SMBA5101	CLINICAL BIOCHEMISTRY	L	T	P	EL	Credits	Total Marks
		4	0	0	0	4	100

COURSE OBJECTIVE

- To enable the students to understand the various mechanisms adopted by the human body for the regulation of metabolic cycles and to learn the inter-relationship between various metabolic pathways and their clinical correlations.

UNIT 1 COMPONENTS OF BLOOD 12 Hrs.

Composition and function of blood, Plasma and blood corpuscles, Structure and function of haemoglobin, abnormal haemoglobins, Blood coagulation – mechanism and regulation, Blood groups, Water and electrolyte, Regulation of water and electrolyte balance, Hydrogen ion homeostasis and acid-base balance.

UNIT 2 CARBOHYDRATES 12 Hrs.

Carbohydrate Classifications, Physic-chemical properties, Biological importance of carbohydrates. Properties of Monosaccharide, Disaccharides and Polysaccharides. Clinical complications of Carbohydrate metabolisms, Diabetes mellitus Type I and Type II. Glycogen storage diseases. Sugar derivatives of biomedical importance and Inter conversion of Hexoses.

UNIT 3 PROTEINS 12 Hrs.

Classification of Protein, Structure and properties of amino acids, Metabolism of Proteins and amino acids, Inborn errors of metabolism, Decarboxylation, Transamination, Deamination, and urea cycle. Nucleic acids- Biosynthesis and degradation of purines and pyrimidines and their clinical role..

UNIT 4 LIPIDS 12 Hrs.

Biological importance and Chemical properties of fatty acids. Metabolism of Lipids, Biosynthesis of saturated and unsaturated fatty acids, β-Oxidation of fatty acid, Biosynthesis of glycerides, phospholipids and cholesterol. Regulation of lipid metabolism and ketone bodies. Disorders of lipid metabolism, lipoproteins and their significance.

UNIT 5 VITAMINS AND HORMONES 12 Hrs.

Structure and Biochemical properties of water soluble and fat-soluble vitamins and their coenzyme activity. Hormones: Mechanism of hormone action and its regulation, Hormones of Pancreas, Pituitary, Adrenal, Thyroid and Sex hormones. Bioenergetics: Electron transport chain, Oxidative Phosphorylation and synthesis of ATP.

Max.60 Hrs.

REFERENCES

1. Murray, R.K., Granner, D,K., Mayes, P.A. and Rodwell, VW. (2000): 25th Ed. Harpers Biochemistry, Macmillan Worth Publishers.
2. Nelson D.L. and Cox, M.M. (2000) : 3rd Ed. Lehninger's Principles of Biochemistry, Macmillan Worth Publishers.
3. Devlin, T.M. (1997): 4th Ed. Text book of Biochemistry with Clinical Correlations, Wiley Liss Inc.
4. Stryer, L. (1998): 4th Ed. Biochemistry, W.H. Freeman and Co.
5 Voet, D. Voet, J..G and Prat, C.W,, (1999) : Fundamentals of Biochemistry.

END SEMESTER EXAM QUESTION PAPER PATTERN

Max.Marks: 100 **Exam Duration: 3 Hrs.**

PART A : 6 Questions of 5 mark each - No choice. **30 Marks**

PART B : 2 Questions from each unit of internal choice, each carrying 14 marks. **70 Marks**

SMBA5102	CLINICAL MICROBIOLOGY	L	T	P	EL	Credits	Total Marks
		4	0	0	0	4	100

COURSE OBJECTIVE

- To explain the detail background of Clinical Microbiology in the perspective of future of Clinical Microbiology.

UNIT 1 FUNDAMENTALS OF CLINCIAL MICROBIOLOGY 12 Hrs.

History of microbial diseases, Pathogens and their classification: Prokaryotic and eukaryotic microorganisms, Host-pathogen interactions: basic terms and concepts, Methods of isolation and identification of microorganisms, Microbiology laboratory safety, Sterilization and disinfection, General epidemiology, Basics of immunology.

UNIT 2 CLINICAL BACTERIOLOGY 12 Hrs.

Bacteria as pathogen: pathogenesis and its evolution, Identification of bacterial pathogens, Morphology and fine structure of bacteria, Virulence factors, Human disease and infection caused by bacteria in the following: respiratory track, urinary track, genital tract, gastrointestinal track, blood stream, nervous system, Epidemiology of bacterial diseases, Antibacterial agents.

UNIT 3 CLINICAL MYCOLOGY & VIRUS 12 Hrs.

Classification of medically important fungi, General aspects of fungal diseases, Fungi as human pathogens, Antifungal agents. Structure, components and classification of animal viruses, Replication, Viral protein synthesis, Viral pathogenesis and defense mechanisms, Viruses as human pathogens: Genetics, history, epidemiology, diagnosis, and treatments, Sub viral pathogens: viroids and Prions.

UNIT 4 CLINCIAL PARASITOLOGY 12 Hrs.

Parasites: basic concepts and classification, medically important protozoans and Helminths, Pathogenesis and Diagnosis, Antiparasitic agents.

UNIT 5 CASE STUDIES IN CLINICAL MICROBIOLOGY 12 Hrs.

Common food borne, water borne, air borne, vector borne infectious diseases in India: bacterial diarrhoea, Hepatitis, Typhoid, Dengue and Malaria, Tuberculosis, Normal microbial flora of human, Hospital infections, Infections in transplant patents, Biological warfare's and terrorism.

Max.60 Hrs.

TEXT / REFERENCE BOOKS

1. Lansing M. Prescott, John P. Harley and Donald A. Klein. Microbiology. McGraw-Hill Company, Newyork.
2. Ananthanarayan, R., and Paniker, C.K.J. Textbook of microbiology. Orient Blackswan publishing.
3. Brooks, Geo F., Carroll, Karen C., Janet S. Butel, and Stephen A. Morse and Meitzner, A. Timothy. Jawetz Melnick & Adelbergs Medical Microbiology. McGraw Hill.
4. Ryan & Ray. Sherris Medical Microbiology: An introduction to Infectious diseases, McGraw Hill.

END SEMESTER EXAM QUESTION PAPER PATTERN

Max.Marks: 100 **Exam Duration: 3 Hrs.**

PART A : 6 Questions of 5 mark each - No choice. **30 Marks**

PART B : 2 Questions from each unit of internal choice, each carrying 14 marks. **70 Marks**

BA5103	HUMAN ANATOMY AND PHYSIOLOGY	L	T	P	EL	Credits	Total Marks
		4	0	0	0	4	100

COURSE OBJECTIVE

- To give detailed background of Human Anatomy and Physiology.

UNIT 1 CELLS AND CELLULAR METABOLISM 12 Hrs.

Introduction to human anatomy and physiology – Basic elements of life, characteristics and maintenance of life – levels of organisms, structure of matter, chemical constituent of cell – movement through cell membrane, life cycle of cells and control of cell reproduction, metabolic process, control of energy and metabolic reactions, metabolic pathway - nucleic acids and protein synthesis – change in genetic information.

UNIT 2 TISSUES AND INTEGUMENTARY SYSTEM 12 Hrs.

Tissues – epithelial, muscular and nervous tissues – integumentary system, types of membranes, skin – accessory organs, disorders, regulations of body temperature – Bone structure, development, function and organization of skeleton – joints, classification, structures and movements – muscle, structure and types, actions and responses.

UNIT 3 BODY SYSTEMS AND FUNCTIONS 12 Hrs.

Blood, circulation and function – lymphatic system-Endocrine system, endocrine glands, structure and function – respiratory system, structure and function – cardiac system, structure and function.

UNIT 4 NERVOUS SYSTEMS AND SENSES 12 Hrs.

Nervous tissue, cell membrane potential, classification of neurons and nerve fiber – meninges, spinal cord, brain – peripheral and autonomic nervous system – somatic and special senses, receptors and sensations (smell, taste, hearing, equilibrium and sight).

UNIT 5 METABOLISM AND NUTRITION 12 Hrs.

Digestive system, structure and function – urinary system, kidney and nephron, structure and function – reproductive system – metabolism and nutrition.

Max.60 Hrs.

TEXT / REFERENCE BOOKS:

1. Fundamentals of Anatomy & Physiology, 11th Edition, 2011, Martini, Nath, and Bartholomew.
2. Essentials of Human Anatomy & Physiology, 12th Edition, 2017, Elaine N. Marieb and Suzanne M. Keller.

