fire Detection.

# UNIT-V

**IoT for Biotechnology:** Agriculture: Drip-irrigation, Seed quality detection system, Biological water treatment system, Alcohol Detection System, Bio fuel cell for low power IoT devices

## **Text Books:**

- 1. Raj and Anupama C. Raman,"The Internet of Things: Enabling Technologies, Platforms, and Use Cases", CRC Press, 2017.
- 2. Jeeva Jose, "Internet of Things", Khanna Publishing House, Delhi, 2018.
- 3. Arshdeep Bahga and Vijay Madisetti, "Internet of Things: A Handson Approach", Universities Press, 2014.

# Suggested Reading:

- 1. Dr. SRN Reddy, Rachit Tirnkral and Manasi Mishra, "Introduction to Internet of Things: A practical Approach", ETI Labs, 2018.
- 2. Adrian McEwen, "Designing the Internet of Things", Wiley, 2013.
- 3. Raj Kamal, "Internet of Things:Architecture and Design", McGraw Hill, 2017.
- 4. Cuno Pfister, "Getting Started with the Internet of Things", 0 Reilly Media, 2011.
- 5. O. Vermesan, P. Friess, "Internet of Things Converging Technologies for Smart Environments and Integrated Ecosystems", River Publishers, Series in Communications, 2013.

## Online Resources / Weblinks / NPTEL Courses:

- 1. Li Da Xu, Wu He, and Shancang Li, "Internet of Things in Industries: A Survey ", IEEE Transactions on Industrial Informatics, Vol. 10, No. 4, Nov. 2014.
- 2. Gotovtsev, Pavel M., and Andrey V. Dyakov. "Biotechnology and Internet of Things for green smart city application." 2016 IEEE 3rd World Forum on Internet of Things (WF-IoT). IEEE, 2016.
- 3. Yanjing, Sun, et al. "Research and design of agriculture informatization system based on IOT." Journal of Computer Research and Development 48 (2011): 316-331.
- 4. Somov, Andrey, et al. "Bacteria to power the smart sensor applications: Biofuel cell for low-power IoT devices." 2018 IEEE 4th World Forum on Internet of Things (WF-IoT). IEEE, 2018.
- 5. Han, Shuqing, et al. "Analysis of the frontier technology of agricultural IoT and its predication research." IOP Conference Series: Materials Science and Engineering. Vol. 231. No. 1. IOP Publishing, 2017.

3 L Hours per week

3 Hours

70 Marks

30 Marks

3

#### BASICS OF DATA SCIENCE USING R

(Elective-IX) Open

Instruction	
Duration of SEE	
SEE	
CIE	
Credits	

Pre-requisites: Probability and Statistics, basics of programming languages.

## **Course Objectives:**

- 1. Understand R programming language.
- 2. Explore the programming skills needed to use R tool for statistical analysis of Biological data.
- 3. Analyze biological data.

Course Outcomes: At the end of the course students will be able to

- 1. Understanding the basics of R, various statistical measures, algorithms useful for data analysis.
- 2. Explore the programming skills needed to use R tool for biological data.
- 3. Analyze biological data using R tool.
- 4. Apply classification and clustering algorithms to bilogical data.
- 5. Identify and work with the technologies and resources related to bioinformatics.

# UNIT-I

**Basics of R:** Introduction, R features, setting up and exploring R environment, loading packages, types of data objects in R, working with R data objects, Controlling work space, importing files.

**Programming with R:** Variables and assignment, operators, control structures, Functions-built-in, writing own functions, package creation.

# UNIT-II

**Data Analysis and Graphics:** Data summary functions in R, Graphics technology in R, saving graphics, additional graphics packages.

**Bayesian Data Analysis**: Need of Bayesian approach, Application of Bayes rule, Priors, Likelyhood functions, evaluating the posterior, Applications of Bayesial Statistics in Bioinformatics.

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**Stochastic Modeling**: Stochastic process and Markov Processes, Classification of Stochastic processes, modeling a DNA sequence with Markov Chain, Characteristics of Markov Chain.

# UNIT-III

MCMC using Brugs: ABO blood type example. Gibbs sampling. Statistical Inference: Sampling distributions, Parameter estimation, interval estimation, bootstrapping, R packages for bootstrapping.

**Hypothesis Testing**: Package ctest, Binomial test, comparing variances, Wilcoxon tests, Chi-Square test, Fisher's Exact tests, Likelyhood Ratio tests.

## UNIT-IV

**ANOVA and Regression**: ANOVA table, performaning ANOVA using R, graphical analysis of ANOVA comparison, Regression: Correlations, linear regression model, fitting and testing of regression mdoel, generalization of the model. **Working with Multivariate Data:** Multivariate data, sample statistics, display of multivariate data, outliers and principal components. Classification of disriminant analysis- classification with two population and more than two populations, cross validation classification trees.

