UPES
UNIVERSITY OF TOMORROW

SCHOOL OF
HEALTH SCIENCES
AND TECHNOLOGY

B.Sc. Clinical Research

Four-Year Program

Program Structure | 2023-2027

UPES Bidholi Campus, P.O. Bidholi via Prem Nagar, Dehradun, Uttarakhand-248007
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School of Health Sciences and Technology

[B.Sc. Clinical Research Four Year Program]

Programme Structure

Template

2023-2027

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1.0 Abbreviations

Cat	-	Category
L	-	Lecture
T	-	Tutorial
P	-	Practical
Cr	-	Credits
UC	-	University Core
PC	-	Program Core
PRJ	-	Project Work (including Seminars, Dissertation, and Internships)
PE	-	Program Elective (includes Specialization courses)
UE	-	University Elective (includes Signatory, Exploratory and Open Electives)
TC	-	Total Credits

2.0 Vision and Mission of the University:

Vision of UPES

To be an Institution of Global standing for developing professionally competent talent contributing to nation building

Mission of UPES

- Develop industry-focused professionals with an international outlook.
- Foster effective outcome-based education system to continually improve teaching-learning and research.
- Inculcate integrative thought process among students to instill lifelong learning.
- Create global knowledge eco-system through training, research & development, and consultancy.
- Practice and promote high standards of professional ethics and develop harmonious relationship with environment and society.

3.0 Vision and Mission of the School

Vision

Leadership in Health Sciences & Technology for improving Planetary, and Public Health

Mission

- To create thought leaders and change makers.
- To design appropriate, holistic, and sustainable programs
- To converge multi-disciplinary efforts to make a difference for people and the planet.

4.0 Programme Educational Objectives

PEO 1 Graduates will be accomplished professionals, innovators, or entrepreneurs actively involved in bio-medical research, academics, and technology development.

PEO 2 Graduates will function in their profession with ethics, social awareness, and responsibility.

PEO 3 Graduates will engage with professionals in allied health and environmental sciences for collaborations and knowledge exchange.

PEO 4 Graduates will be successful in pursuing higher studies in allied health science.

PEO 5 Graduates will pursue career paths in academia or research.

Program Outcomes (POs):

At the end of programme student should be able to:

PO1 Gain Knowledge of basic and applied aspects of clinical research and allied sciences.

PO2 Demonstrate basic laboratory skills in clinical research and understanding of advanced analytical tools to gather scientific evidence.

PO3 Ability to comprehend basic analytical problems, apply critical thinking skills and offer scientific solutions.

PO4 Demonstrate and execute time management during completion of academic exercises, assignments, and research projects.

PO5 Demonstrate awareness of roles, responsibilities, and ethical standards as per academia and industry alignments.

PO6 Demonstrate leadership abilities, problem solving capability and decision making with high ethical standards.

PO7 Demonstrate good interpersonal communication skills.

PO8 Demonstrate eagerness for tackling critical societal issues concerning human and planetary health.

PO9 Recognize the need for and prepare to engage in life-long learning to adapt with technological changes.

Program Specific Outcomes (PSOs) for Clinical Research

PSO1. Demonstrate knowledge on good clinical practice, record-keeping practices within all stages of clinical trials and post marketing processes to ensure compliance with research approvals and professional and ethical standards of practice.

PSO2 Apply elements of research methodology to design and execute basic experiments and work towards developing solutions for emerging health, social and environmental problems.

PSO3 Apply knowledge of clinical research to pursue a wide range of careers in higher academia and research, public health, environmental organizations, societal organizations, relevant industries, and entrepreneurial activities.

6.0 Overview of Credit Allocation/ Credit Break up

Category-wise Credit distribution

Category	Number of Credits	Credit Percentage (%)
University Core (UC)	16	10
Programme Core (PC)	115	71.8
Programme Elective (PE)	14	8.75
University Elective (UE)	-	-
Projects (PRJ)	15	9.37
Mandatory Non-Credit Courses	7 Courses	-
Total	160	100

- University core subjects are those subjects that are mandatory for all similar programmes.
- Program Core courses in a curriculum are program specific. To be eligible for the degree, students must successfully finish each of the PC-listed courses.
- Program Elective courses provide the students the opportunity to study courses that are more complex and specialized, in their field of specialization.
- University electives are courses that a student can opt for from outside of his/ her programme, from across the university. This allows students to pursue their interests in other subjects as well. The number of credits that a student may take under University Elective is regulated.

7.0 Programme Structure

The term "Program Structure" refers to a list of courses (Core, Elective, and Open Elective) that make up an academic program, describing the syllabus, credits, hours of instruction, assessment, and examination systems, minimum amount of credits necessary for program graduation, etc.

B.Sc. Clinical Research Programme

SEMESTER I

Cat	Course Code	Course Title	L	T	P	TC
PC	HSCC1025	Human Anatomy and Physiology (Common with FND)	3	1	2	6
PC	HSCR1001	Fundamentals of Clinical Research	3	1	2	6
PC	HSCR1002	Community Health and Disease	3	1	2	6
UC		Living Conversations (SFL)	1	1	-	2
MNC		Ability Enhancement/Co-curricular	0	-	-	0

SEMESTER II

Cat	Course Code	Course Title	L	T	P	TC
PC		Principles of Biochemistry	2	1	1.5	4.5
PC		Computer Application and Bioinformatics	2	1	1.5	4.5
PC		Fundamentals of Biostatistics	2	1	1.5	4.5
UC		Critical Thinking and Writing (SFL)	1	1	0	2
PE		Elective Course	2	1	1.5	4.5

SEMESTER III

Cat	Course Code	Course Title	L	T	P	TC
PC		Pharmacology and Toxicology	2	1	1.5	4.5
PC		Design and Management of Clinical Trials	2	1	1.5	4.5
PC		Clinical Sampling and Analytical Techniques	2	1	2	5
UC		Environmental Science	3	1	-	4
UC		Leadership and Teamwork	1	1	-	2
MNC		Ability Enhancement/Co-curricular	0	-	-	0

SEMESTER IV

Cat	Course Code	Course Title	L	T	P	TC
PC		Pharmacovigilance	2	1	1.5	4.5
PC		Clinical Pharmacokinetics	2	1	1.5	4.5
PC		Bioethics and Drug Safety	2	1	1.5	4.5
UC		Working With Data	1	1	-	2
MNC		Ability Enhancement/Co-curricular	0	-	-	0
PE		Elective Course	2	1	1.5	4.5

SEMESTER V

Cat	Course Code	Course Title	L	T	P	TC
PC		Global Regulations in Clinical Trials	2	1	1.5	4.5
PC		Epidemiology and Global Health (with FND)	2	1	1.5	4.5
PC		Immunology	2	1	1.5	4.5
PC		Bioinstrumentation	2	1	1.5	4.5
UC		Design Thinking	1	1	-	2
MNC		Ability Enhancement/Co-curricular	0	-	-	0
MNC		Industrial Training/Survey/Project			4	Qualifying

SEMESTER VI

Cat	Course Code	Course Title	L	T	P	TC
PC		Pharmacotherapeutics	4	1	1	6
PC		Biopharmaceutics	4	1	1	6
PC		Data Management Technologies	4	1	1	6
UC		Start your Start Up (SFL)	1	1	-	2
MNC		Ability Enhancement/Co-curricular	0	-	-	0
MNC		Industrial Training/Survey/Project			4	Qualifying

SEMESTER VII

Cat	Course Code	Course Title	L	T	P	TC
PC		Health Economics and Outcome Research	4	1	-	5
PC		Emerging Technologies in Clinical Trials	3	1	1	5
PC		Research Methodology	3	1	1	5
PC		Good laboratory and Manufacturing Practices	3	1	1	5