END SEMESTER EXAM QUESTION PAPER PATTERN

Max.Marks: 100 **Exam Duration: 3 Hrs.**

PART A : 6 Questions of 5 mark each - No choice. **30 Marks**

PART B : 2 Questions from each unit of internal choice, each carrying 14 marks. **70 Marks**

SMBA5104	BIOLOGY OF THE IMMUNE SYSTEM	L	T	P	EL	Credits	Total Marks
		4	0	0	0	4	100

COURSE OBJECTIVE

- To provide basic understanding in biology of immune system and also to give fundamentals of immunological techniques.

UNIT 1 INTRODUCTION TO IMMUNOLOGY 12 Hrs.

Properties of immune response, Innate and acquired immunity, Active and passive immunity, Cells and tissue of immune system: Lymphocytes, classes of lymphocytes, Antigen presenting cells, NK cells, Mast cells, Dendritic cell, Organ of immune system, Bone marrow, Thymus, Lymph node, Spleen, CALT, MALT.

UNIT 2 MOLECULAR IMMUNOLOGY 12 Hrs.

Molecular structure of antibodies, Classification, Isotypes, Synthesis assembly and expression of immunoglobulin molecules, Nature of antigens, Function and diversity, Generation of antibody diversity.

UNIT 3 ANTIGENS 12 Hrs.

Different characteristics of antigens, Mitogens, Hapten, Immunogen, Adjuvants. MHC: Discovery of MHC complex, Role of MHC, Structure of MHC molecule, binding of peptides to MHC molecules, MHC restriction.

UNIT 4 MECHANISM OF IMMUNE RESPONSE 12 Hrs.

Cytokines, T-cell receptors, Cell activation, Complement system, Antigen processing and presentation, Regulation of immune response. Immunological techniques: Antigen – antibody reactions, Immuno diffusion, Immuno electrophoresis, ELISA, RIA, and Fluorescence activated cell sorter.

UNIT 5 APPLIED IMMUNOLOGY 12 Hrs.

Immune system in health and disease, Autoimmunity, Hypersensitivity, Tumor immunity, Tissue and Organ transplant, Synthetic vaccines. Hybridoma Technology: Fusion of myeloma cells with lymphocytes, Production of monoclonal antibodies and their application.

Max.60 Hrs.

TEXT / REFERENCE BOOKS

1. Kuby- immunology (4th edition) by R.A Goldsby, T.J Kindt, B.A. Osborne.
2. Essentials of immunology (13th edition): Ivan Riot- John Wiley & Sons, Inc., 2017.
3. Fundamentals of immunology: Paul W. E. (Eds.) Lippincott Williams & Wilkins Publishers, 2003
4. Antibodies A laboratory Manual: Harlow and David Lane (1988), Cold spring Harbor laboratory.

END SEMESTER EXAM QUESTION PAPER PATTERN

Max.Marks: 100 **Exam Duration: 3 Hrs.**

PART A : 6 Questions of 5 mark each - No choice. **30 Marks**

PART B : 2 Questions from each unit of internal choice, each carrying 14 marks. **70 Marks**

SMBA6101	CLINICAL BIOCHEMISTRY LAB PRACTICAL-I	L	T	P	EL	Credits	Total Marks
		0	2	2	0	2	100

COURSE OBJECTIVE

- To make the students to understand a broad range of experimental techniques in clinical Biochemistry and to enable them to demonstrate their ability to use the techniques in conducting scientific experiments and observations.

ESTIMATIONS OF CLINICALLY RELEVANT ANALYTES GLUCOSE

1. Estimation of plasma glucose
2. Glucose tolerance test
3. Stability check of glucose standards

ESTIMATIONS OF CLINICALLY RELEVANT LIPIDS

4. Estimation of serum total protein
5. Estimation of serum cholesterol
6. Estimation of serum triglycerides
7. Estimation of HDL cholesterol
8. Estimation of serum bilirubin
9. Estimation of serum albumin
10. Estimation of serum transaminases
11. Estimation of serum alkaline phosphatase

RENAL FUNCTION TESTS

12. Estimation of serum alkaline phosphatase
13. Estimation of serum urea
14. Estimation of serum creatinine

MINERALS AND ELECTROLYTES

15. Analysis of calculi
16. Estimation of serum calcium
17. Estimation of serum phosphorus
18. Estimation of serum iron

BLOOD COMPONENTS

19. RBC, WBC, Platelet count
20. Blood group identification

TEXT / REFERENCE BOOKS

1. Practical Clinical Biochemistry methods and interpretations 4th Edition (English, Ranjna Chawla).
2. Varleys Practical Clinical Biochemistry 6th Edition (English, Hardcover, Alan H. Gowenlock).
3. Practical Biochemistry 5th Edition (English, Paperback, R. C. Gupta).
4. Manual of Practical Biochemistry for MBBS 2nd Edition (English, Paperback, S. K. Gupta, Veena Singh Ghalaut, Anju Jain).

SMBA6102	MICROBIAL TECHNIQUES LAB PRACTICAL-II	L	T	P	EL	Credits	Total Marks
		0	2	2	0	2	100

COURSE OBJECTIVE

- To make the students to understand a broad range of experimental techniques in microbiology and to enable them to demonstrate their ability to use the techniques in conducting scientific experiments and observations.

PRACTICALS

1. Techniques for Isolation microorganisms
2. Preservation of microorganisms
3. Bacterial staining techniques
2. Microscopic examination of live bacterial population
3. Biochemical Activities of Microorganisms: IMViC, Catalase, Oxidase,
4. Microbiological Analysis of Food products
5. Microbiological Analysis of water
6. Antibiotic Sensitivity Testing
7. Species Identification of unknown bacterial cultures using Molecular Techniques
8. Plating of clinical specimens on media for isolation, purification identification and quantitation
9. Isolation and identification of pathogenic yeasts and moulds and recognition of common laboratory contaminants.

TEXT / REFERENCE BOOKS

1. Microbiology, Laboratory Manual by Capuccino and Sherman 6th Edition, Pearson Education, (2006).
2 James G. Cappuccino and Natalie Sherman. 2004 (6th edition), Microbiology A Laboratory Manual- Pearson Education.
3. Beister, L.1996. Microbiology in Pratice (6th edition) Adeland Wesley, Langman, New York.

SEMESTER II

SMBA5201	CELL AND MOLECULAR BIOLOGY	L	T	P	EL	Credits	Total Marks
		4	0	0	0	4	100

COURSE OBJECTIVE

- To know about the general concepts of cellular structure and function. To gain and understand the basic concepts in Molecular biology.

UNIT 1 INTRODUCTION TO CELLULAR ORGANIZATION 10 Hrs.

Cellular compartmentation and organelle architecture. The Nucleus: Chromosomal DNA and its packaging, Structure of nucleic acids, organization of the bacterial chromosome, organization of eukaryotic chromosomes.

UNIT 2 MEMBRANE STRUCTURE AND FUNCTIONS 12 Hrs.

The lipid bilayer, Membrane proteins, Principles of membrane transport, Ion channels and electrical properties of membranes. The transport of molecules into and out of the Nucleus, The transports of protein into mitochondria, chloroplasts, Peroxisomes, endoplasmic reticulum, Transport from ER through the Golgi apparatus.

UNIT 3 BASICS MOLECULAR GENETIC MECHANISMS 12 Hrs.

Chromosome duplication and segregation, Mechanisms of DNA polymerase, types of DNA polymerases, replicon model, eukaryotic replication, role of telomerase. Replication errors and their repair, Mutagens, repair of DNA damage and Transposons.

UNIT 4 TRANSCRIPTION OF GENES AND FORMATION OF FUNCTIONAL MRNA 14 Hrs.

Types of RNA polymerases, sigma factor, transcription mechanism, rho dependent and independent termination, eukaryotic transcription, RNA processing, RNA polymerase I and III promoter, mechanism of splicing, RNA editing, mRNA transport, inhibitors of transcription. Mechanism of translation, eukaryotic translation factors, peptide bond formation, Wobble hypothesis.

UNIT 5 CELL SIGNALING 12 Hrs.

General principles of cell signaling, Kinase receptors. Cell cycle and division: The general strategy of the cell cycle, mechanism of cell division. Cancer, Proto – oncogenes and viral oncogenes, Tumor suppressor genes.

Max.60 Hrs.

