

**SCHOOL OF BIOTECHNOLOGY & GENETIC ENGINEERING  
DEPARTMENT OF MICROBIAL BIOTECHNOLOGY**

**Syllabus  
M.Sc., Industrial Biotechnology (CBCS –UD)  
2018-2020 BATCH & ONWARDS  
SEMESTER: III**



**Bharathiar University  
Coimbatore-46**

## SEMESTER: III

### PAPER IX: 18MBTAC09 BIOINFORMATICS AND NANOBIO TECHNOLOGY

#### COGNITIVE LEVEL 1

Understanding and learning the basics of the nanoscience technology and bioinformatics roles in applied biology.

#### COURSE OBJECTIVES

This paper is aimed to provide an enhanced and understanding the basics of the nano-biotechnology for the students to perceive various nanomaterial syntheses and characterization.

The bioinformatics provides the introductory knowledge concerning genomics, proteomics and their applications, including the primary tools used for the structural elucidation and characterization of the biomolecules.

#### UNIT I

**Bioinformatics** - Definition, History, Web servers, computer systems, languages, - machine, high level and assembly. Internet basics – internet connection, web browsing and URL. **Introduction to biological databases** - Sequence databases, structural databases, specialized databases, sequence retrieval system from net - SRS, Entrez,

#### UNIT II

**Structure prediction** –similarity and database structure tools, FASTA, BLAST - Sequence and similarity – sequence alignment – local, global pairwise and multiple sequence, Introduction to phylogenetic trees.

#### UNIT III

**Genomics:** Methods of preparing genomic DNA; Types of genomics -structural, functional, comparative and environmental genomics. Metagenomics–study onUncultivablemicrobes. SNPs-EST- RAPD-RFLP; DNA sequence analysis methods:Sanger Di-deoxy method and Fluorescence method;Strategies for Whole Genome Sequencing – Hierarchical and Whole Genome Shotgun Sequencing- De novo and reference based assembly; Pyrosequencing.

#### UNIT IV

**Proteomics:**Protein sequencing; Protein modifications and proteomics; Protein engineering; Protein chips and functional proteomics;Relation between gene and protein. Approaches for study of proteomics. Types of proteomics -expression proteomics, structural proteomics and functional proteomics; Proteomics industry.**Infectomics:** Introduction and definitions of Infectomics. Genomics and proteomics of microbial infections –Structural and functional strategies.Types of Infectomics -ecological, immuno-and chemical Infectomics. DNA and protein microarrays, cloning, PCR, gene knockout and knockin, antisense strategies, Bio sensors. Future of Infectomics.

## UNIT V

**Nanoscience basics:** Definition, Nanotechnology- Nano biotechnology- Nanomaterial- Nanocomposites- Classification of nanostructure- Top down & Bottom-up approach- Quantum dots- Bio inspired nanomaterials; Nanomaterial synthesis, Physical methods (Plasma, Laser), Chemical method (Sol-gel, Co-precipitation) & Biological method (Microbes, plant).  
**Nanomaterial characterization:** Electron microscopy – TEM, SEM & AFM – For particle imaging, XRD and FTIR for analyze the size, shape, structure, chemistry and crystallography. Drug delivery nanoparticles in cancer therapy, military application of nanotechnology- Future perspectives.

## TEXT BOOKS

1. Introduction to bioinformatics by T.A Atwood
2. Introduction to computers by Alexis Leon and Mathews Leon
3. Genomics: The Science and Technology Behind the Human Genome Project (2000). Edited by C.Cantor and C.L.Smith, Wiley -Interscience, New York
4. J.W. Dale. (1998). Molecular Genetics of Bacteria, 3rd Edition. Wiley Publishers.
5. Singer M and Berg P. (1991). Genes and Genomes. University Science Books.
6. Lewin B. (2005). Genes IX. Oxford University press.
7. A. Pandey and M. Mann. (2000). Proteomics to study genes and genomes Nature.
8. Sheng-He Huang, Timothy Triche, Ambrose Y. Jong. (2002). Infectomics: genomics and proteomics of microbial infections. Springer-Verlag publications.
9. **Fundamentals of Nanotechnology.** Gabor L. Hornyak, John J. Moore, H.F. Tibbals, Joydeep Dutta. December 22, 2008 by CRC Press. Textbook - 786 Pages.
10. **Introduction to Nanoscience.** Stuart Lindsay. Oxford university press. Textbook – 448 pages.