SEMESTER VIII

Cat	Course Code	Course Title	L	T	P	TC
PRJ		**Industrial Training / Start-up** (For BSc Honours Students) **Research Project** (For BSc Honours Students with Research)	-	-	15	15
PE		Elective Course	3	2	-	5

*Q – Qualifying

8.0 List of Electives as per NEP Minor electives

8.1 ELECTIVES (SEMESTER II)

Cat	Course Code	Course Title	L	T	P	TC
		Biosafety Guidelines	2	1	1.5	4.5
		Community Health and Disease	2	1	1.5	4.5
		Fundamentals of Clinical Research	2	1	1.5	4.5

8.2 ELECTIVES (SEMESTER IV)

Cat	Course Code	Course Title	L	T	P	TC
		Clinical Pharmacokinetics	2	1	1.5	4.5
		Bioethics and Drug Safety	2	1	1.5	4.5
		Regulatory Aspects in Clinical Research	2	1	1.5	4.5

8.3 ELECTIVES (SEMESTER VIII)

Cat	Course Code	Course Title	L	T	P	TC
		Pharmacovigilance	3	2	0	5
		Ayush and Lifestyle	3	2	0	5
		Site Management Operations	3	2	0	5

8.0 List of Electives as per NEP

S.N.	Electives	Credits
1	Skill Enhancement/Vocational-I: **Living Conversations (SFL)**	2
2	Ability Enhancement/Co-curricular-I	Qualifying
3	Skill Enhancement/Vocational-II: **Critical Thinking and Writing**	2
4	Ability Enhancement/Co-curricular-II	Qualifying
5	Minor Elective (Exploratory Elective) either in Ist or IInd Semester	4.5
6	Skill Enhancement/Vocational-III: **Environmental Science**	4
7	Skill Enhancement/Vocational-IV: **Leadership and Teamwork**	2
8	Ability Enhancement/Co-curricular-III	Qualifying
9	Skill Enhancement/Vocational-V: **Working with Data**	2
10	Ability Enhancement/Co-curricular-IV	Qualifying
11	Skill Enhancement/Vocational-VI: **Design Thinking**	2
12	Industrial Training/Survey/Project	Qualifying
13	Ability Enhancement/Co-curricular-V	Qualifying
14	Skill Enhancement/Vocational-VII: **Start your Start Up (SFL)**	2
15	Ability Enhancement/Co-curricular-VI	Qualifying
16	Industrial Training/Survey/Project	Qualifying
17	Industrial Internship/Startup - BSc Honours students Research Project-BSc Honours with Research students	15
18	Minor elective	5

9.0 Course Syllabus/ Course Plans

SEMESTER I

Human Anatomy and Physiology L-T-P-C: 3-1-2-6

COURSE OBJECTIVES

This course's objective is to cover human anatomy and lay out the physiology of various systems including cardiovascular, respiratory, reproductive, skeletal, nervous systems, special senses, among others. It helps students to explore the amazing inner workings of the body, which is a complex collection of interacting systems that carry out the important functions that let you move, think, feel, and live.

COURSE OUTCOMES

On completion of this course, the students will be able to

CO1. Explain the gross morphology, structural organization, and body systems.

CO2. Discuss and correlate body systems with various homeostatic mechanisms and their imbalances.

CO3. Identify and distinguish various types of cells, tissues, and organs.

CO4. Perform various experiments related to various organ systems.

CO5. Analyze the coordinated working pattern of different organs of each system.

Co-Relationship Matrix

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Indicate the relationships by1- Slight (low) 2- Moderate (Medium) 3-Substantial (high)

Program Outcomes / Course Outcomes	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PSO1	PSO2	PSO3
CO 1	3	-	-	-	-	-	-	-	1	-	-	-
CO 2	3	-	-	-	-	-	-	-	1	-	-	-
CO 3	-	3	-	-	-	-	-	-	1	-	-	-

CO4	-	3	-	2	-	1	1	-	1	-	2	1
CO5	-	3	2	2	-	1	1	-	1	-	2	1
Average	3	3	2	2	-	1	1	-	1	-	2	1

Syllabus **60 Hours**

UNIT – I: Introduction to Human Anatomy and Physiology (12 Hours)

Introduction to anatomy and physiology, Level of Organization (atomic, molecular), Cellular Level of Organization, Tissue Level of Organization, Cell Structure and functions, cell-cell communication, intracellular cell signalling including Adenyl cyclase, ATP, AMP, GMP, Tyrosine Kinase, Phosphorylase, cell-cell signalling, cell division, homeostasis, negative and positive feedback.

Integumentary System: Anatomy and functions of skin

Skeletal System: Axial skeleton system, appendicular skeleton system, neuromuscular junction, joins, muscle contraction.

UNIT- II: Circulatory System and Special Senses (12 Hours)

- Body fluids and blood: Body fluids, composition, and functions of blood, hemopoiesis, formation of hemoglobin, anemia, mechanisms of coagulation, blood grouping, Rh factors, transfusion, its significance, and disorders of blood
- Lymphatic system: Lymphatic organs and tissues, lymphatic vessels, lymph circulation and functions of lymphatic system, Immune System, and its classification.
- Special Senses: Structure and functions of eye, ear, nose and tongue and their disorders.

UNIT III: Nervous and Cardiovascular System (12 Hours)

- Nervous system: Organization of nervous system, neuron, neuroglia, classification and properties of nerve fibre, electrophysiology, action potential, nerve impulse, receptors, synapse, neurotransmitters. Central nervous system: Meninges, ventricles of brain and cerebrospinal fluid. Structure and functions of brain, spinal cord.
- Peripheral Nervous System: Classification of peripheral nervous system: structure and functions of sympathetic and parasympathetic nervous system. Origin and functions of spinal and cranial nerves.
- Cardiovascular System Heart: Anatomy of heart, blood circulation, blood vessels, structure and functions of artery, vein and capillaries, elements of conduction system of heart and heartbeat, its regulation by autonomic nervous system, cardiac output, cardiac cycle. Regulation of blood pressure, pulse, electrocardiogram, and disorders of heart.

UNIT IV: Digestion, Respiration and Hormone Regulation (12 Hours)

- Digestive system: Anatomy of GI Tract with special reference to anatomy and functions of stomach, (Acid production in the stomach, regulation of acid production through parasympathetic nervous system, pepsin role in protein digestion) small intestine and large intestine, Energetics Formation and role of ATP, Creatinine Phosphate and BMR
- Respiratory system: Anatomy of respiratory system with special reference to anatomy of lungs, mechanism of respiration, regulation of respiration Lung Volumes and capacities transport of respiratory gases, artificial respiration, and resuscitation methods
- Endocrine system: Classification of hormones, mechanism of hormone action, structure and functions of pituitary gland, thyroid gland, parathyroid gland, adrenal gland, pancreas, pineal gland, thymus, and their disorders

UNIT V: Genitourinary System and Introduction to genetics (12 Hours)

- Urinary system: Anatomy of urinary tract with special reference to anatomy of kidney and nephrons, functions of kidney and urinary tract, physiology of urine formation, role of RAS in kidney and disorders of kidney.
- Reproductive system: Anatomy of male and female reproductive system, Functions of male and female reproductive system
- Introduction to genetics Chromosomes, genes and DNA, protein synthesis, genetic pattern of inheritance

Practical Course Content 60 Hours

Practical physiology is complimentary to the theoretical discussions in physiology. Practical allows the verification of physiological processes discussed in theory classes through experiments on living tissue, intact animals, or normal human beings. This is helpful for developing an insight on the subject.

1. Study of compound microscope.
2. Microscopic study of epithelial and connective tissue
3. Microscopic study of muscular and nervous tissue
4. Identification of axial bones
5. Identification of appendicular bones
6. Introduction to hemocytometry.
7. Enumeration of white blood cell (WBC)count
8. Enumeration of total red blood corpuscles (RBC)count

9. Determination of bleeding time, clotting time
10. Estimation of hemoglobin content
11. Determination of blood group and erythrocyte sedimentation rate (ESR).
12. Determination of heart rate and pulse rate.
13. Recording of blood pressure.
14. Study of various organ system with the help of models
15. Determination of respiratory volumes with the help of spirometer.