TEXT / REFERENCE BOOKS:

1. Molecular Biology of the Gene, 5th Edition, Watson et al., Pearson Education.
2. Molecular biology by David freifelder.
3. Molecular biology- Baltimore.
4. Molecular biology- Lodish.
5. Molecular biology of cell by Albert et.al. John Wiley & Sons.
6. The Cell by Cooper.ASM Press.
7. Cell and Molecular Biology by Gerald Karp. John Wiley & sons.

END SEMESTER EXAM QUESTION PAPER PATTERN

Max.Marks: 100 **Exam Duration: 3 Hrs.**

PART A : 6 Questions of 5 mark each - No choice. **30 Marks**

PART B : 2 Questions from each unit of internal choice, each carrying 14 marks. **70 Marks**

SMBA5202	HUMAN GENETICS	L	T	P	EL	Credits	Total Marks
		4	0	0	0	4	100

COURSE OBJECTIVE

- To know about the general concepts of Human Genetics. To gain and understand the basic concepts in Human Genetic

UNIT 1 **12 Hrs.**

Introduction to human genetics, History of Human Genetics, Early perception, Genome organization and function, heritability, chromosomal disorders.

UNIT 2 **12 Hrs.**

Pedigrees- gathering family history, pedigree symbols, construction of pedigrees, presentation of molecular genetic data in pedigrees, Pedigree analysis and Importance of pedigree.

UNIT 3 **12 Hrs.**

Monogenic traits, Autosomal inheritance-dominant, recessive. Sex-linked inheritance, mitochondrial inheritance, genomic imprinting, spontaneous mutations, male lethality, X-inactivation, Consanguinity and its effects.

UNIT 4 **12 Hrs.**

Complex traits, 'Nature vs nurture', role of family and shared environment, monozygotic and dizygotic twins, Polygenic inheritance of continuous (quantitative) traits, Dysmorphology, Genetic susceptibility in multifactorial disorders (alcoholism, diabetes mellitus, obesity).

UNIT 5 **12 Hrs.**

Human cytogenetics, Techniques in human chromosome analysis, Human karyotype: banding, nomenclature of banding, Pathology of human chromosomes, Nomenclature of aberrant karyotypes, chromosome abnormalities in cancer, Genetics of fetal wastage, Pharmacogenetics, ecogenetics and teratogenetics.

Max.60 Hrs.

TEXT / REFERENCE BOOKS

1. Atherly et al., The Science of Genetics Saunders.
2. EJ Mongia and AP Mongia, Basic Human Genetics.
3. Fairbanks et al., Genetics Wadsworth.
4. Gardner et al., Principles of Genetics John Wiley.
5. Snustad et al., Principles of Genetics Wiley and sons.
6. Griffiths et al., An Introduction to Genetic Analysis Freeman.
7. Curt Stern, Principles of Genetics.
8. Snustad et al., Principles of Genetics Wiley and sons.
9. Strickberger, Genetics Mcmillan.
10. Thomson and Thomson, Genetics in Medicine.

END SEMESTER EXAM QUESTION PAPER PATTERN

Max.Marks: 100 **Exam Duration: 3 Hrs.**

PART A : 6 Questions of 5 mark each - No choice. **30 Marks**

PART B : 2 Questions from each unit of internal choice, each carrying 14 marks. **70 Marks**

SMBA5203	PHARMACOLOGY	L	T	P	EL	Credits	Total Marks
		4	0	0	0	4	100

COURSE OBJECTIVE

- To provide basic understanding in Pharmacology and also give fundamentals of Pharmacology concepts.

UNIT 1 **12 Hrs.**

Introduction to Pharmacology, Definitions – Pharmacology, Pharmacokinetics, Pharmacodynamics, Drug, Pharmacotherapeutics, Clinical pharmacology, Chemotherapy, Pharmacy and Toxicology, Drug Nomenclature, Routes of drug administration, systemic routes. Dosage forms of Drug – Definition and brief about the dosage forms – solid dosage forms, liquid dosage forms, semisolid dosage forms, sterile products, gas and novel drug delivery system.

UNIT 2 **12 Hrs.**

Sources of Drugs – Natural sources and synthetic sources, Pharmacodynamics – Principles and mechanism of drug action, dose response curve and adverse drug reaction, Factors Modifying Drug Action (Body size, age, sex, species and race, genetics, environmental factors, psychological factor, pathological states, other drugs, accumulation, tolerance).

UNIT 3 **12 Hrs.**

Drugs acting on kidneys and GIT: Diuretics - Classification of drugs, prototype drug- actions, and side effect, Anti-diuretics- Classification of drugs, prototype drug- actions and side effect, Drugs for peptic ulcer - classification of drugs, prototype drug actions and side effect.

UNIT 4 **12 Hrs.**

Cardiovascular Pharmacology: Hypertension - classification of drugs, prototype drug- actions and side effect, CHF - classification of drugs, prototype drug- actions and side effect, coronary artery disease- classification of drugs, prototype drug- actions and side effect, Arrhythmia - classification of drugs, prototype drug- actions and side effect.

UNIT 5 **12 Hrs.**

Endocrine Pharmacology: Diabetes Mellitus- Insulin – types of insulin, methods of insulin delivery, management of acute complication of diabetes, oral hypoglycemic drugs- classification of drugs and side effect, Thyroid hormone and Thyroid inhibitors- Anatomy & physiology of thyroid gland, classification of drugs and side effect, Corticosteroids- Anatomy & physiology of adrenal gland, classification of drugs and side effect, Estrogen, Progestins and Contraceptives- Classification of drugs and side effect, Oxytocin and other drugs acting on uterus- Classification of drugs and side effect, Drug affecting calcium balance- Physiology of calcium balance, classification of drugs and side effect.

Max.60 Hrs.

REFERENCE BOOKS

1. Rang & Dale's Pharmacology, 7th Edition. By Humphrey P. Rang, Maureen M. Dale, James M. Ritter, Rod J. Flower, and Graeme Henderson. Publisher: Elsevier.
2. Lippincott Illustrated Reviews: Pharmacology, 6th Edition. By Richard A Harvey, Michelle A Clark, Richard Finkel, Jose A Rey, Karen Whalen. Publisher: Lippincott Williams and Wilkins.
3. Basic and Clinical Pharmacology, 12th Edition. By Bertram G. Katzung, Susan B. Masters, Anthony J. Trevor. Publisher: Lange.

4. Goodman and Gilman's The Pharmacological Basis of Therapeutics. 12th Edition. Laurence Brunton, Bruce Chabner, Bjorn Knollman. Publisher: Mc Graw Hill.
5. Essentials of Medical Pharmacology, 7th edition. By K D Tripathi. Publisher: Jaypee.
6. Ganong's Review of Medical Physiology, 24th Edition. Authors: Kim E. Barrett, Susan M. Barman Scott Boitano, Heddwen Brooks. Publisher: Lange.

END SEMESTER EXAM QUESTION PAPER PATTERN

Max.Marks: 100 **Exam Duration: 3 Hrs.**

PART A : 6 Questions of 5 mark each - No choice. **30 Marks**

PART B : 2 Questions from each unit of internal choice, each carrying 14 marks. **70 Marks**

SMBA5204	CLINICAL RESEARCH	L	T	P	EL	Credits	Total Marks
		4	0	0	0	4	100

COURSE OBJECTIVE

- To provide basic understanding in Clinical Research and also give fundamentals of Clinical Research techniques.

UNIT 1 **12 Hrs.**

Introduction to Clinical Trials - Glossary of terms in clinical trials, history, requirements, new drug development process, need for new drug, selection of a chemical compound as a potential drug, screening of chemical compounds, translation medicine, assessment of preclinical data Phases of clinical trials- Phase I, Phase II, Phase III and Phase IV, Principles of controlled clinical trials.

UNIT 2 **12 Hrs.**

Clinical trial design (observational and interventional) protocol, consent in clinical trials, placebo, bias and methods to prevent bias, ethics in clinical trials, monitoring, problems and solutions of controlled clinical trials. Multicentre clinical trials Requirements, regulations and feasibility. Improving patient enrolment and retention in Clinical Trials.

UNIT 3 **12 Hrs.**

Legal issues in clinical trials, Drug regulations, Good clinical practice, Systematic review and meta-analysis, evidence-based medicine, Toxicity studies – Acute, sub-acute and chronic toxicity studies, Mutagenicity, Carcinogenicity and Teratogenicity.