## REFERENCE BOOKS

1. Genome Mapping – A Practical Approach (1997) by P.H. Dear, Oxford University Press, Oxford.
2. Reviews and Articles from Journals such as Nature, Science, PNAS (USA), NucleicAcids Research, Trends Series & Current Opinion Series.
3. Protein Research: New Frontiers in Functional Genomics (1997). Edited by M.R. Wilkins, K.L. Williams, R.D.Appel and D.F. Hochstrasser, Springer – Verlag, NewYork2-D Proteome Analysis Protocols (1998). Edited by A.L. Link, Humana Press, Totowa, NJ.
4. Proteins and Proteomics. 2002. R.J. Simpson. Cold Spring Harbor Lab. Press. New York.
5. Cantor and Smith, Genomics. John Wiley & Sons, 1999.
6. Introduction to Genomics - Arthur M Lesk, Oxford University Press, 2007.
7. R.M.Twyman, Principles of Proteomics, BIOS Scientific Publishers, 2004.
8. P.Michael Conn, Handbook of Proteomic Method. Humana Press, Totowa, New Jersey, USA, 2003.
9. L.Stryer, Biochemistry, W. H. Freeman and Co., New York, 2007.

10. Introduction to Nanoscience and Nanotechnology 1st Edition by Chris Binns. Wiley publishers. 320 Pages.
11. Nanotechnology: A Gentle Introduction to the Next Big Idea by Mark A. Ratner; Daniel Ratner. Pearson Education (US). 208 Pages.
12. Textbook of Nanoscience and Nanotechnology. Authors: Murty, B.S., Shankar, P., Raj, B., Rath, B.B., Murday, J. Springer, 2013. 244 Pages.

#### Outcomes

- **To acquire the theory and practical experience of the use of common computational tools and databases which facilitate investigation of molecular biology concepts.**
- **To acquire knowledge and understanding of fundamentals of genomics and proteomics, transcriptomics and metabolomics and their applications in various applied areas of biology.**
- **To acquire basic science behind the properties of materials at nanometre scale, and the principles behind advanced experimental and computational techniques for studying nanomaterials.**

## **PAPER X: 18MBTAC10 BIOSAFETY, BIOETHICS & IPR**

### **COGNITIVE LEVEL 1**

Learning includes Basic concepts of Intellectual Properties, Intellectual property Rights, applications, advantages, Government rules and regulations for the same. Major issues concerned to the field of Biotechnology like Biosafety and GMO.

### **Course Objectives:**

To make the students to:

- aware / understand the laws governing patents, trade secrets, copy rights and Be trademarks with special emphasis to biotechnology at national and international level.
- Familiarize with various criteria of patents and sort out the requirements of patent and trade secret.
- Get acquainted with principles of biosafety and gain knowledge about basic and advanced laboratory practices and safety precautions followed during biotechnological work.
- Be aware of the general guidelines for research in microorganisms, animals and plants
- Gain Ethical, Legal and Social Implications of Human Genome Project.

### **CONTENTS**

#### **UNIT I:**

Introduction to ethics and bioethics Perspective of Ethics, Personal vs professional ethics: Moral Reasoning – Ethical theories Deontological, Utilitarianism – Ethical leadership (integrity and ingenuity) - framework for ethical decision making- Michael Macdonald model & Storch model.

#### **UNIT II:**

Biotechnology and ethics Biotechnology in agriculture and environment: benefits and risks – benefits and risks of genetic engineering – ethical aspects of genetic testing – ethical aspects relating to use of genetic information – genetic engineering and biowarfare.