# UNIT-V

**Clustering methods**: measures of dissimilarities, K-means clustering, K-Medoid clustering, Hierarchical clustering-Agglomeratve and divisive

**R Packages:** Bioconductor and SeqinR.

**Data Technologies**: R for Data manipulation, example, Database technologies, Bioinformatics resources on the WWW.

# Text Books:

- 1. Kim Seefeld, Ernest Linder, "Statistics using R with Biological examples", 2007 (https://cran.r-project.org/doc/contrib/ Seefeld\_StatsRBio.pdf).
- 2. Robert Gentleman, "R Programming for Bioinformatics", 1st Edition, CRC Press, 2008.

# Suggested Reading / Online Resources:

- 1. Arvil Cohhlan "A Little Book of R for Bioinformatics", Release 1.0, CC ver 3.0
- 2. https://epdf.tips/r-programming-for-bioinformatics.html
- 3. https://epdf.tips/r-programming-for-bioinformatics.htmlhttps:// www.cyclismo.org/tutorial/R/objectOriented.html

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4. https://www.w3schools.in/r/object-oriented/

16ME 001

#### ENTREPRENEURSHIP

(Elective-IX) Open

Instruction	3 L Hours per week
Duration of SEE	3 Hours
SEE	70 Marks
CIE	30 Marks
Credits	3

Course Objectives: Student will understand

- 1. The environment of industry and related opportunities and challenges
- 2. Concept a procedure of idea generation
- 3. Elements of business plan and its procedure
- 4. Project management and its techniques
- 5. Behavioral issues and Time management

Course Outcomes: At the end of the course students will be able to

- 1. Identify opportunities and deciding nature of industry
- 2. Brainstorm ideas for new and innovative products or services
- 3. Analyze the feasibility of a new business plan and preparation of Business plan
- 4. Use project management techniques like PERT and CPM
- 5. Analyze behavioural aspects and use time management matrix

## UNIT-I

**Indian Industrial Environment:** Competence, Opportunities and Challenges, Entrepreneurship and Economic growth, Small Scale Industry in India, Objectives, Linkage among small, medium and heavy industries, Types of enterprises, Corporate Social Responsibility.

## UNIT-II

**Identification and characteristics of Entrepreneurs:** First generation entrepreneurs, environmental influence and women entrepreneurs, Conception and evaluation of ideas and their sources, Selection of Technology, Collaborative interaction for Technology development.

## UNIT-III

**Business Plan**: Introduction, Elements of Business Plan and its salient features, Technical Analysis, Profitability and Financial Analysis, Marketing Analysis, Feasibility studies, Executive Summary.

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## UNIT-IV

**Project Management:** During construction phase, project organization, project planning and control using CPM, PERT techniques, Human aspects of project management, Assessment of tax burden

# UNIT-V

**Behavioral Aspects of Entrepreneurs**: Personality, determinants, attributes and models, Leadership concepts and models, Values and attitudes, Motivation aspects, Change behavior

**Time Management**: Approaches of time management, their strengths and weaknesses. Time management matrix and the urgency addiction

## **Text Books:**

- 1. Vasant Desai, "Dynamics of Entrepreneurial Development and Management", Himalaya Publishing House, 1997.
- 2. Prasanna Chandra, "Project-Planning, Analysis, Selection, Implementation and Review", Tata Mcgraw-Hill Publishing Company Ltd. 1995.
- 3. S.S. Khanka, "Entrepreneurial Development", S. Chand & Co. Pvt. Ltd., New Delhi

## **Suggested Reading:**

- 1. Robert D. Hisrich, Michael P. Peters, "Entrepreneurship", 5/e, Tata Me Graw Hill Publishing Company Ltd., 2005
- 2. Stephen R. Covey and A. Roger Merrill, "First Things First", Simon and Schuster Publication, 1994.
- 3. G.S. Sudha, "Organizational Behavior", National Publishing House, 1996.

#### With effect from the Academic Year 2019-20

Instruction	3Hours per week	
CIE	50 Marks	
Credits	2	

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 following aspects:

- 1. Introduction to the field
- 2. Literature survey
- 3. Consolidation of available information
- 4. Summaryand 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 for 20 minutes in PowerPoint, followed by Question and Answers session for 10 minutes.
- 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 3<sup>rd</sup> week to the last week of the semester and any change in schedule shall be discouraged.

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

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

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.	4. Questions and answers			
5.	Report in a prescribed format	20		

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#### PROJECT

Instruction	6 Hours per week
CIE	50 Marks
SEE	100 Marks
Credits	6

The object of Project is to enable the student extend further the investigative study, 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 team work;
- 4. Detailed Analysis/Modelling/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.

Guidelines for the award of marks in CIE: (Max. Marks: 50)CIE (Continuous Internal Evaluation) Max. Marks: 50

Evaluation by	Max.Marks	Evaluation Criteria / Parameter
Department	05	Review 1
Review	08	Review 2
Committee	12	Submission
Supervisor	05	Regularity and Punctuality
	05	Work Progress
	05	Quality of the work which may lead to publications
	05	Report Preparation
	05	Analytical/Programming/Experimental Skills

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

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

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