REFERENCE and Textbooks

- Principles of Anatomy and Physiology by Tortora Grabowski. Palmetto, GA, U.S.A. Wiley Publisher 16th edition, 2020.
- Ross and Wilson: Anatomy and physiology in Health and Illness, 11th Edition, Church Hill Livingstone, 2011.
- West, J.B.: Best and Taylor's Physiological Basis of Medical Practice, 11th Edition,2007
- Physiological basis of Medical Practice-Best and Tailor. Williams & Wilkins Co, Riverview, MI USA Wolters Kluwer India Pvt. Ltd.; Thirteenth edition (1 January 2011); Wolters Kluwer India Pvt. Ltd.
- Textbook of Medical Physiology- Arthur C, Guyton, and John. E. Hall. Miamisburg, OH, U.S.A. 11th Edition, Elsevier Saunders, 2006.
- Keel and Neil: Samson and Wright's Applied Physiology (12th edition), Oxford University Press. London.2004
- Essentials of Medical Physiology by K. Sembulingam and P. Sembulingam. Jaypee brothers' medical publishers, New Delhi.

Modes of Evaluation: Quiz/Assignment/Presentation/ Written Exam/ Examination
Scheme: Continuous Assessment- 50%, mid semester examination- 20% and End term examination- 30%

Theory Assessment:

	Continuous Assessment/Internal Assessment (50)			**Total**

Components	Surprise Test/Quiz	Assignments	Group Discussion /Presentations	Project Based Learning/ Tutorials based learning	**Mid Term Exam**	**End Term Exam**	
Weightage (%)	10	10	10	20	20	30	100

Laboratory Assessment:

	Continuous Assessment/Internal Assessment			**End Term Examination**		
Components	Experimental Performance	Viva voce	Lab record	Major Experiments (Practical)	Viva voce	Total
Weightage (%)	30	20	20	20	10	100

Fundamentals of Clinical Research L-T-P-C: 3-1-2-6

COURSE OBJECTIVES: This module covers the basics of clinical research, clinical trial definition, the drug development process and ethical regulations governing clinical research. Learners would also be exposed to scope of clinical research, career prospects, and overview of documentations.

COURSE OUTCOMES:

On completion of this course, the students will be able to

CO1. Explain the process of drug discovery and drug development and extrapolate data from animals to humans.

CO2. Define the terms in clinical trials and understand the phases of clinical trials, their importance in clinical research and trial related issues.

CO3. Describe the study design and methodologies in clinical trials, requirements, and regulations.

CO4. Understand the roles of regulatory agencies EMA, US FDA, industry sponsors, in clinical research.

CO5. Apply practical knowledge base for various approaches to clinical research.

Co-Relationship Matrix

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Indicate the relationships by1- Slight (low) 2- Moderate (Medium) 3-Substantial (high)

Program Outcomes / Course Outcomes	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PSO1	PSO2	PSO3
CO 1	3	-	-	-	-	-	-	-	1	3	-	2
CO 2	3	-	-	-	-	-	-	-	1	3	-	2
CO 3	3	3	-	-	1	-	1	-	1	3	-	2
CO4	3	3	2	2	1	1	1	-	1	3	2	2
CO5	3	3	2	2	1	1	1	-	1	3	2	2

Average	**3**	**3**	**2**	**2**	**1**	**1**	**1**	**-**	**1**	**3**	**2**	**2**

SYLLABUS **(60 HOURS)**

UNIT I: Introduction to Clinical Research **14 hours**

Glossary, Overview of clinical research and its importance

Historical perspectives and ethical considerations; Types of clinical research studies (observational, experimental, etc.)

Drug Discovery and Development Process: Drug discovery and target identification; Preclinical testing and animal models; Investigational new drug (IND) application process

UNIT II: Clinical Trial Fundamentals **10 hours**

Good Clinical Practices: Phases of clinical trials (Micro dosing, Phase I to Phase IV), Randomization and blinding, Outcome measures and endpoints, Tertiary endpoints.

UNIT III: Clinical Trials Designs **12 hours**

ICH-E6 Regulations, Clinical trial design (observational and interventional) protocol consent in clinical trials, placebo, bias, and methods to prevent bias, monitoring, problems, and solutions of controlled clinical trials.

UNIT IV: Research Design and Methodology **10 hours**

Study designs (observational, experimental, cross-sectional, cohort, case-control, etc.); Sampling techniques and sample size determination; Data collection methods (questionnaires, interviews, medical records, etc.)

UNIT V: Regulation in Clinical Research **14 hours**

Introduction of Clinical Trial Regulation; European Medicine Agency; Food and Drug Administration (US FDA); NDA and ANDA filing, Drug and cosmetic act; Schedule Y; ICMR Guidelines; Good Clinical Practice (GCP) guidelines; Protection of human subjects and privacy

Practical **60 Hours**

1. Introduction to Clinical Research: and Ethical considerations and regulations, Research Study Designs
2. Observational studies (cross-sectional, case-control, cohort) Developing a Research Question and Hypothesis
3. Experimental studies (randomized controlled trials), Prospective vs. retrospective studies, Developing a Research Question and Hypothesis
4. Formulating a research question, Developing testable hypotheses, Importance of feasibility and relevance

5. Study Protocol Development, Components of a study protocol, Informed consent process and documentation
6. Data collection methods and tools,
7. Basic statistical concepts: Commonly used statistical tests and software,
8. Ethical Considerations and Human Subjects Protection:

REFERENCE and Textbooks

1. Friedman, L.M., Furberg, C.D., DeMets, D.L., Reboussin, D.M. and Granger, C.B., 2015. Fundamentals of clinical trials. springer.
2. Bacchieri, A. and Della Cioppa, G., 2007. Fundamentals of clinical research: bridging medicine, statistics, and operations. Milan: Springer.
3. Rees, J., 2004. The fundamentals of clinical discovery. Perspectives in Biology and Medicine, 47(4), pp.597-607.
4. Spriet, A., Dupin-Spriet, T. and Simon, P., 1994. Methodology of clinical drug trials. Karger Publishers.
5. Chow, S.C. and Liu, J.P., 2008. Design and analysis of clinical trials: concepts and methodologies (Vol. 507). John Wiley & Sons.
6. EDITION, T., 1988. Principles and Practice of Pharmaceutical Medicine.
7. Karlberg, J.P.E. and Speers, M.A., 2010. Reviewing clinical trials: a guide for the ethics committee. Hong Kong.
8. Kayser, O. and Warzecha, H. eds., 2012. Pharmaceutical biotechnology: drug discovery and clinical applications. John Wiley & Sons.

Modes of Evaluation: Quiz/Assignment/Presentation/ Written Exam/ Examination Scheme: Continuous Assessment- 50%, mid semester examination- 20% and End term examination- 30%

Theory Assessment:

	Continuous Assessment/Internal Assessment (50)				**Mid Term Exam**	**End Term Exam**	**Total**
Components	Surprise Test/Quiz	Assignments	Group Discussion /Presentations	Project Based Learning/ Tutorials based learning			

Weightage (%)	10	10	10	20	20	30	100

Laboratory Assessment:

	Continuous Assessment/Internal Assessment			**End Term Examination**		
Components	Experimental Performance	Viva voce	Lab record	Major Experiments (Practical)	Viva voce	Total
Weightage (%)	30	20	20	20	10	100

Community Health and Disease	L-T-P-C: 3-1-2-6

COURSE OBJECTIVES: This course focuses on the principles and practices of community health and disease prevention. It examines the social, environmental, and behavioral factors that influence health at the community level.