### **UNIT III:**

Ethical implications of cloning Reproductive cloning , therapeutic cloning ; Ethical, legal and socio-economic aspects of gene therapy, germ line, somatic, embryonic and adult stem cell research- GM crops and GMO's – biotechnology and biopiracy – ELSI of human genome

### **UNIT IV:**

Introduction to biosafety Biosafety issues in biotechnology – risk assessment and risk management – safety protocols: risk groups – biosafety levels – biosafety guidelines and regulations (National and International) – operation of biosafety guidelines and regulations – types of biosafety containment

### **UNIT V:**

Introduction to intellectual property and intellectual property rights Types, patents, copy rights, trade marks, design rights, geographical indications – importance of IPR – patentable and non patentables – patenting life – legal protection of biotechnological inventions – world intellectual property rights organization (WIPO)

### **REFERENCES:**

1. Principles of cloning, 2nd Edition, Jose Cibelli, Robert Lanza , Keith H.S. Campbell, , Michael D. West, 2013
2. Ethics in Engineering 4th Edition by Martin, Mike W.; Schinzinger, Tata McGraw Hill Science, 2005
3. Ethical Issues in Biotechnology, Richard Sherlock, John D. Morrey, Jan 1 2002, Rowman & Littlefield.
4. <http://books.cambridge.org/0521384737.htm>
5. <http://online.sfsu.edu/%7Erone/GEessays/gedanger.htm>
6. [http://www.actahort.org/members/showpdf?booknrarnr=447\\_125](http://www.actahort.org/members/showpdf?booknrarnr=447_125)
7. <http://www.cordis.lu/elsa/src/about.htm>
8. <http://www.csmt.ewu.edu/csmt/chem/jcorkill/bioch480/bioLN98.html>
9. <http://www.accessexcellence.org/AE/AEPC/BE02/ethics/ethintro.html>

### **COURSE OUTCOME:**

After learning the course the students should be able to:

- Develop fundamental understanding Intellectual properties and IPR

- Understand the applications and advantages of IPR
- Understand the Biosafety and its relation to Biotechnology
- Understand GMO
- Understand rules regulations for GMO.

## **PAPER XI: 18MBTMC11 RESEARCH TECHNIQUES**

### **COGNITIVE LEVEL 1**

To Understand and learn the basics concepts of the research methods and techniques.

### **COURSE OBJECTIVES**

The objectives of this course are to emphasize the methodologies used to do research, use framework of these methodologies for understanding effective lab practices and scientific communication and appreciate scientific ethics.

### **UNIT: 1**

**BASIC CONCEPTS:** Definition of Research, Qualities of Researcher, Components of Research Problem, Various Steps in Scientific Research, Types of Research; Hypotheses Research Purposes - Research Design - Survey Research - Case Study Research. Sources of Data: Primary Data, Secondary Data; Procedure Questionnaire - Sampling Merits and Demerits. Research ethics.

### **Unit 2**

**WRITING RESEARCH PROPOSAL:** Developing an outline Preamble, the problem, specific aims, background and significance, hypothesis to be tested, study design, setup, measurement procedures, and analysis of data, displaying preliminary data in tables, graphs and charts. Report Writing- Prewriting considerations, Thesis writing, Formats of report writing, Formats of publications in Research journals, presenting the research funding in open defense.

### **UNIT: 3**

**RESEARCH REPORTS:** Structure and Components of Research Report, editing and evaluation of final draft, evaluating the final draft; Good Research Report, observation and research report. Pictures and Graphs; Research proposal/ Grant- definition, structure, budget allocation, specific aims, background and significance. Hierarchy of funding agencies in India and their operations. H-index, i10 index, Impact factor, Plagiarism. Title and abstract for a given

text - Choosing and indexing key words from a given paper- Writing the paper based on a given set of instructions to authors.

#### UNIT: 4

**Bioinstrumentations: Separation of Biomolecules:** Centrifugation-Preparative, Analytical and Density gradient centrifugation. Chromatographic Techniques-Theory and application of Paper, TLC and HPLC Chromatography, Gel Filtration, Ion Exchange, Column, Gel permeation, Chiral, Hydroxy apatitie , Immuno adsorption, Affinity Chromatography. Electrophoretic Techniques: Theory and Application of PAGE, SDS PAGE. Staining & detection methods-Isoelectroporesis, iso electric principle.