UNIT 4 **12 Hrs.**

Quality Assurance studies: Guidelines and operational techniques, Drug regulations: International: Food and Drug Administration and European Medicine Agency. Introduction of FDA, Regulations and working principles of FDA, Introduction of European Medicine Agency Clinical.

UNIT 5 **12 Hrs.**

Data Management- Introduction, planning of trial, database, flow of data, creating database, Data Validation, system validation, data entry, E- data capture. Therapeutic drug monitoring - Efficacy and safety measurement, endpoint auditing's: Research Auditing and Inspections, Preparing Clinical Trial Report.

Max.60 Hrs.

REFERENCE BOOKS

1. Methodology of Clinical Drug Trials, 2nd Edition. Spriet A., Dupin-Spriet T., Simon P. Publisher: Karger.
2. Design and Analysis of Clinical Trials: Concepts and Methodologies, 3rd Edition. SheinChung Chow, Jen-Pei Liu. Publisher: Wiley.
3. Principles and Practice of Pharmaceutical Medicine, 3rd Edition. Lionel D. Edwards, Anthony W. Fox, Peter D. Stonier. Publisher: Wiley-Blackwell.

END SEMESTER EXAM QUESTION PAPER PATTERN

Max.Marks: 100 **Exam Duration: 3 Hrs.**

PART A : 6 Questions of 5 mark each - No choice. **30 Marks**

PART B : 2 Questions from each unit of internal choice, each carrying 14 marks. **70 Marks**

SMBA6201	MOLECULAR BIOLOGY LAB PRACTICAL-I	L	T	P	EL	Credits	Total Marks
		0	2	2	0	2	100

COURSE OBJECTIVE

- To learn about the basic techniques in Molecular Biology.

LIST OF EXPERIMENTS

1. Agarose Gel Electrophoresis.
2. Bacterial genomic DNA isolation.
3. Extraction of DNA from Bovine Spleen.
4. DNA Extraction from Agarose Gel.
5. Bacterial Transformation.
6. Phenol Extraction of rRNA (Rat liver).
7. Protein sample preparation from bacterial, animal and plant cells.
8. Spectrophotometric determination of protein concentration.
9. SDS-PAGE.
10. Western Blotting techniques.
11. Overview of Two-Dimensional Gel Electrophoresis.
12. Peptide sequencing.

REFERENCE BOOKS

1. Green, M. R., & Sambrook, J. (2012). Molecular cloning: a laboratory manual.
2. Sambrook, J., & Russell, D. W. (2001). Inverse PCR. Molecular Cloning; A Laboratory Manual, 8-81.
3. Sambrook, J., Fritsch, E. F., & Maniatis, T. (1989). Molecular cloning (Vol. 1, No. 7.58). New York: Cold spring harbor laboratory press.

SMBA6202	CLINICAL DATA MANAGEMENT – PRACTICAL II	L	T	P	EL	Credits	Total Marks
		0	2	2	0	2	100

COURSE OBJECTIVE

- To make the students to understand a broad range of experimental techniques and to enable them to demonstrate their ability to use the techniques in conducting scientific experiments and observations.

LIST OF EXPERIMENTS

MS- Excel – Introduction to excel and RDBMS

Clinical Data Management – Overview, regulation, data management plan, data acquisition and CRF designing, database designing and implementation, data entry and verification and data analysis.

Soft Skills - Introduction and definition, motivation, SWOT analysis, goal setting, business etiquettes, business dressing, business communication, understanding body language and gestures, listening skill, giving and accepting feedback, group discussion.

Communication – Types of communication, pronunciation; consonants and vowel sounds. Grammar; noun, adjectives, use of definite and indefinite articles, tenses.

Vocabulary - Antonyms, synonyms, homonyms, one word substitution, common phrases and idiomatic expressions. Vocabulary power; words related to various concepts of life and activities.

Reference Books

1. Practical Computer Literacy, 3rd Edition. June Jamrich Parsons, Dan Oja. Publisher: CENGAGE Learning.
2. Practical Guide to Clinical Data Management by Susanne Prokscha

SMBA5301	PHARMACO-VIGILANCE AND SAFETY MONITORING	L	T	P	EL	Credits	Total Marks
		4	0	0	0	4	100

COURSE OBJECTIVE

- To study the various types of Pharmaco-vigilance and Safety monitoring techniques and their analysis

UNIT 1 GENERAL OVERVIEW OF PHARMACOVIGILANCE 12 Hrs.

Introduction, Definitions, Adverse Event (AE), Adverse Drug Reaction (ADR), Serious Adverse Drug Reaction (SAE), Unexpected Adverse Reaction, Suspected-unexpected serious Adverse reaction (SUSAR), Signal and Detection of Signal, Diagnosis and management of adverse drug reactions, Periodic safety Update Report (PSUR), Individual case safety report, Spontaneous reporting, Risk Evaluation and Mitigation Strategy, Significance of Pharmacovigilance, Audit in Pharmacovigilance.

UNIT 2 PHARMACOVIGILANCE AND ICH GUIDELINE 12 Hrs.

ICH-E2A Clinical Safety Data Management – Definitions and Standards for Expedited Reporting, ICH-E2C Clinical Safety Data Management – Periodic Safety Update Reports for Marketed Drugs, ICH-E2D Post Approval Safety Management – Definitions and Standards for Expedited Reporting, ICHE2E Pharmacovigilance Planning.

UNIT 3 PHARMACOVIGILANCE REGULATIONS AND GUIDELINES 12 Hrs.

Role of Pharmacovigilance in Drug Regulation, Regulatory aspects in Pharmacovigilance, European Union PV guidelines, Australian PV guidelines, Good Pharmacovigilance Practices (GPP), Expedited reporting requirements.

UNIT 4 PHARMACOVIGILANCE IN INDIA OTHER COUNTRIES 12 Hrs.

Pharmacovigilance centers in India, CDSCO Indian PV guidelines-National Pharmacovigilance Program (NPP), Adverse Event reporting form: MEDWATCH, CDSCO Adverse Event Reporting Form, CIOMS form for Serious Adverse event reporting, Anonymised Single Patient reports (ASPR-MHRA), Medication errors reporting. Global Pharmacovigilance & safety standards- Pharmacovigilance activity in USA, Australia, WHO Monitoring of safety aspects – Uppasla Monitoring Center (UPC).

UNIT 5 PERIODIC SAFETY UPDATE REPORTS (PSUR) FOR MARKETED DRUGS 12 Hrs.

Brief Introduction and Purpose of Periodic Safety Update Report, PSUR Content, PSUR Process, Various Regulatory Requirement for PSUR.

Max.60 Hrs.

REFERENCES BOOKS

1. A Handbook of Bioanalysis and Drug Metabolism by Gary Evans.
2. Clinical trial risk management by Martin Robinson & Simon Cook.
3. Clinical Trials: A Practical Guide to Design, Analysis & Reporting by Duolao Wang & Ameet Bakhai.
4. Data Monitoring committees in Clinical Trials Ebook by Susan S Ellenberg, Thomas R Flemming, David L Demets.
5. Drug Safety Evaluation by Shayne C Gad.
6. Guideline for Drug Regulatory Submissions by Sandy Weiberg.
7. Handbook of Bioequivalence testing by Sarfaraz K. Niazi.

END SEMESTER EXAM QUESTION PAPER PATTERN

Max.Marks: 100 **Exam Duration: 3 Hrs.**

PART A : 6 Questions of 5 mark each - No choice. **30 Marks**

PART B : 2 Questions from each unit of internal choice, each carrying 14 marks. **70 Marks**

SMBA5302	CLINICAL RESEARCH OPERATIONS MANAGEMENT	L	T	P	EL	Credits	Total Marks
		4	0	0	0	4	100

COURSE OBJECTIVE

- To understand the fundamental in clinical research operations management.

UNIT 1 **12 Hrs.**

Operation in CRO and SMO Site Selection Criteria- Site Selection parameters: Location, Staffing, Qualifications, History, Clinical trial experience, Area of therapeutic experience, Investigational pharmacy, ICH-GCP compliance, Patient enrollment, Site Selection Check list, Site Initiation Visit (SIV), Single Centre/Multi Centre Trial- Definition, benefits of Single centre and or Multi centre, Differences between Single centre & Multi centre.