COURSE OUTCOMES: On completion of this course, the students will be able to

CO1: Explain and understand the concept of community health, its significance, and epidemiological studies.

CO2: Identify and distinguish the social, environmental, and behavioral determinants of health in community.

CO3: Describe the principles and strategies for preventing diseases at community level.

CO4: Describe the ethical considerations in community health and disease prevention.

CO5: Analyze and evaluate the public health intervention programs like health promotion campaigns and disease surveillance in community health and disease prevention.

Co-Relationship Matrix

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Indicate the relationships by1- Slight (low) 2- Moderate (Medium) 3-Substantial (high)

Program Outcomes / Course Outcomes	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PSO1	PSO2	PSO3
CO 1	3	-	-	-	-	-	-	-	1	-	-	-
CO 2	3	-	-	-	-	-	-	-	1	-	-	-
CO 3	-	-	-	-	3	-	-	-	1	-	-	-
CO4	-	3	-	2	-	1	1	-	1	-	-	-
CO5	-	3	2	2	3	1	1	3	1	-	2	-

Average	**3**	**3**	**2**	**2**	**1**	**1**	**1**	**3**	**1**	**-**	**2**	**-**

Syllabus **60 Hours**

UNIT I Introduction to Community Health **12 Hours**

Definition and scope of community health, social determinants of health, Health disparities in communities, Epidemiology of Common Diseases, Measures of disease frequency and association

UNIT II Community Health Assessment and Study designs **12 Hours**

Community Health Assessment, Methods of assessing community health needs, Collection, and analysis of health data, Study designs in epidemiology risk factors and causation of diseases, Disease surveillance and outbreak investigation.

UNIT III Health Centres and Disease Prevention **12 Hours**

Identifying health priorities in communities, Health Promotion and Disease Prevention, Health Promotion and Disease Prevention, Health behavior theories and models

Health Centres: Community Health Centres, Primary Health Centres, Hospitals, and their organization. Role of Health Centres in Disease Surveillance and Disease Prevention

UNIT IV Disease Surveillance Programs **14 Hours**

Role of Health Centres in Disease Surveillance and Disease Prevention.

Strategies for health promotion and behavior change, Primary, secondary, and tertiary prevention approaches, Community-Based Interventions, Community organizing and mobilization, Designing and implementing community health programs, Evaluation of community interventions.

UNIT V Environment Health Safety **10 Hours**

Introduction to Environmental Health and Safety, Environmental risk factors and health effects, Water and air quality management, Occupational health, and safety

References

1. Harkness, G.A. and DeMarco, R.F., 2016. Community and public health nursing: Evidence for practice. Wolters Kluwer.
2. Dicker, R.C., Coronado, F., Koo, D. and Parrish, R.G., 2006. Principles of epidemiology in public health practice; an introduction to applied epidemiology and biostatistics. Third edition

3. Hunt, R., 2009. Introduction to community-based nursing. Lippincott Williams & Wilkins.
4. Grim, M.L. and Fertman, C.I. eds., 2010. Health promotion programs: from theory to practice. John Wiley & Sons.
5. Brown, A.E.C., Hobart, T.R. and Morrow, C.B. eds., 2019. Bioethics, Public Health, and the Social Sciences for the Medical Professions: An Integrated, Case-Based Approach. Springer.
6. Szklo, M. and Nieto, F.J., 2014. Epidemiology: beyond the basics. Jones & Bartlett Publishers.
7. Schneider, M.J., 2020. Introduction to public health. Jones & Bartlett Learning.

Practical Course Content **60 Hours**

Practical activities and experiences enhance student's understanding of community health and disease:

1. Field Visits: Visit local community health centers, public health departments, or non-governmental organizations (NGOs)
2. Community Health Assessments, identify health needs, collect, and analyze data, and develop recommendations for improving community health.
3. Health Promotion Campaigns: Plan and implement a health promotion campaign targeting a specific health issue in the community.
4. Participatory Research: Engage in participatory research projects that involve community members as active partners in the research process.
5. Volunteer Work: Volunteer with community organizations or public health agencies that focus on community health.
6. Reflection and Discussion: Reflect and describe various challenges, successes, and ethical considerations encountered during practical activities related to community health.

Modes of Evaluation: Quiz/Assignment/Presentation/ Written Exam/ Examination
Scheme: Continuous Assessment- 50%, mid semester examination- 20% and End term examination- 30%

Theory Assessment:

	Continuous Assessment/Internal Assessment (50)				**Mid Term Exam**	**End Term Exam**	**Total**
Components	Surprise Test/Quiz	Assignments	Group Discussion /Presentations	Project Based Learning/ Tutorials based learning			
Weightage (%)	10	10	10	20	20	30	100

Laboratory Assessment:

	Continuous Assessment/Internal Assessment			**End Term Examination**		
Components	Experimental Performance	Viva voce	Lab record	Major Experiments (Practical)	Viva voce	Total
Weightage (%)	30	20	20	20	10	100

Living Conversations (SFL)Credits 2

Ability Enhancement/Co-curricular

SEMESTER II

Principles of Biochemistry	L-T-P-C:2-1-1.5-4.5

Course Objectives

The main objective of the course will be to expose students to thermodynamics basis, bioenergetics of reaction, the basic role of biomolecules and their chemical interactions inside the cell. It provides deeper insight into structures, properties and functions of major biomolecules and metabolic pathways in the living systems.

Course Outcomes

Course outcomes: After the completion of course, the students will be able to:

CO1: Understand thermodynamics basis of life, bioenergetics of a reaction and pathway and different intermolecular interactions in structural organization of proteins.

CO2: Describe the structure and functions of different chemical building blocks (carbohydrates, proteins, and lipids) of life.

CO3: Identify and draw structures of various types of biomolecules (carbohydrate, lipids, and proteins).

CO4: Classify enzymes in different categories and explain what enzyme does, how enzyme works and primary biochemical pathways leading to synthesis and catabolism of major biomolecules.

CO5: Demonstrate skills to prepare the solutions, buffers and identify and analyze any biological molecules in the given sample.

Co-Relationship Matrix

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Indicate the relationships by1- Slight (low) 2- Moderate (Medium) 3-Substantial (high)

Program Outcomes / Course Outcomes	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PSO1	PSO2	PSO3
CO 1	2	-	-	-	-	-	-	-	1	-	-	-
CO 2	2	-	-	-	-	-	-	-	1	-	-	-
CO 3	2	2	-	-	-	-	-	-	1	-	-	-
CO4	2	2	2	2	1	-	1	-	1	-	2	-
CO5	2	2	2	2	1	-	1	-	1	-	2	-
Average	**2**	**2**	**2**	**2**	**1**	**-**	**1**	**-**	**1**	**-**	**2**	**-**

Syllabus **(45 Hours)**

Unit-I Introduction to biophysics (**12 Hours)**

Introduction and history of biophysics, main features of quantum theory, elementary particles, and their interactions. Bioenergetics, endergonic and exergonic reactions, Laws of thermodynamics, entropy, enthalpy, Gibb's free energy, standard Gibb's free energy, ATP, and different high energy compounds. Properties and role of water. Buffers - action, capacity, relationship between pH & pKa (Henderson -Hasselbalch equation) and its importance.

Unit-II Proteins & Enzymes (**11 Hours)**

Amino acids and peptides- classification, chemical and physical properties, Introduction to protein structure and function, secondary, tertiary, and quaternary structure of proteins, fibrous and globular proteins, protein folding and Anfinsen's experiment. Amino acid metabolism-Amino acid deamination and transamination, urea cycle. Introduction to enzymes, classification of enzymes, mechanism of action, Michaelis-Menten equation and significance of Km, Vmax and Kcat.