#### UNIT: 5

**Structural analysis of Biomolecules:** UV, NMR, GC-MS, LC-MS, Mass Spectroscopy, MALDI-ToF, 2D gel, Fluorescence Spectroscopy, Colorimetry, flame photometry and ESR principles

#### Text Books

11. Handbook of Biomedical Instrumentation – R.S. Khandpur, Tata McGraw Hill
12. Biophysical chemistry – Upadhyay., Upadhyay and Nath
13. Practical Biochemistry – Principles and techniques -Wilson. K and Walker. J,

#### REFERENCE BOOKS:

1. Wilkinson & Bhandarkar: Methodology and Techniques of Social Research.
2. Pauline Vyoung: Scientific Social Surveys and Research.
3. Panneerselvam, R., Research Methodology, Prentice Hall of India, New Delhi, 2004.
4. Kothari: Research Methodology.
5. Sellitz, et al: Research Methods in Social Relations.
6. Jerrold H. Zar. Biostatistical Analysis (4<sup>th</sup> edition).
7. Janet Buttolph Johnson and Richard A. Joslyn, Political Science Research Methods (Washington D.C.: CQ Press, 2001), pp. 131-145.
8. Instrumental methods of chemical analysis – P.K. Sharma
9. A Biologist's guide to principle and techniques of practical biochemistry – Brigian L. Williams.
10. Experimental methods in Biophysical chemistry- Nicolau, C.
11. Chromatographic methods- Alan Braithwaite, Frank J. Smith
12. Gel Electrophoresis of Nucleic acids-A Practical approach. Rickwood D and BD Hames.
13. Introduction to Spectroscopy- Donald L. Pavia Gary M. Lipman, George S Kriz.

#### OUTCOMES



- To acquire the methodologies of scientific research, applying these to recent paper publications;
- To acquire practice scientific reading, writing and presentations;
- To acquire the basic science behind the research techniques

## **PAPER XII: 18MBTAC12 BIOPROCESS TECHNOLOGY**

### **COURSE OBJECTIVES:**

- To introduce the role of microbes in industries
- To impart knowledge on different types of fermentors and fermentation processes
- To familiarize with the various industrial production process involving microbes
- To provide the information on the role of various factors influencing the fermentation processes

### **CONTENTS**

#### **UNIT I**

**Types and design of bioreactor: Fermentor structure** - Construction material, Basic components – Agitator, aerator, valves and steam traps, seals and stirrer glands. **Measurement and control of parameters** (on-line and off line sensors) – temperature, flow rate, pressure, pH, DO, gas analysis, computer control pathways. **Fermentors** - Air-lift, stirred tank, tower, fluidized bed, packed bed, pulsed, photo bioreactors, CSTR, PFR.

#### **UNIT II**

**Process kinetics: Growth kinetics - Batch, Continuous and fed batch; Kinetics** - batch, fed-batch and continuous process; Sterilization methods - batch sterilization, continuous sterilization of medium. and air. Solid state and submerged; aerobic and anaerobic fermentation. **Inoculum development** – Development of inocula for yeast, bacterial, mycelial and vegetative fungal processes; aseptic inoculation of the fermentor. **Mixed microbial populations; Immobilization** - immobilization of cells and co-immobilization; **Chemical kinetics** and classification of chemical reactors. **Transport phenomena** - Mass transfer, heat transfer, oxygen transfer; transfers in immobilized cells.

#### **UNIT III**

**Production kinetics: Design for single and multiple reaction: size comparisons of single reactor for single reactions, multiple reactor systems for single reaction, reactions in parallel, in series, and series-parallel reactions of first order. Heterogeneous reactions** - kinetics and mechanism of heterogeneous, non catalytic, and catalytic reactions; Non ideal flow - residence time distribution studies, C,E, F and I curves; RTD in ideal reactors; Models for Non ideal flow – zero – parameter model, One parameter model and two parameter model

#### **UNIT IV**

**Downstream processing:** Removal of microbial cells and solid matter, foam separation, precipitation, filtration, centrifugation, cell disruptions, liquid-liquid extraction, chromatography, membrane process, drying and crystallization.

## UNIT V

**Quality analysis:** Quality analysis and product formulation - Product appearance, product stabilization and shelf life analysis, usage specific formulations, quality analysis and control. Fermentation economics of citric acid – process economics and project economics.