UNIT 2 **12 Hrs.**

Roles and Responsibilities of Clinical Trial Personnel, Investigator, CROs/SMOs, CRA/Monitor, Auditor, Clinical Data Manager, Biostatistician and Documentation. Investigator's Brochure, Nonclinical Studies, Nonclinical Pharmacology, Pharmacokinetics and Product Metabolism in Animals, Toxicology, Effects in Humans, Safety and Efficacy, Marketing Experience, Summary of Data and Guidance for the Investigator, Study Protocol - The contents of a trial protocol should generally include the topics.

UNIT 3 **12 Hrs.**

Study title, purpose of research, study design, study procedures, Women of childbearing potential, Possible risks, Possible benefits, Compensation, Possible benefits to other people, Withdrawal of the consent, Right to new information, Contact persons, Patient consent form, Patient Information Sheet, Patient visit diary, Clinical Study Report- Title Page, Synopsis, List of Abbreviations and definitions of terms, ethics.

UNIT 4 **12 Hrs.**

Importance of Essential Documents, Pre-Study Document, Financial aspects of the trial, Approval letter from the IRB, IRB Composition, Investigational product, accountability at site, Subject enrolling log, Audit certificate, Post Study Documents, Final report by investigator to IRB, Final report by investigator to regulatory authorities, Clinical study report to document results and interpretation, Study Completion documents, Study Termination/closure documents

UNIT 5 **12 Hrs.**

Procedures in Clinical Trial, Quality Assurance and Quality Control in Clinical Research –Introduction, Regulatory requirement of quality Assurance (QA), Role and Responsibilities of QA personnel, Different types of Audits, Quality System and Quality Policy, Continual Process Improvement, Interventions, Study Drug Packaging and Distribution Study Drug Receipt, Dispensing, Accountability, Storage, Disposal, Regulatory Requirement. An over view of clinical trial interventions, Purpose of monitoring & Monitor's responsibilities, Selection and qualification of monitors.

Max.60 Hrs.

REFERENCE BOOKS

1. Business Development for the Biotechnology and Pharmaceutical Industry by Martin Austin Clinical Drug Trials & Tribulations Ebooks by James Swarbrick.
2. Clinical Research Coordinator Handbook. Ebook by Deborah Rosenbaum, Michelle Dresser.

3. Clinical Trial Medicine. Ebook by Richard Chin, Bruce Y. Lee.

END SEMESTER EXAM QUESTION PAPER PATTERN

Max.Marks: 100 **Exam Duration: 3 Hrs.**

PART A : 6 Questions of 5 mark each - No choice. **30 Marks**

PART B : 2 Questions from each unit of internal choice, each carrying 14 marks. **70 Marks**

SMBA5303	REGULATORY AFFAIRS, GLP, IPR AND BIOETHICS IN CLINICAL RESEARCH	L	T	P	EL	Credits	Total Marks
		4	0	0	0	4	100

COURSE OBJECTIVE

- To understand the basic principles of Regulatory affairs, GLP, IPR and Bioethics in Clinical Research.

UNIT 1 ETHICAL ASPECTS 12 Hrs.

Ethical principles underlined research involving human subjects, respect for persons, beneficence, justice, legal authorities for Institutional Review Board (IRB), Heath and Human Services regulations (HHS), FDA regulations, regulatory requirements, duties of IRBs, IRB membership, role of IRB in reviewing Clinical Drug Trials, Assessment of scientific design, competence of investigator, selection of subjects, balancing benefits and risks, Compensation for research related injuries, special issues like role of lay member of IRB, review of multi institutional trials, duty to monitor, financial risks of clinical trial subject, compliance with new regulations.

UNIT 2 HISTORY OF GOOD CLINICAL PRACTICES (GCP) 12 Hrs.

Introduction to ICH-International Conference on Harmonization of technical requirements for registration of Pharmaceuticals for human use guidelines Milestones in the evaluation of GCP , The Nuremberg Code, Principles of ICH-GCP, Applicable GCP Guidelines: International Conference on Harmonization of technical requirements for registration of Pharmaceuticals for human use guidelines (ICH-GCP), Indian Council of Medical Research- Ethical Guidelines for Biomedical Research on Human participants (ICMR), Indian Good Clinical Practices.

UNIT 3 INTERNATIONAL REGULATORY BODIES AND GUIDELINES 12 Hrs.

US Food and Drug Administration (USFDA): The FDA and Food Drug and Cosmetics Act, New drug development and approval : the principal steps o India: Regulatory laws, Schedule Y, registration of new drugs, requirements for registration, regulatory environment and practices, Medicines and Healthcare Products Regulatory Agency (MHRA): Overview of regulatory environment/ background, regulatory authorities, regulatory requirements and procedures, European Agency for Evaluation of medicinal Products(EMEA): National registration, the decentralized procedures, mutual recognition procedures, Brazil: Overview of regulatory affairs Good Laboratory practices (GLP) :Organization and Personnel, Quality assurance program, Facilities, Equipments, reagents and Materials, Standard operating procedures, Storage of Records and Reports.

UNIT 4 INTELLECTUAL PROPERTY RIGHTS 12 Hrs.

Terminology, Patent Laws, TRIPS (Trade Related Intellectual Property Rights) Agreement, Trademarks, copyrights.

UNIT 5 CLINICAL TRIAL APPLICATION REQUIREMENTS 12 Hrs.

Investigational New drug (IND): Classifications, IND application submission check list, FDA IND review check list, IND application process, Information for sponsors-investigator submitting IND, IND forms and instructions. New Drug Application (NDA): Pre NDA meeting, NDA submission Check list, FDA NDA review check list. Abbreviated New drug Application (ANDA): ANDA content, ANDA Submission check list, FDA ANDA review check list, ANDA process for generic drugs, guidance documents for ANDAs,

ANDA forms and electronic submissions. Orphan Drugs Application: Submission check list, FDA orphan drug review check list, FDA documents.

Max.60 Hrs.

REFERENCE BOOKS

1. Good Laboratory Practice Regulations, by Sandy Weinberg, Drugs and the Pharmaceutical Sciences.
2. Good Pharmaceutical Manufacturing practice, Rational and compliance by John Sharp, CRC Press
3. Establishing a cGMP Laboratory Audit System, A practical Guide by David M. Bleisner, Wiley Publication.
4. How to practice GLP by PP Sharma, Vandana Publications.
5. Laboratory Auditing for Quality and Regulatory compliance by Donald C.Singer, Drugs and the Pharmaceutical Sciences.
6. Drugs & Cosmetics Act, Rules & Amendments.
7. The law & strategy of Biotechnology patents by Sibley. Butterworth publications.
8. Intellectual property rights - Ganguli - Tat McGrawhill.
9. Intellectual property right - Wattal - Oxford Publishing House.

END SEMESTER EXAM QUESTION PAPER PATTERN

Max.Marks: 100 **Exam Duration: 3 Hrs.**

PART A : 6 Questions of 5 mark each - No choice. **30 Marks**

PART B : 2 Questions from each unit of internal choice, each carrying 14 marks. **70 Marks**

SMBA5304	BIOSTATISTICS	L	T	P	EL	Credits	Total Marks
		4	0	0	0	4	100

COURSE OBJECTIVE

- To study the various types of Biostatistics techniques and their analysis.

UNIT 1 **12 Hrs.**

Introduction- Biostatistics and standard terminology, Basic knowledge about presentation of data - Type of diagram, one dimensional diagram, two-dimension diagram, three-dimensional, pie diagram and pictogram, Graphic representation of data - Histogram, frequency, polygon and frequency curve.

UNIT 2 **12 Hrs.**

Sampling - Definition, selection of samples, merit and limitation of sampling, methods of sampling. Measures of central tendency - Mean, median, mode and relation between arithmetic mean, geometric mean and harmonic mean.

UNIT 3 **12 Hrs.**

Measures of dispersion - Mean deviation, advantage and disadvantage of mean deviation, coefficient of mean deviation, standard deviation, application of standard deviation and coefficient of variation. Definition and application - Correlation, regression, Chi-square test and t-test.

UNIT 4 **12 Hrs.**

Probability: Definition and Application 2. Parametric Tests: Definition and Application Analysis of variance-One Way and Two-Way a) McNemar's test b) Exact probability test 3. Rank score tests – Definition and Application a) Wilcoxon signed rank test, b) Wilcoxon two sample rank test, c) The Mann Whitney Test, d) The Spearman Test.

UNIT 5 **12 Hrs.**

The Friedman Test. 4. F-test – testing of two population variances 5. Study design and choosing a statistical test Design-Assignments

Max.60 Hrs.