Unit-III Carbohydrates **(12 Hours)**

Monosaccharides-structure of aldoses and ketoses, open and ring structure of sugars, conformations of sugars, mutarotation, anomers, epimers and enantiomers. Disaccharides-

maltose, lactose, and sucrose. Polysaccharides-homo and heteropolysaccharides, structural and storage polysaccharides. Anabolism and catabolism, glycolysis citric acid cycle and gluconeogenesis.

Unit-IV Lipids **(10 Hours)**

Definition, biological functions, general formulae, nomenclature and properties of fatty acids, essential and non-essential fatty acids, classification of lipids, building blocks of lipids - fatty acids, glycerol, ceramide, saponification number and iodine number, suitability of triglycerides as storage lipids, saponification number and iodine number. Introduction to lipid micelles, monolayer and bilayer, transport of fatty acids.

Practical **(45 Hours)**

[1]. To prepare different solutions-based molarity, normality, and percentage.
[2]. To prepare buffer solution and pH measurement
[3]. Qualitative test for carbohydrates
[4]. Qualitative test for amino acids.
[5]. Titration of Amino acid (Neutral) with a strong base and acid.
[6]. Quantitative estimation of protein by Bradford/Bicinchoninic acid method
[7]. Assay of salivary amylase.
[8]. Qualitative test for lipids.
[9]. Quantitative test for lipids- Salkowski/Lieberman-Burchard test.
[10]. Colorimetric estimation of urea/blood urea nitrogen (BUN).

Reference Books

1. Lehninger: Principles of Biochemistry (2017) 7th ed., Nelson, D.L. and Cox, M.M., W.H. Freeman, and Company (New York), ISBN 13: 978-1464126116.
2. Textbook of Biochemistry with Clinical Correlations an Indian Adaptation (2022) 7th ed., Devlin, T.M., John Wiley & Sons, Inc., ISBN: 978-9354641558.
3. Biochemistry (2019) 9th ed., Berg, J.M., Tymoczko, J.L. and Stryer, L., W.H Freeman and Company (New York), ISBN 13:978-1319114671.
4. Principles and Techniques of Biochemistry and Molecular Biology (2018) 8th ed., Wilson, K. and Walker, J. Cambridge University Press, ISBN 13: 978-1316614761.
5. Introduction to Practical Biochemistry, Sawhney, S.K. and Singh R. so Narosa Publishing House (New Delhi), ISBN-13: 978-8173193026.

Modes of Evaluation: Quiz/Assignment/Presentation/ Written Exam/ Examination
Scheme: Continuous Assessment- 50%, mid semester examination- 20% and End term examination- 30%

Theory Assessment:

	Continuous Assessment/Internal Assessment (50)				**Mid Term Exam**	**End Term Exam**	**Total**
Components	Surprise Test/Quiz	Assignments	Group Discussion /Presentations	Project Based Learning/ Tutorials based learning			
Weightage (%)	10	10	10	20	20	30	100

Laboratory Assessment:

	Continuous Assessment/Internal Assessment			**End Term Examination**		
Components	Experimental Performance	Viva voce	Lab record	Major Experiments (Practical)	Viva voce	Total
Weightage (%)	30	20	20	20	10	100

Computer Applications and Bioinformatics	L-T-P-C:2-1-1.5-4.5

Course Objectives

Theory:

- The basic objective is to give students an introduction to the basic practical techniques of Computer Application and Bioinformatics.
- Emphasis will be given to the application of Computer Application and Bioinformatics and biological databases to problem solving in real research problems.
- The students will become familiar with the use of a wide variety of internet applications, computer application, biological database, sequence alignment, biological database management, molecular docking and drug designing and will be able to apply these methods to research problems.

Practical:

- The aim is to provide practical training in bioinformatics methods including accessing the major public sequence databases, structure database, drug database.
- Use of the different computational tools to find sequences, protein structure and drug molecules.
- Analysis of protein and nucleic acid sequences by various software packages.
- It also provides a step by step, theoretical and practical introduction to the development of useful tools for automation of complex computer jobs and making these tools accessible on the network from a web browser.

Course Outcomes

After completion of the course, students will be able to

CO1: Understand the basics of computer application and bioinformatics.

CO2: Identify and define the basic concepts of bioinformatics and its significance in biological data analysis.

CO3: Demonstrate the ability to choose the methods to symbolize and manage the different types of biological database, sequence alignment and phylogenetic tree analysis.

CO4: Overview about biological macromolecular structures and structure prediction methods, molecular docking, and drug designing.

CO5: Develop competency in bioinformatics for solving different biological problems, data handling process and data retrieval process from different, biological databases, usage

of different software for analyzing biological data, sequence alignment, molecular docking, and drug designing.

Co-Relationship Matrix

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Indicate the relationships by1- Slight (low) 2- Moderate (Medium) 3-Substantial (high)

Program Outcomes / Course Outcomes	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PSO1	PSO2	PSO3
CO 1	2	-	-	-	-	-	-	-	1	-	-	-
CO 2	2	2	-	-	-	-	1	-	1	-	2	-
CO 3	2	2	-	-	-	-	1	-	1	-	2	-
CO4	2	2	2	2	1	-	1	-	1	-	2	-
CO5	2	2	2	2	1	-	1	-	1	-	2	-
Average	**2**	**2**	**2**	**2**	**1**	**-**	**1**	**-**	**1**	**-**	**2**	**-**

Syllabus **45 Hours**

Unit I: Introduction to Computer Application **05 hrs**

Basics of computer hardware, software, and networking. Operating Systems software and Application Systems software. Windows features, Microsoft office, data format for biological samples.

Unit II: Biological Databases **10 hrs**

Definition and History and Applications of Computational Biology and Bioinformatics, Internet resources, various databases and bioinformatics tools, organization of databases. Sequencing database, 3D Structure Database, Chemical Structure database, Gene Expression database,

Derived Databases, Structure classification database, Protein-Protein interaction database and Pathway database.

Unit III: Sequence Alignment and Phylogenetic Tree 10 hrs

File formats, Basic concepts of sequence analysis, Scoring matrices, Pair wise sequence alignments, Multiple sequence alignment, Database Searches: Keyword-based searches and Sequence-based searches. Phylogenetic Trees: phylogenetic tree representation, building phylogenetic trees,

Unit IV: Structure Prediction 10 hours

Overview and Introduction to Protein Structure, Sequence-Sequence Alignment Methods, Sequence Based Secondary Structure Prediction. Visualization of structures using Rasmol or ADT. Fundamentals of the methods for 3D structure prediction, Homology/comparative Modeling. AI based protein structure prediction.

Unit V: Molecular Docking and Drug Designing 10 hours

General approach to discovery of new drugs, lead discovery, lead modification physiochemical, principles of drug action, 3D database search, computer aided drug design, AI based drug screening, docking, molecular modelling in drug design, structure-based drug design.

Recommended Books/ Resources:

- Bioinformatics and Computational Biology-A Primer for Biologists by Basant K. Tiwary. 2022, ISBN: 978-981-16-4240-1
- Lopes H, editor. Computational Biology and Applied Bioinformatics. InTech; 2011. Available from: http://dx.doi.org/10.5772/772
- Encyclopedia of Bioinformatics and Computational Biology-ABC of Bioinformatics. Shoba Ranganathan, Kenta Nakai, Christian Schonbach. August 21, 2018, ISBN: 9780128114148
- Introduction to Bioinformatics, Teresa Attwood, David Parry-Smith, Pearson Education. ISBN: 978-8178085074
- Bioinformatics: A Practical Guide to the Analysis of Genes and Proteins, Second Edition, Andreas D. Baxevanis, B. F. Francis Ouellette. A John Wiley & Sons, Inc., Publication. ISBN: 978-0471478782

- Jianyuan Deng and others, Artificial intelligence in drug discovery: applications and techniques, Briefings in Bioinformatics, Volume 23, Issue 1, January 2022, bbab430, https://doi.org/10.1093/bib/bbab430

Practicals **45 hrs**

List of Experiments:

1. Referencing in Scientific literature and their practical usage, PubMed
2. Sequence retrieval
3. Biological Databases: Study of different biological databases (esp. the ones given below), Format.
4. Pair wise sequence alignment, Local and Global alignment – Algorithms
5. DOT matrix analysis
6. Databases search for homologous sequence using (BLAST) and (FASTA)
7. MSA: (Clustal W, Clustal X), Algorithms-MSA, Progressive alignment etc, Problems with MSA method, Statistics behind MSA
8. MUSCLE, T-COFFEE
9. Protein structure prediction tools (2D and 3D structure prediction)
10. Molecular Docking using Autodock
11. Drug Designing using Chemsketch
12. AI application in computational biology and bioinformatics

Modes of Evaluation: Quiz/Assignment/Presentation/ Written Exam/ Examination Scheme: Continuous Assessment- 50%, mid semester examination- 20% and End term examination- 30%

Theory Assessment:

	Continuous Assessment/Internal Assessment (50)				**Mid Term Exam**	**End Term Exam**	**Total**
Components	Surprise Test/Quiz	Assignments	Group Discussion /Presentations	Project Based Learning/ Tutorials based learning			

Weightage (%)	10	10	10	20	20	30	100

Laboratory Assessment:

	Continuous Assessment/Internal Assessment			**End Term Examination**		
Components	Experimental Performance	Viva voce	Lab record	Major Experiments (Practical)	Viva voce	Total
Weightage (%)	30	20	20	20	10	100

Fundamentals of Biostatistics	L-T-P-C:2-1-1.5-4.5

Course Objectives

This course introduces the fundamental principles and techniques of Biostatistics. It emphasizes the application of statistical methods in Health Sciences & Technology. Students will learn to analyze and interpret data, conduct hypothesis testing, and apply statistical techniques to make evidence-based decisions in various healthcare and research settings. The course also provides hands-on experience with statistical software and practical exercises to reinforce the concepts learned.

Course Outcomes

Upon completion of the course, students will be able to

CO1. Understand the basic concepts and principles of biostatistics and its relevance to healthcare and clinical research.

CO2. Apply appropriate statistical techniques to analyze and investigate scientific questions in healthcare and research settings.

CO3. Design and conduct basic experiments or studies to investigate scientific questions in the relevant disciplines.

CO4. Apply statistical software tools to perform data analysis, interpret the output, and effectively communicate the findings of statistical analyses in healthcare and clinical research.

Co-Relationship Matrix

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Indicate the relationships by1- Slight (low) 2- Moderate (Medium) 3-Substantial (high)

Program Outcomes / Course Outcomes	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PSO1	PSO2	PSO3
CO 1	2	-	-	-	-	-	-	-	1	-	-	-
CO 2	2	2	-	-	-	-	1	-	1	-	2	-

CO 3	2	2	-	-	-	-	1	-	1	-	2	-
CO4	2	2	2	2	1	-	1	-	1	-	2	-
Average	**2**	**2**	**2**	**2**	**1**	**-**	**1**	**-**	**1**	**-**	**2**	**-**

Syllabus **45 Hours**

Unit I: Introduction to Biostatistics and Data Types **5 Hours**

Understand the importance of biostatistics in healthcare and clinical research. Define different types of data. Variables: continuous, nominal, ordinal. Scales of measurement.

Unit II: Descriptive Statistics and Probability Distributions **15 Hours**

Measures of central tendency: mean, median and mode. Measures of variability: range, variance, and standard deviation. Frequency distributions and graphical representations of data: histograms, box plots, and scatter plots. Basic principles of Probability. Discuss probability distributions: discrete and continuous, normal distribution.

Unit III: Sampling Techniques and Sampling Distributions **5 Hours**

Understand different sampling techniques and their applications. Discuss sampling distributions and the Central Limit Theorem. Calculate confidence intervals and understand their interpretation.

Unit IV: Hypothesis Testing – Parametric and Non-parametric methods **10 Hours**

One-Sample Tests: formulate null and alternative hypotheses, conduct hypothesis tests for one-sample mean and proportion, Interpret test results and inferencing. Two-Sample Tests: hypothesis testing for two independent samples, Compare means and proportions between groups. Paired T-tests. Analysis of Variance (ANOVA), Understand the principles of analysis of variance, one-way ANOVA, and result interpretation. Apply post hoc tests for multiple comparisons.

Nonparametric tests for situations with violated assumptions and their interpretations: Chi square tests, Wilcoxon-Signed rank test, Kruskal-Wallis, Fischer's Exact Test. Compare parametric and nonparametric tests.

Unit V: Correlation and Regression Analysis **5 Hours**

Understand the concepts of correlation and regression. Correlation coefficients. Perform simple linear regression and assess the model's goodness of fit. Multiple regression for multiple variables.

Unit VI: Survival Analysis **5 Hours**

Understand the principles and applications of survival analysis. Estimate survival probabilities using Kaplan-Meier curves. Apply Cox proportional hazards regression.

Practical **45 Hours**

1. Perform basic data manipulation tasks such as importing, exporting, and cleaning data using suitable statistical software (e.g., R, SPSS, or SAS).
2. Calculate measures of central tendency (mean, median, mode) and variability (range, variance, standard deviation), construct frequency distributions and generate box plots, scatter plots, histograms using the given data.
3. Formulate null and alternative hypotheses. Perform one-sample and two-sample hypothesis tests. Interpret and communicate results using appropriate statistical language.
4. Conduct one-way ANOVA to compare means across multiple groups and perform post hoc tests for multiple comparisons and interpret the results.
5. Apply nonparametric tests and compare the results with their parametric counterparts.
6. Perform chi-square tests to analyze categorical data. Test for independence and homogeneity in contingency tables and interpret results to assess associations between variables.
7. Calculate correlation coefficients between variables, interpret and evaluate the strength of the relationship.
8. Perform simple linear regression analysis. Make predictions using regression models.
9. Design a basic study and analyze the experimental data using appropriate statistical tests and draw conclusions.

Reference Books

1. Dawson, B. and Trapp, R.G. 2019. Basic and Clinical Biostatistics. 5th ed. Lange medical books/McGraw-Hill Inc.
2. Zar, Jerrold H. 2014. Biostatistical Analysis. 5th ed. Pearson Education.
3. Selvin, S. 2011. Biostatistics: Statistical Tools for Epidemiological Research. Oxford University Press.

4. Lepš, J. and Šmilauer, P. 2020. Biostatistics with R: An introductory guide for Field Biologists. 1st ed. Cambridge University Press.

Modes of Evaluation: Quiz/Assignment/Presentation/ Written Exam/ Examination
Scheme: Continuous Assessment- 50%, mid semester examination- 20% and End term examination- 30%

Theory Assessment:

	Continuous Assessment/Internal Assessment (50)				**Mid Term Exam**	**End Term Exam**	**Total**
Components	Surprise Test/Quiz	Assignments	Group Discussion /Presentations	Project Based Learning/ Tutorials based learning			
Weightage (%)	10	10	10	20	20	30	100

Laboratory Assessment:

	Continuous Assessment/Internal Assessment			**End Term Examination**		
Components	Experimental Performance	Viva voce	Lab record	Major Experiments (Practical)	Viva voce	Total
Weightage (%)	30	20	20	20	10	100

Critical Thinking and Writing	Credits 2

Ability Enhancement/Co-curricular-I	Qualifying

Elective Course	L-T-P-C:2-1-1.5-4.5

Biosafety Guidelines	L-T-P-C: 2-1-1.5-4.5

Course Objective: This course provides details of biosafety principles and guidelines for working with biological agents in laboratory and healthcare settings. This course will cover the important concepts of containment measures, risk assessment, personal protective equipment (PPE), regulatory frameworks and waste management. Students will gain a comprehensive understanding of biosafety practices ensuring safe storage, handling, and disposal of biological materials.