### TEXT BOOKS

1. Fundamentals of Bioanalytical Techniques and Instrumentation, Ghosal and Srivastava, PHI Learning Pvt. Ltd., 2009.
2. Principles of Fermentation technology, Stanbury PF and Whitaker A. Pergamon Press, 1984.
3. Introduction to Biochemical Engineering, D.G.Rao, Tata McGraw Hill Publishers, 2005.
4. Bioprocess Engineering: Basic Concepts, 2<sup>nd</sup> edition, Shuler,M.L. and Kargi, F., Prentice Hall, Engelwood Cliffs, 2001

### COURSE OUTCOMES:

- CO1: Able to select and design a fermentation process for a specific product
- CO2: Capable of identifying industrially important microbes and its potential applications
- CO3: Able to device means to improve the production rate of existing fermentation processes
- CO4: Capable of designing processes for higher production yield at economically cheaper rate
- CO5: Ideally skilled for employment in biotechnology industries

### REFERENCES

1. Instrumentation, measurement and analysis, II edition, Nakra BC and Chaudhry KK, Tata McGrawHill Publishing Co. Ltd., New Delhi, 2004
2. Fermentation Microbiology and Biotechnology , Mansi El-Mansi and Charlie Bryce, Taylor and Francis Ltd., 2002.
3. 3. Manual of Industrial Microbiology and Biotechnology, III edition, Arnold L. Demain and Julian Davies, ASM press, Washington DC, 1999.
4. Biochemical Engineering Fundamentals, Baily,J., Bailey J. and Ollis,D.F., McGraw-Hill Book Co. New York, 1986.
5. Pharmaceutical Biotechnology: Fundamentals and Applications, 3rd edition, Daan J. A. Crommelin, Robert D. Sindelar, and , Bernd Meibohm, 2007.
6. Handbook of Downstream processing, Edin Goldberg, Blackie and Academic Professional, 1997.

### **PRACTICAL III- 18MBTACP3 APPLIED MICROBIOLOGICAL TECHNIQUES**

1. Diagnostic Microbiology: Isolation and identification of pathogens from clinical specimens-Swab/ Urine
2. Haemolytic testing of bacteria
3. Differential test of *Staphylococci* through growth on agar plates (Mannitol agar, DNA agar plate and Coagulase test method)
4. Isolation and identification of clinically important fungi - *Candida albicans*, *Aspergillus* sp
5. Antibiotic susceptibility test. - Kirby Bauer technique
6. Identification and enumeration of Lymphocytes.
7. Agglutination reaction - Blood grouping & Rh Typing – Cross matching demonstration.
8. Precipitation reaction – ODD Test.
9. Serological Tests – WIDAL (Slide & Tube Test), RPR.
10. Immunoelectrophoresis – Counter Current & Rocket Immunoelectrophoresis.
11. ELISA – HIV, HBV & HCV.
12. Separation techniques: Chromatography - Paper, TLC and Column.
13. Molecular visualization of proteins (PYMOL)
14. Gene structure and function prediction (GENEMARK)
15. Gene structure prediction (GENSCAN)
16. Protein sequence analysis and protein secondary structure prediction (EXPASY and PROTEOMICS tools)
17. Molecular phylogeny (PHYLIP)
18. Analysis of protein and nucleic acid sequences (EMBOSS)

## ELECTIVE

### ELECTIVE PAPER V: 18MBTGE14 A PHARMACEUTICAL CHEMISTRY

#### Objectives:

1. To enable the students to understand the basics of drug administration and metabolism.
2. To provide the knowledge about drug discovery, designing, and testing.
3. To impart the real-life difficulties encountered in the pharmaceutical industry.
4. The course gives a detailed outline on the natural resources for the drug production.

#### CONTENTS

##### UNIT I

**Introduction to Pharmaceuticals :** Routes of drug administration, Pharmacokinetics: Absorption, Distribution, Metabolism- Oxidation, reduction, hydrolysis, conjugation and Elimination, absorption enhancement / solubility factor/ bioavailability; Pharmacodynamics; Assay systems and models (e.g., Knock-out Mice); Inter species scaling.

##### UNIT II

**Drug discovery:** Need for developing new drugs: Substances derived from bacteria, plants, insects, and animals; Sources of active principles; Combinatorial Synthesis: Chemistry, Biology, and Biotechnology.