REFERENCE BOOKS

1. Biostatistics, 1st Edition. Sai Subramanian. Publisher: Career Publications.
2. Pharmaceutical Biostatistics, 1st Edition. Shadab Ahmed Khan, Ismali, Ahmed and Husain. Publisher: Birla Publications.
3. Biostatistics for Pharmacy, 1st Edition. Khan and khanum. Publisher: Ukaaz Publication.
4. Basic & Clinical Biostatistics, 4th Edition. Beth Dawson, Robert G. Trapp. Publisher: Lange.

END SEMESTER EXAM QUESTION PAPER PATTERN

Max.Marks: 100 **Exam Duration: 3 Hrs.**

PART A : 6 Questions of 5 mark each - No choice. **30 Marks**

PART B : 2 Questions from each unit of internal choice, each carrying 14 marks. **70 Marks**

SMBA6301	STATISTICAL ANALYSIS SYSTEM LAB-PRACTICAL	L	T	P	EL	Credits	Total Marks
		0	2	2	0	2	100

COURSE OBJECTIVE

- To understand the concepts of Statistical Analysis System

LIST OF EXPERIMENTS

1. Statistical Analysis System (SAS)
2. Understanding DATA Step Processing in SAS.
3. Creating a table using SAS program.
4. Producing Descriptive Statistics using SAS.
5. Producing HTML, PDF and XML Output using SAS
6. Survival Graph using GraphPad Prism tool.
7. Drawing following charts using statistical tools;
8. Pie chart.
9. Scatter plot.
10. Bar diagram (Horizontal and Vertical).
11. Creating a pictogram using given data.
12. Tabulation rules.

REFERENCE BOOKS

1. Statistical Methods for Reliability Data. (1998) William Q. Meeker and Luis A. Escobar. Wiley
2. Survival Analysis Using the SAS System: A Practical Guide. (1995) Paul D. Allison. SAS Institute Inc.

SMBAPROJ	PROJECT WORK	L	T	P	EL	Credits	Total Marks
		0	0	30	0	14	100

OBJECTIVE

- To promote students for studying the problem and make innovative solutions leads to novel product development.

METHODOLOGY

Students are expected to do a major research project within the stipulated time. Criteria for selecting the topic will be based on the area of specialization by the students. Emphasis will be given to producing works that are of specialization by the student.

SMBAINT	INTERNSHIP	L	T	P	EL	Credits	Total Marks
		0	0	10	3	6	100

OBJECTIVE

- To help student get exposed to research laboratories and industry.

METHODOLOGY

The student will be attached to the research laboratories and industry for a period of 15 days on an internship basis. The intern will be exposed to a particular area of specialization. The department in coordination with the industry will closely monitor the progress of the intern. A report and a Viva – Voce will complete the process of evaluation.

DISCIPLINE SPECIFIC ELECTIVE ELECTIVES – I

SMBA7001	PUBLIC HEALTH SYSTEM AND OUTREACH PROGRAMMES	L	T	P	EL	Credits	Total Marks
		4	0	0	0	4	100

COURSE OBJECTIVE

- To understand the basic concepts and methods of epidemiology. To get familiarized with the Emergency Epidemic Management System.

UNIT 1 **12 Hrs.**

Basic concepts and methods of Epidemiology and application to the variety of disease problems – Health for all and primary Health care – Clinical trials – community trails – ethical considerations – inference from epidemiological studies.

UNIT 2 **12 Hrs.**

National Health Programmes related to Communicable diseases- Malaria, Filaria, Tuberculosis, Leprosy, AIDS and STD National Health Programmes related to Non Communicable diseases – Cancer, Blindness, Diabetes, and Mental Health-Reproductive and child health programme (RCH)-Health related national programmes - Integrated Child development scheme, water supply and sanitation, minimum needs programme.

UNIT 3 **12 Hrs.**

Alcoholism and drug dependency: Alcohol and alcoholism – opiod drug use – cocaine and other commonly abused drugs – nicotine addiction – setting up de-addiction and rehabilitation centers.

UNIT 4 **12 Hrs.**

Environmental and Occupational hazards – Hazards of environment and work place – Sterilizations – Autoclaves – Waste disposal management (Solids and Liquids) – Incinerators.

UNIT 5 **12 Hrs.**

Emergency Epidemic Management System – Safety systems – Immunization and Isolation systems – Communication systems – Public Health Service Systems – Health and Population Policy and Strategies – District Health Organization – Regionalization of health care.

Max.60 Hrs.

REFERENCE BOOKS

1. Gilienfeld, Foundation of epidemiology
2. Brilliant Lawrence, Smallpox eradication in India
3. Ronald Gold et.el., Pre-test self assessment and review
4. Principles of internal medicine Harrisons Volume 2

END SEMESTER EXAM QUESTION PAPER PATTERN

Max.Marks: 100 **Exam Duration: 3 Hrs.**

PART A : 6 Questions of 5 mark each - No choice. **30 Marks**

PART B : 2 Questions from each unit of internal choice, each carrying 14 marks. **70 Marks**

SMBA7002	PATIENT CARE MANAGEMENT	L	T	P	EL	Credits	Total Marks
		4	0	0	0	4	100

COURSE OBJECTIVE

- To understand the importance of patient care management.
- To be acquainted with the disaster and safety & Security Management in Hospitals.

UNIT 1 **12 Hrs.**

Patient centric management-Concept of patient care, Patient-centric management, Organization of hospital departments, Roles of departments/managers in enhancing care, Patient counseling and Practical examples of patient centric management in hospitals-Patient safety and patient risk management.

UNIT 2 **12 Hrs.**

Quality in patient care management-Defining quality, Systems approach towards quality, towards a quality framework, Key theories and concepts, Models for quality improvement & Variations in practice.

UNIT 3 **12 Hrs.**

Patient classification systems and the role of casemix, Types of patient classification systems, ICD 9 (CM, PM), Casemix classification systems, DRG, HBG, ARDRG, Casemix innovations and Patient empowering classification systems.

UNIT 4 **12 Hrs.**

Medical ethics and auditory procedures-Ethical principles, Civic rights, Consumer Protection Act, Patient complaints powers and procedures of the district forum, State and National commission, Patient appeals, Autopsy, Tort liability, Vicarious liability, Medical negligence, Central and State laws, Use of investigational drugs, Introduction/need and procedures for medical audit, Audit administration and Regulating committees-Confidentiality and professional secrecy, ethics of trust and ethics of rights – autonomy and informed consent, under trading of patient rights – universal accessibility – equity and social justice, human dignity

UNIT 5 **12 Hrs.**

Disaster preparedness - Policies and procedures for general safety, fire safety procedure for evacuation, disaster plan and crisis management. Policies & procedures for maintaining medical records, e-records, legal aspects of medical records, its safety, preservation and storage.

Max.60 Hrs.

REFERENCE BOOKS

1. Goel S L & Kumar R. Hospital Core Services: Hospital Administration of the 21st Century 2004 ed., Deep & Deep Publications Pvt Ltd: New Delhi.
2. Gupta S & Kant S. Hospital & Health Care Administration: Appraisal and Referral Treatise 1998 ed., Jaypee, New Delhi.

END SEMESTER EXAM QUESTION PAPER PATTERN

Max.Marks: 100 **Exam Duration: 3 Hrs.**
PART A : 6 Questions of 5 mark each - No choice. **30 Marks**
PART B : 2 Questions from each unit of internal choice, each carrying 14 marks. **70 Marks**

SMBA7003	CLINICAL DATA MANAGEMENT	L	T	P	EL	Credits	Total Marks
		4	0	0	0	4	100

COURSE OBJECTIVE

- To acquire enveloping knowledge of Clinical Data Management to know wider field of clinical research.

UNIT 1 **12 Hrs.**

Introduction to Clinical Data Management (CDM): Definition, Steps in CDM, Data management process and work flow, Code of Ethics for CDM professionals, CDM and case record form (CRF), needs of CRF users, standardization of CRFs, guidelines for designing CRF.

UNIT 2 **12 Hrs.**

Data Entry/Remote data entry: First data entry, second data entry, heads up and heads down data entry, audit trail, 21CFR part 11, computerized system in clinical trials, QAQC in data entry, Tracking CRF pages and corrections, CRF work flow, tracking challenges, tracking of query forms.