Course Outcomes: Upon completion of this course, the student will be able to

CO1: Explain the importance of biosafety and its role in preventing occupational hazards and the spread of infectious diseases.

CO2: Familiarize students with national and international biosafety guidelines, regulations, and standards.

CO3: Develop knowledge and skills to assess risks associated with biological agents and implement appropriate containment measures.

CO4: Identify different types of personal protective equipment (PPE) and their proper use in biosafety practices.

CO5: Explain the techniques for safe handling, storage, and transport of biological materials.

Co-Relationship Matrix

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Indicate the relationships by1- Slight (low) 2- Moderate (Medium) 3-Substantial (high)

Program Outcomes / Course Outcomes	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PSO1	PSO2	PSO3
CO 1	2	-	-	-	-	-	-	-	1	-	-	-
CO 2	2	-	-	-	-	-	-	-	1	-	-	-
CO 3	2	2	2	-	1	-	1	-	1	-	2	-

CO4	2	2	2	1	1	-	1	1	1	1	2	1
CO5	2	2	2	1	1	-	1	1	1	1	2	1
Average	**2**	**2**	**2**	**1**	**1**	**-**	**1**	**1**	**1**	**1**	**2**	**1**

Syllabus **45 Hours**

UNIT 1. **Introduction to Biosafety** **13 Hours**

Definition and importance of biosafety, Historical overview and major biosafety incidents, Regulatory frameworks and guidelines (e.g., WHO, CDC, OSHA) Risk Assessment and Management, Principles of risk assessment Identification and characterization of biological hazards, Biosafety levels and facility design considerations, Containment and Engineering Controls, Primary, secondary, and tertiary containment measures, Laboratory design and engineering controls, biological safety cabinets and other containment equipment, Digital monitoring systems and smart technologies for real-time biosafety monitoring

UNIT 2 Personal Protective Equipment (PPE) and Transport of Biological Materials

12 Hours

Personal Protective Equipment (PPE), Selection and use of PPE based on risk assessment

Proper donning and doffing of PPE, Maintenance and disposal of PPE, Innovative PPE technologies (e.g., smart textiles, antimicrobial coatings) and their application in biosafety.

Safe Handling and Transport of Biological Materials, Packaging, labeling, and documentation requirements, Shipping regulations and transport considerations, Security measures for handling select agents and toxins, Implementation of blockchain and traceability systems for secure tracking and monitoring of biological materials.

UNIT 3. **Waste Management and Decontamination** **10 Hours**

Introduction to waste management and decontamination, proper disposal of biohazardous waste, Decontamination techniques and disinfectants, Spill response and emergency procedures, Biosafety in Specific Settings, Healthcare-associated infections (HAIs), Biosafety in clinical laboratories and diagnostic facilities, Biosafety in animal research facilities, Novel decontamination methods (e.g., advanced oxidation processes, plasma sterilization).

UNIT 54 **Emerging Trends and Technologies in Biosafety** **10 Hours**

Advanced containment systems and technologies, Genome editing and biosafety implications, Biosafety challenges in the era of globalization and bioterrorism threats, Biosafety in Specific Settings, including the application of automation, robotics, and artificial intelligence in biosafety practices, Gene drive technology, viral vectors, and their biosafety considerations.

Practical **45 hours**

1. Perform a comprehensive risk assessment to identify potential hazards and implement appropriate safety measures.
2. To study Containment Levels: Laboratories are classified into different containment levels (e.g., BSL-1, BSL-2, BSL-3, BSL-4) based on the level of risk associated with the biological agents being handled.
3. To study Personal Protective Equipment (PPE): includes gloves, lab coats, safety glasses or goggles, and sometimes respirators or face shields.
4. To study Engineering Controls.
5. To study and write Standard Operating Procedures (SOPs)
6. To study about Decontamination methods
7. To study proper handling and disposal of biological agents
8. To understand the role of biosafety committees or offices responsible for overseeing compliance with biosafety guidelines

Textbooks and References

1. Chosewood, L.C., and Wilson, D.E., 2009. Biosafety in microbiological and biomedical laboratories. US Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institutes of Health.
2. Richmond, J.Y. and McKinney, R.W., 2009. Biosafety in microbiological and biomedical laboratories. US Government Printing Office.
3. National Academies of Sciences, Engineering, and Medicine, 2016. Soliciting Stakeholder Input for a Revision of Biosafety in Microbiological and Biomedical Laboratories (BMBL): Proceedings of a Workshop. National Academies Press.
4. Fleming, D.O. and Hunt, D.L., 2006. Biological safety: principles and practices (No. Ed. 4). ASM Press.
5. Burnett, L.C., Lunn, G. and Coico, R., 2009. Biosafety: guidelines for working with pathogenic and infectious microorganisms. Current protocols in microbiology, 13(1), pp.1A-1.

Modes of Evaluation: Quiz/Assignment/Presentation/ Written Exam/ Examination Scheme: Continuous Assessment- 50%, mid semester examination- 20% and End term examination- 30%

Theory Assessment:

	Continuous Assessment/Internal Assessment (50)			**Total**

					Mid Term Exam	End Term Exam	
Components	Surprise Test/Quiz	Assignments	Group Discussion /Presentations	Project Based Learning/ Tutorials based learning			
Weightage (%)	10	10	10	20	20	30	100

Laboratory Assessment:

	Continuous Assessment/Internal Assessment			**End Term Examination**		
Components	Experimental Performance	Viva voce	Lab record	Major Experiments (Practical)	Viva voce	Total
Weightage (%)	30	20	20	20	10	100

Fundamentals of Clinical Research L-T-P-C: 2-1-1.5-4.5

COURSE OBJECTIVES: This module covers the basics of clinical research, clinical trial definition, the drug development process and ethical regulations governing clinical research. Learners would also be exposed to scope of clinical research, career prospects, and overview of documentations.

COURSE OUTCOMES

On completion of this course, the students will be able to

CO1. Explain the process of drug discovery and drug development and extrapolate data from animals to humans.

CO2. Define the terms in clinical trials and understand the phases of clinical trials, their importance in clinical research and trial related issues.

CO3. Describe the study design and methodologies in clinical trials, requirements, and regulations.

CO4. Understand the roles of regulatory agencies EMA, US FDA, industry sponsors, in clinical research.

Co-Relationship Matrix

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Indicate the relationships by1- Slight (low) 2- Moderate (Medium) 3-Substantial (high)

Program Outcomes / Course Outcomes	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PSO1	PSO2	PSO3
CO 1	3	-	-	-	-	-	-	-	1	3	-	2
CO 2	3	-	-	-	-	-	-	-	1	3	-	2
CO 3	3	3	-	-	1	-	1	-	1	3	-	2
CO4	3	3	2	2	1	1	1	-	1	3	2	2

Average	**3**	**3**	**2**	**2**	**1**	**1**	**1**	**-**	**1**	**3**	**2**	**2**

SYLLABUS **45 HOURS**

UNIT I: Introduction to Clinical Research **10 hours**

Glossary, Overview of clinical research and its importance

Historical perspectives and ethical considerations; Types of clinical research studies (observational, experimental, etc.)

Drug Discovery and Development Process

UNIT II: Clinical Trial Fundamentals **5 hours**

Good Clinical Practices: Phases of clinical trials (Micro dosing, Phase I to Phase IV), Randomization and blinding.

UNIT III: Clinical Trials Designs **10 hours**

ICH-E6 Regulations, Clinical trial design (observational and interventional) protocol consent in clinical trials, placebo, bias, and methods to prevent bias, monitoring, problems, and solutions of controlled clinical trials.

UNIT IV: Research Design and Methodology **10 hours**

Study designs (observational, experimental, cross-sectional, cohort, case-control, etc.); Sampling techniques and sample size determination; Data collection methods (questionnaires, interviews, medical records, etc.)