##### UNIT III

**Drug designing:** Procedure followed in drug design; Molecular modification of lead compounds and proteins; Prodrug and soft drugs; Physico-chemical parameters in drug design; QSAR; Active site determination of enzymes; Design of enzyme inhibitors; Protein molecular modeling by computer: Docking studies; Structure based drug designing using software.

##### UNIT IV

**Pharmaceutical products:** Microbial products - Antibiotics (penicillin, streptomycin, tetracycline), vitamins, probiotics. Plant secondary metabolites -alkaloids, flavanoids, steroids, terpenoids. Animal vaccines-Subunit vaccines, peptide vaccines, attenuated and vector vaccines. Clinical trials.

##### UNIT V

**Therapeutic proteins:** Insulin, human growth hormone, clotting factors, interferons, interleukins, tissue plasminogen activators, erythropoietin, DNaseI, alginate lyase, muteins; Production, advantages, limitations and applications of monoclonal antibody.

#### Course Outcome:

- CO1: The concepts gained through this subject will help the students to understand the right choice of drug from, the mode of drug administration and correct drug concentration required.
- CO2: The course will give insight on various natural raw materials as resources for the drug production and the candidates will gain the ability to think of an unexplored resource for a new type of diseases.
- CO3: Students will understand various methods of drug designing through virtual-wet lab combinations and will impart the technical details of pre-clinical trials.

### **TEXT BOOKS**

1. Daan Crommelin, Robert D Sindelar, "Pharmaceutical Biotechnology", Taylor and Francis Publications, New York, 2002.
2. Remington's Pharmaceutical sciences, 18<sup>th</sup> edition, Mack publishing & Co., Easton, PA (20 Ed, 2000).

### **REFERENCE**

1. Heinrich Klefenz, "Industrial Pharmaceutical Biotechnology", WILEY-VCH Publication, Germany, 2002.
2. Jay P Rho, Stan G Louie, "Hand book of Pharmaceutical Biotechnology", Pharmaceutical products press, New York, 2003.
3. Lachman L Lieberman, HA, Kanig, J, "Theory and practice of industrial pharmacy", 3<sup>rd</sup> edition, Varghese publishing & Co, New Delhi, 1986.

## ELECTIVE PAPER VI: 18MBTGE14 B GOOD MANUFACTURING PRACTICES AND QUALITY ASSURANCE

### Cognitive Level 2

#### Objective:

1. Provide the student with an understanding of the principles and practice of GMP
2. Enable them to realise the importance and compliance of GMP.
3. Impart knowledge on the Administrative structure in the Industries
4. Will be taught about the designing an Industry and construction of SOPs

### CONTENTS

#### UNIT I

**Principles and Importance of GMP** – Definition of GMP, Quality management, Personnel, Risk management, Quality control, Documentation, Inspections. **Public Health Protection** - adulteration definition - approved chemicals (lubricants, steam additives, etc.) - toxic chemical control and storage - hazard review: chemical, physical, biological - potential sources (humans, animals, environment) and controls **Premises** - Design, construction, and maintenance of the production and staff areas in the facility, Layout (design) of the facility - separation from farm/animals/pets (small scale) - perimeter, entrances, drainage - construction, heating/ventilation, humidity control - separation raw versus. pasteurize; product flow - equipment / pipe layout / drainage - water source (treatment, hardness) monitoring

#### UNIT II

**Equipment** - Design, construction, and maintenance of equipment, Equipment arrangement and operation, cleaning-in-place process. **Personnel** - Ensuring facility personnel are qualified for their job responsibilities, personal health and disease control, personal hygiene; clothing, habits, hand wash, restrooms, plant traffic control.

#### UNIT III

**Sanitation** - Sanitation programs: Cleaning and sanitation compounds and their uses – for process equipments - for environmental cleaning (drains, coolers, etc.) - influence of water quality, formulation control - concentrations and time. Environment sanitation and monitoring - environmental monitoring / pathogen testing - pest control programs.

#### UNIT IV

**Raw Material Testing** - Testing raw materials - Identifying when product or raw materials must be tested - Accepting raw materials from a vendor without additional regular testing - Supplier certification. **Good practices in production and control** - Controlling the manufacturing process - Stages in the production cycle – contracting quality tools – R & D - Self-inspection programs for fabricators, packagers/labelers - Testing requirements for packaging materials including supplier certification. **Finished Product Testing** - Finished product testing - Writing product specifications - Conditions and options for finished product testing, distributors - product storage - packaging, distribution. **Process Control** - refrigeration (potential hazardous compounds), pasteurization - culture, pH, incubation temperature, aging temperature.