UNIT 3 **12 Hrs.**

Data Capture: Definition, paper based and electronic data capture, dataflow in paper CRFs and e-CRFs, tools for data capture, advantages and disadvantages of paper CRF/ e-CRF o Data Coding: Definition, data quality, coding significance, coding dictionaries, Coding symbols for a thesaurus of adverse reaction terms (COSTART), problems with Coding data, special search categories, coding of AE data.

UNIT 4 **12 Hrs.**

Data cleaning/validation: Definition, Discrepancy management system, edit check specifications, query management, cleaning data checklist, SAE reconciliation, managing laboratory data, data locking/freezing, Overview of Data management Software(s)

UNIT 5 **12 Hrs.**

Introduction to Biostatistics and its role in Clinical Research: Population and Sample, Parameter & Statistic, Types of variables, Measures of Central Tendency-Mean, different types of mean, Median, Mode, Histograms, Scatter Plots, Construction and Labeling of graphs, Normal & Binomial Distribution, Research Hypothesis testing, Sample size calculation & Power, p-value, Confidence Interval, Randomization methods, Blinding in Clinical research.

Max.60 Hrs.

REFERENCE BOOKS

1. Handbook for good clinical research practice WHO Library Catalogue.
2. Clinical Research Environment in India by Umakanta Sahoo, Faiz Kermani, ICFAI University Press.
3. Clinical Trials. Lelia Duley and Barbara Farrell (eds), BMJ Books, London.
4. Articles: ICH-GCP, Schedule Y, US FDA guidelines, WHO Guidelines.
5. Bioavailability and Bioequivalence in pharmaceutical technology by Tapan Kumar and Ganeshan M, CBS publishers and distributers.

6. Design of experiments. A realistic approach by V L Anderson and Robert Mclean, Marcel Dekker, New York, USA.
7. Fundamentals of Clinical Research: Bridging Medicine, Statistics and Operations, Antonella Bacchieri and Giovanni Della Cioppa, Springer.

END SEMESTER EXAM QUESTION PAPER PATTERN

Max.Marks: 100 **Exam Duration: 3 Hrs.**

PART A : 6 Questions of 5 mark each - No choice. **30 Marks**

PART B : 2 Questions from each unit of internal choice, each carrying 14 marks. **70 Marks**

SMBA7004	INSTRUMENTATION METHODS	L	T	P	EL	Credits	Total Marks
		4	0	0	0	4	100

COURSE OBJECTIVE

- To provide basic understanding and sound knowledge on various basic as well as modern instruments and techniques especially which are specific to medical biotechnology. This would help the students to understand the principles of various instruments engaged in the biological research.

UNIT 1 PRINCIPLES AND APPLICATION OF SPECTROSCOPY 12 Hrs.

Absorption of Radiation, Beers Lambert law, Deviations, Instrumentation, Double beam and single beam spectrometers, sources of radiation detectors, photometric accuracy, spectrophotometer operation, instrumentation optical materials sources, detectors spectrophotometers, Fourier transform, spectrophotometers, calibration and standardization, atomization, flame atomization, sources of radiation, background correction, detection limits, inferences and applications. Spectro-fluorimetry and its applications.

UNIT 2 CHARACTERIZATION TECHNIQUES 12 Hrs.

Nuclear Magnetic Resonance **(**NMR)**,** Infrared and Raman Spectroscopy and their application. Mass spectrometry, Atomic absorption and atomic emission spectroscopy.

UNIT 3 PRINCIPLES AND APPLICATIONS OF X-RAYS 12 Hrs.

The absorption of x-rays, monochromatic X-ray sources, X-ray detectors, x-ray diffraction, x-ray fluorescence, power and single crystal diffraction methods, comparison of X-ray diffraction and neutron diffraction.

UNIT 4 BIOPHYSICAL TECHNIQUES AND INSTRUMENTATION 12 Hrs.

Sedimentation, Ultra Centrifugation, Gradient centrifugation, Electrophoresis – SDS-PAGE and Agarose Gel electrophoresis, Chromatography techniques – TLC, HPLC, GLC and its application. Fluorescent activated cell sorter (FACS).

UNIT 5 MICROSCOPY 12 Hrs.

Phase contrast microscopy, Electron microscopy (TEM and SEM), Fluorescent Microscopy, Confocal microscopy, Atomic Force microscope (AFM).

Max.60 Hrs.

TEXT / REFERENCE BOOKS

1. Ewing GW, Instrumental Methods of Chemical Analysis, McGraw Hill Book Company, 1989.
2. Principles of Instrumental Analysis 5th Edn. Skoog.D.A, Thompson, Brooks and Cole.
3 Willard and Merrit, Instrumental Methods and Analysis, VI Edition, CBS Publishers and Distributors.
4. Braun H., Introduction to Chemical Analysis, McGraw Hill, 1987.

END SEMESTER EXAM QUESTION PAPER PATTERN

Max.Marks: 100 **Exam Duration: 3 Hrs.**

PART A : 6 Questions of 5 mark each - No choice. **30 Marks**

PART B : 2 Questions from each unit of internal choice, each carrying 14 marks. **70 Marks**

DISCIPLINE SPECIFIC ELECTIVE ELECTIVES - II

SMBA8001	BIO-ENTREPRENEURSHIP	L	T	P	EL	Credits	Total Marks
		3	0	0	0	4	100

COURSE OBJECTIVE

- Gain knowledge of the context, concepts and process of entrepreneurship. Be better able to conceive and develop entrepreneurial opportunities. Be able to determine the feasibility of a new business concept.

UNIT 1 PROJECT PLANNING 12 Hrs.

Scope – problem statement – project goals – objectives – success criteria – assumptions – risks – obstacles – approval process – projects and strategic planning. Project implementation – project resource requirements – types of resources – men –materials, finance. Case studies.

UNIT 2 PROJECT MONITORING 12 Hrs.

Evaluation – control – project network technique –planning for monitoring and evaluation – project audits – project management information system – project scheduling – PERT & CPM –project communication – post project reviews and Case studies. Project team management – recruitment – organizing – human resources – team operating rules – project organization – various forms of project organizations. Closing the project – types of project termination – strategic implications – project in trouble – termination strategies – evaluation of termination possibilities.

UNIT 3 FUNDAMENTALS OF ENTREPRENEURSHIP 12 Hrs.

Ideas to Reality, Proof of Concepts to Product realization, Strategic Management, Forms of Ownership and Franchising, Buying an existing Business, Business Models, Mobilization of Financial resources; Bank loans & Venture capitalism. Building a good Marketing Plan, Concepts in MSME. Accounting for planning, control, and motivation. Factors influencing capital acquisition and allocation. Financial decision making; Decision making under uncertainty; positive and normative models; Current issues in financial management. Case studies.

UNIT 4 INDUSTRIAL R&D AND PRODUCT DEVELOPMENT 12 Hrs.

Product development and project management in Agri, Pharma, Health and other biotech industries. Overview of issues and techniques involved in conducting & outcome of research. The multidisciplinary nature of outcomes research: research design and methods, data collection measurement instruments and clinical endpoints, quality of life issues, behavior change, and cost-effectiveness. Analysis Transition from R&D to business units. Product development, market learning and transition from R&D. Management of radical innovation technologies vs. stage gate approach in product development. Case studies.

UNIT 5 RIGHTS AND RESPONSIBILITIES OF BUSINESS UNDER THE INDIAN CONSTITUTIONALSYSTEM 12 Hrs.

Basic standards, rules, principles and issues relating to the law of corporations; core issues affect the corporate governance of business; relationship between management, boards and shareholders. Business laws applied to Biotech industries. Regulatory issues in Biotech industries with special

reference to clinical trial of pharma products and field trials of Agricultural products. Regulatory processes details. Intellectual property in biotech. Business. Models around intellectual property, licensing issues. Product development for commercial ventures. Bioethics and Current legal issues. Ethics of new technology. Case studies.

Max.60 Hrs.