## UNIT V

**Quality Control Department and Audits** - Establishing a QC department - Investigating product quality. Audits- Records -Maintaining accurate, clear, and precise documents - Identifying individuals responsible for maintaining documents. Validation - Qualification, Process validation, Cleaning validation and Computer validation. GMP regulations - US-FDA, Europe, Japan, ICH, PICS/S, WHO.

## TEXT BOOKS

Compendium of Good Practices in Biotechnology, BIOTOL series

## REFERENCE BOOKS

1. **A WHO guide to good manufacturing practice (GMP) requirements: Volume 1,2,3,4,5. Part 2-Validation**, by Gillian Chaloner-Larsson, Ph.D, GCL Bioconsult, Ottawa
2. **Good Manufacturing Practices for Pharmaceuticals, Sixth Edition by: Graham Bunn**  
Publisher: Informa Healthcare; 6 edition | 424 pages (2007) [http://ebookey.org/Good-Manufacturing-Practices-for-Pharmaceuticals-Sixth-Edition\\_859976.html#uPYoXd8huFeqqXB9.99](http://ebookey.org/Good-Manufacturing-Practices-for-Pharmaceuticals-Sixth-Edition_859976.html#uPYoXd8huFeqqXB9.99)
3. A Primer – Good Laboratory Practices and current manufacturing practice, by Ludwig Huber, Published by Agilent Technologies, Germany (2002)  
<http://www.chem.agilent.com/Library/primers/Public/59886197.pdf>.
4. GMP manual: Good manufacturing practices and implementation, [http://www.gmp-publishing.com/media/ebooks/flyer/files/gmpmanual\\_eu\\_4c\\_online.pdf](http://www.gmp-publishing.com/media/ebooks/flyer/files/gmpmanual_eu_4c_online.pdf).

## Course Outcome

On finishing the course work the students will be able to

1. Propose the plan of an Industry
2. Outline the eligibility of the workers to be recruited in each section
3. Design the hierarchy of administration in the Industry
4. Aware of the rules and regulation to be followed in an Industry
5. Certifications to be obtained for an Industry based on its type of production

## **IV SEMESTER ELECTIVE**

### **ELECTIVE IVB: 18MBTGE15A ENTREPRENEURSHIP DEVELOPMENT**

**Objective:** To enable the students to acquire knowledge about the various concepts of Entrepreneurship and to develop and enhance entrepreneurial competency and drive to startups.

#### **Unit I:Introduction**

Entrepreneurship – Meaning, Definition and concepts – Evolution of Entrepreneurship – Theories of Entrepreneurship – Role of Entrepreneurship in Economic Development, Factors affecting Entrepreneurship - Entrepreneur – Qualities, nature, types and traits – Entrepreneur Vs. Intrapreneur – Entrepreneur Vs. Manager – Entrepreneurship Development – meaning and importance.

#### **Unit II: Entrepreneurial mobility and motivation**

Entrepreneurial mobility, Factors affecting Entrepreneurial mobility, types of Entrepreneurial mobility – Meaning and concept of Entrepreneurial competency, developing Entrepreneurial competencies and Culture – Entrepreneurial Motivation – meaning and concept of motivation – motivation theories – Entrepreneurship Development Programs (EDPs) – Needs and objectives – phases of EDPs and evaluation of EDPs.

#### **Unit III: Entrepreneurship Development and Government**

Role of Government in promoting Entrepreneurship, MSME policy in India – District Industries Centres (DIC), Small Industries Service Institute (SISI), Entrepreneurship Development Institute of India (EDII), National Institute of Entrepreneurship Development Board (NEDB) – Recent initiatives by the Central and State Governments to boost startups and entrepreneurship in India , Startup India, Skill India, MSDE and NSDC– Financial Support System for entrepreneurship development.