TEXT / REFERENCE BOOKS

1. Beenet P Lientz, Kathyn, Project Management – for 21st Century - Academic Press, 1995.
2. Martin Grossmann Entrepreneurship in Biotechnology: managing for growth from start-up to initial public offering. Verlag. Springer-2003.
3. Holger Patzelt and Thomas Brenner. Handbook of Bio-entrepreneurship By Springer 2008 Graham Dutfield, IPR, Trade and Biodiversity, Earthscan publications, 2000.
4. Damian Hine, John Kapeleris. Innovation and entrepreneurship in biotechnology, an international prospective. By Edward Elgar Publishing. 2006.
5. P. S. Teng. Bioscience entrepreneurship in Asia: creating value with biology. By World Scientific Publishing Co. Pvt. Ltd. 2008.
6. A.K. Singh. Entrepreneurship Development and Management by Firewall Media, 2006.
7. Ramachandran, Entrepreneurship Development by. Tata McGraw-Hill Education, 2008.

END SEMESTER EXAM QUESTION PAPER PATTERN

Max.Marks: 100 **Exam Duration: 3 Hrs.**

PART A : 6 Questions of 5 mark each - No choice. **30 Marks**

PART B : 2 Questions from each unit of internal choice, each carrying 14 marks. **70 Marks**

SMBA8002	HUMAN RESOURCES MANAGEMENT	L	T	P	EL	Credits	Total Marks
		4	0	0	0	4	100

COURSE OBJECTIVE

- To understand and appreciate the importance of the human resources vis-a- vis other resources of the organization.
- To familiarize the students with methods and techniques of HRM. To equip them with the application of the HRM tools in real world business situations.

UNIT 1 **12 Hrs.**

Human Resources Management - Context and Concept of People Management in a Systems Perspective - Organization and Functions of the HR and Personnel Department - HR Structure and Strategy; Role of Government and Personnel Environment including MNCs.

UNIT 2 **12 Hrs.**

Recruitment and Selection - Human Resource Information System [HRIS] - Manpower Planning - Selection – Induction and Orientation - Performance and Potential Appraisal - Coaching and Mentoring - HRM issues and practices in the context of Outsourcing as a strategy.

UNIT 3 **12 Hrs.**

Human Resources Development –Training and Development Methods - Design and Evaluation of T&D Programmes - Career Development - Promotions and Transfers - Personnel Empowerment including Delegation - Retirement and Other Separation Processes.

UNIT 4 **12 Hrs.**

Financial Compensation- -Productivity and Morale - Principal Compensation Issues and Management - Job Evaluation - Productivity, Employee Morale and Motivation - Stress Management - Quality of Work Life.

UNIT 5 **12 Hrs.**

Building Relationships - Facilitating Legislative Framework - Trade Unions - Managing Conflicts - Disciplinary Process - Collective Bargaining - Workers Participation in Management - Concept, Mechanisms and Experiences.

Max.60 Hrs.

REFERENCE BOOKS

1. Venkata Ratnam C. S. & Srivatsava B. K., Personnel Management and Human Resources, Tata Mc-Graw Hill, New Delhi.
2. Aswathappa, Human Resource Management, Tata McGraw Hill, New Delhi.
3. Garry Dessler &Varkkey, Human Resource Management, Pearson, New Delhi.
4. Alan Price, Human Resource Management, Cengage Learning, New Delhi.
5. Pravin Durai, Human Resource Management, Pearson, New Delhi.

END SEMESTER EXAM QUESTION PAPER PATTERN

Max.Marks: 100 **Exam Duration: 3 Hrs.**

PART A : 6 Questions of 5 mark each - No choice. **30 Marks**

PART B : 2 Questions from each unit of internal choice, each carrying 14 marks. **70 Marks**

	HEALTHCARE ENVIRONMENT AND MANAGEMENT	L	T	P	EL	Credits	Total Marks
SMBA8003		4	0	0	0	4	100

COURSE OBJECTIVE

- To familiarize with the healthcare environment
- To understand the concepts of management with relevance to hospitals

UNIT 1 **12 Hrs.**

Introduction - Theoretical frame work - Environment - Internal and External – Environmental Scanning - Economic Environment - Competitive Environment - Natural Environment - Politico Legal Environment – Socio Cultural Environment - International and Technological Environment.

UNIT 2 **12 Hrs.**

A Conceptual Approach to Understanding the Health Care Systems – Evolution – Institutional Setting - Out Patient services – Medical Services – Surgical Services – Operating departmen Pediatric services – Dental services – Psychiatric services – Casualty & Emergency services Hospital Laboratory services – Anesthesia services – Obstetrics and Gynecology services Neuro – Surgery service – Neurology services.

UNIT 3 **12 Hrs.**

Overview of Health Care Sector in India – Primary care – Secondary care – Tertiary care – Rural Medical care – urban medical care - curative care - Preventive care - General & special Hospitals - Understanding the Hospital Management – Role of Medical, Nursing Staff, Paramedical and Supporting Staff - Health Policy - Population Policy - Drug Policy – Medical Education Policy.

UNIT 4 **12 Hrs.**

Health Care Regulation – WHO, International Health regulations, IMA, MCI, State Medical Council Bodies, Health universities and Teaching Hospitals and other Health care Delivery Systems.

UNIT 5 **12 Hrs.**

Epidemiology – Aims – Principles – Descriptive, Analytical and Experimental Epidemiology - Methods – Uses.

Max.60 Hrs.

REFERENCE BOOKS

1. Seth, M.L. Macroeconomics, Laksminarayana Agrawal, Edu,Pub.Agra.
2. Peter, Z & Fredrick, B. Health Economics, Oxford Pub., New York.
3. Shanmugansundaram, Y., Health Economics, Oxford Pub. New York.

END SEMESTER EXAM QUESTION PAPER PATTERN

Max.Marks: 100 **Exam Duration: 3 Hrs.**

PART A : 6 Questions of 5 mark each - No choice. **30 Marks**

PART B : 2 Questions from each unit of internal choice, each carrying 14 marks. **70 Marks**

SMBA8004	SEPARATION TECHNIQUES	L	T	P	EL	Credits	Total Marks
		4	0	0	0	4	100

COURSE OBJECTIVE

- The main objective of this course is to familiarize students with the fundamental principles of separation processes used in analytical chemistry such as various extraction techniques, gas and liquid chromatography, size and ion chromatography and electrophoresis. By completion of the course, students are also expected to gain independent laboratory skills in certain separation techniques and they will have the ability to interpret data from analytical separation method.

UNIT 1 **12 Hrs.**

Review of conventional processes, recent advances in separation techniques based on size, surface properties, ionic properties and other special characteristics of substances, Process concept, Theory and equipment used in cross flow filtration, cross flow electro filtration, dual functional filter, Surface based solid – liquid separations involving a second liquid, Siro floc filter.

UNIT 2 **12 Hrs.**

Membrane Separations. Types and choice of membranes, Plate and frame, tubular, spiral wound and hollow fiber membrane reactors and their relative merits, Commercial, pilot plant and laboratory membrane permeators involving dialysis, reverse osmosis, Nanofiltration, ultrafiltration, Microfiltration and Donnan dialysis, Economics of membrane operations, Ceramic membranes.

UNIT 3 **12 Hrs.**

Separations by adsorption techniques. Mechanism, Types and choice of adsorbents, Normal adsorption techniques, Affinity chromatography and immunochromatography, Types of equipment and commercial process,

UNIT 4 **12 Hrs.**

Ionic separations. Controlling factors, Applications, Types of equipment employed for electrophoresis, Di-electrophoresis, ion exchange chromatography and electrodialysis, Commercial processes.

UNIT 5 **12 Hrs.**

Separations involving Lyophilization, Pervaporation and permeation techniques for solid, liquids and gases, Industrial viability and examples, zone melting, Adductive crystallization, other separation processes, Industrial effluent treatment by modern techniques.

Max.60 Hrs.

TEXT / REFERENCE BOOKS

1. Lacey, R.E. and S.Looeb – Industrial Processing with Membranes Wiley – Inter Science, N.Y.
2. King, C.J. Separation Processes, Tata McGraw–Hill Publishing Co. Ltd., 1982.
3. Schoew, H.M. – New Chemical Engineering Separation Techniques, Interscience Publishers.
4. Ronald W. Roussel – Handbook of Separation Process Technology, John Wiley, New York.
5. Kestory, R.E. – Synthetic polymeric membranes, Wiley. Interscience, N.Y.
6. Osadar, Varid Nakagawal – Membrane Science and Technology, Marcel Dekkar.

END SEMESTER EXAM QUESTION PAPER PATTERN

Max.Marks: 100 **Exam Duration: 3 Hrs.**

PART A : 6 Questions of 5 mark each - No choice. **30 Marks**

PART B : 2 Questions from each unit of internal choice, each carrying 14 marks. **70 Marks**