#### **Unit IV: Business sectors and forms**

Business Sectors, Meaning and classifications - primary, secondary and tertiary sectors - Business Organisation – Forms of business organization, Sole Proprietorship, Partnership firms, Joint stock companies, Co-operative Society – their features, relative merits, demerits & suitability – Concept of Social Enterprise and Social Entrepreneurship, Social Entrepreneurs, Sustainability issues in Social Entrepreneurship – Entrepreneurial failure, issues, reasons and revamps.

#### **Unit V: Project Management**



Project Management, Concept, features, classification of projects, issues in Project Management – Project identification, Formulation, design and evaluation, Project appraisal, Project Report Preparation, Specimen of a Project Report – Starting a small scale unit, Procedure and legal formalities, Steps in setting SSI unit, incentives and subsidies – Evaluating entrepreneurial performance.

**Suggested books for Reference:**

1. Robert D. Hisrich, Michael P. Peters, “Entrepreneurship Development”, Tata McGraw Hill
2. Vasanth Desai, “Dynamics of Entrepreneurial Development and Management”, Himalayas Publishing House.
3. P. Saravanavelu, “Entrepreneurship Development”, Eskapee Publications.
4. N.P. Srinivasan & G.P.Gupta, “Entrepreneurship Development”, Sultanchand & Sons.
5. Satish Taneja, Entrepreneur Development”, New Venture Creation.
6. Barringer M.J. “Entrepreneurship”, Prentice-Hall, 1999

## **ELECTIVE IVA: 18MBTGE15B TEACHING TECHNIQUES IN SCIENCE**

### **Expected learning outcomes:**

After completing the course, the student will be able to -

- Acquire knowledge about teaching- learning process and techniques.
- Comprehend different methods of teaching science.
- Acquire knowledge about various skills of Microteaching.
- Understand and apply the concept of unit plan and lesson plan in teaching science.

### **Unit I: Teaching Learning Process**

Teaching: Meaning, Scope, Importance. Learning: Meaning, Scope, Importance. Teaching Learning Process. Bloom's Taxonomy of Learning objectives in Science.

### **Unit II: Methods of Teaching Science**

Pedagogy: Meaning, concept. Different pedagogy of teaching Science: Seminar, Conference, Symposium and Workshop. Methods of Teaching in Science: Lecture-cum-Discussion Method, Laboratory Method, Observation Method, Project Method and Problem Solving Method.

### **Unit III : Micro-teaching skills in Science**

Micro-teaching: Meaning, Importance, Steps and Cycle. Skills of Micro-teaching: Set Induction, Explaining, Stimulus variation, reinforcement and Closure.

### **Unit IV: Teachingof Science**

Formulation of Instructional Objectives. Unit Planning: Meaning and Steps. Lesson Planning: Meaning and Steps. Improvised of teaching aids in general science.

### **Unit V: Evaluation in Science**

Evaluation : Definition and Objectives. Types of Evaluation: Formative and Summative. Achievement test: Development and Construction.

### **References:**

- Kumar, K.L. (1996). Educational technology. New Delhi: New Age International Publishers.
- Srivastava, A.P. (1987). Teaching and learning in 21st century. New Delhi: Indian Books Centre.

- Vedanayagam, E.G. (1989).Teaching technology for college teachers. New York: Sterling Publishers.
- Sharma, S.R. (2003). Effective classroom teaching modern methods, tools & techniques. Jaipur: Mangal Deep.
- Neel A, GlasGow, Cathy & Hicks. What successful teachers do. Chennai: Tamil Nadu Book House.
- Sampath, K., Panneerselvam, A. &Santhanam, S. (1984). Introduction to educational technology. II revised Edition. New Delhi: Sterling Publishers.
- Witch, W.A. &Schulles, C.F. (1973). Instructional technology: Its nature and use New York: Harpu& Row.
- Maheshkumar. (2004). Modern teaching of information technology. New Delhi: Anmol Publishers.
- Jaganath, Mohanty. (2003). Modern trends in educational technology. Hyderabad: Neelkamal.
- Rameshvarma, et al. (2005). Modern trends in teaching technology. New Delhi: Anmol Publishers.
- Janardan, P. et al. (2003). Advanced educational technology. New Delhi: Kanishka.
- Siidiqui. (2005).Challenges of educational technology. Coimbatore: Global Books Syndicate