UNIT V: Regulation in Clinical Research **10 hours**

Introduction of Clinical Trial Regulation; European Medicine Agency; Food and Drug Administration (US FDA); NDA and ANDA filing, Drug and cosmetic act; Schedule Y; ICMR Guidelines; Protection of human subjects and privacy

Practical **45 hours**

1. Introduction to Clinical Research: and Ethical considerations and regulations, Research Study Designs
2. Observational studies (cross-sectional, case-control, cohort) Developing a Research Question and Hypothesis
3. Experimental studies (randomized controlled trials),
4. Prospective vs. retrospective studies,
5. Developing a Research Question and Hypothesis
6. Formulating a research question,
7. Developing testable hypotheses, Importance of feasibility and relevance
8. Study Protocol Development, Components of a study protocol, Informed consent process and documentation

REFERENCE and Textbooks

9. Friedman, L.M., Furberg, C.D., DeMets, D.L., Reboussin, D.M. and Granger, C.B., 2015. Fundamentals of clinical trials. springer.
10. Bacchieri, A. and Della Cioppa, G., 2007. Fundamentals of clinical research: bridging medicine, statistics, and operations. Milan: Springer.
11. Rees, J., 2004. The fundamentals of clinical discovery. Perspectives in Biology and Medicine, 47(4), pp.597-607.
12. Spriet, A., Dupin-Spriet, T. and Simon, P., 1994. Methodology of clinical drug trials. Karger Publishers.
13. Chow, S.C. and Liu, J.P., 2008. Design and analysis of clinical trials: concepts and methodologies (Vol. 507). John Wiley & Sons.
14. EDITION, T., 1988. Principles and Practice of Pharmaceutical Medicine.
15. Karlberg, J.P.E. and Speers, M.A., 2010. Reviewing clinical trials: a guide for the ethics committee. Hong Kong.
16. Kayser, O. and Warzecha, H. eds., 2012. Pharmaceutical biotechnology: drug discovery and clinical applications. John Wiley & Sons.

Modes of Evaluation: Quiz/Assignment/Presentation/ Written Exam/ Examination Scheme: Continuous Assessment- 50%, mid semester examination- 20% and End term examination- 30%

Theory Assessment:

	Continuous Assessment/Internal Assessment (50)				**Mid Term Exam**	**End Term Exam**	**Total**
Components	Surprise Test/Quiz	Assignments	Group Discussion/Presentations	Project Based Learning/ Tutorials based learning			
Weightage (%)	10	10	10	20	20	30	100

Laboratory Assessment:

	Continuous Assessment/Internal Assessment			**End Term Examination**		
Components	Experimental Performance	Viva voce	Lab record	Major Experiments (Practical)	Viva voce	Total
Weightage (%)	30	20	20	20	10	100

Community Health and Disease	L-T-P-C: 2-1-1.5-4.5

COURSE OBJECTIVES: This course focuses on the principles and practices of community health and disease prevention. It examines the social, environmental, and behavioral factors that influence health at the community level.

COURSE OUTCOMES: On completion of this course, the students will be able to

CO1: Explain and understand the concept of community health, its significance, and epidemiological studies.

CO2: Identify and distinguish the social, environmental, and behavioral determinants of health in community.

CO3: Describe the principles and strategies for preventing diseases at community level.

CO4: Describe the ethical considerations in community health and disease prevention.

Co-Relationship Matrix

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Indicate the relationships by1- Slight (low) 2- Moderate (Medium) 3-Substantial (high)

Program Outcomes / Course Outcomes	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PSO1	PSO2	PSO3
CO 1	3	-	-	-	-	-	-	-	1	-	-	-
CO 2	3	-	-	-	-	-	-	-	1	-	-	-
CO 3	-	-	-	-	3	-	-	-	1	-	-	-
CO4	-	3	-	2	-	1	1	-	1	-	-	-
Average	**3**	**3**	**2**	**2**	**3**	**1**	**1**	**3**	**1**	**-**	**2**	**2**

Syllabus **45 Hours**

UNIT I Introduction to Community Health **5 Hours**

Definition and scope of community health, social determinants of health, Health disparities in communities, Epidemiology of Common Diseases, Measures of disease frequency and association

UNIT II Community Health Assessment and Study designs **10 Hours**

Community Health Assessment, Methods of assessing community health needs, Collection, and analysis of health data, Study designs in epidemiology risk factors and causation of diseases, Disease surveillance and outbreak investigation.

UNIT III Health Centres and Disease Prevention **10 Hours**

Identifying health priorities in communities, Health Promotion and Disease Prevention, Health Promotion and Disease Prevention, Health behavior theories and models

Health Centres: Community Health Centres, Primary Health Centres, Hospitals, and their organization. Role of Health Centres in Disease Surveillance and Disease Prevention

UNIT IV Disease Surveillance Programs **10 Hours**

Role of Health Centres in Disease Surveillance and Disease Prevention.

Strategies for health promotion and behavior change, Primary, secondary, and tertiary prevention approaches, Community-Based Interventions, Community organizing and mobilization, Designing and implementing community health programs, Evaluation of community interventions.

UNIT V Environment Health Safety **10 Hours**

Introduction to Environmental Health and Safety, Environmental risk factors and health effects, Water and air quality management, Occupational health, and safety,

References

8. Harkness, G.A. and DeMarco, R.F., 2016. Community and public health nursing: Evidence for practice. Wolters Kluwer.
9. Dicker, R.C., Coronado, F., Koo, D. and Parrish, R.G., 2006. Principles of epidemiology in public health practice; an introduction to applied epidemiology and biostatistics. Third edition
10. Hunt, R., 2009. Introduction to community-based nursing. Lippincott Williams & Wilkins.
11. Grim, M.L. and Fertman, C.I. eds., 2010. Health promotion programs: from theory to practice. John Wiley & Sons.
12. Brown, A.E.C., Hobart, T.R. and Morrow, C.B. eds., 2019. Bioethics, Public Health, and the Social Sciences for the Medical Professions: An Integrated, Case-Based Approach. Springer

13. Szklo, M. and Nieto, F.J., 2014. Epidemiology: beyond the basics. Jones & Bartlett Publishers.
14. Schneider, M.J., 2020. Introduction to public health. Jones & Bartlett Learning.

Practical **45 Hours**

Practical activities and experiences enhance student's understanding of community health and disease:

1. Community Health Assessments, identify health needs, collect, and analyze data, and develop recommendations for improving community health.
2. Health Promotion Campaigns: Plan and implement a health promotion campaign targeting a specific health issue in the community.
3. Participatory Research: Engage in participatory research projects that involve community members as active partners in the research process.
4. Volunteer Work: Volunteer with community organizations or public health agencies that focus on community health.
5. Reflection and Discussion: Reflect and describe various challenges, successes, and ethical considerations encountered during practical activities related to community health.

Modes of Evaluation: Quiz/Assignment/Presentation/ Written Exam/ Examination Scheme: Continuous Assessment- 50%, mid semester examination- 20% and End term examination- 30%

Theory Assessment:

	Continuous Assessment/Internal Assessment (50)				**Mid Term Exam**	**End Term Exam**	**Total**
Components	Surprise Test/Quiz	Assignments	Group Discussion/Presentations	Project Based Learning/ Tutorials based learning			
Weightage (%)	10	10	10	20	20	30	100

Laboratory Assessment:

	Continuous Assessment/Internal Assessment			**End Term Examination**		
Components	Experimental Performance	Viva voce	Lab record	Major Experiments (Practical)	Viva voce	Total
Weightage (%)	30	20	20	20	10	100

SEMESTER III

Pharmacology and Toxicology	L-T-P-C:2-1-1.5-4.5

Course Objectives

The main purpose of the subject is to understand what drugs do to the living organisms and how their effects can be applied to therapeutics. The subject covers the information about the drugs like, mechanism of action, physiological and biochemical effects (pharmacodynamics) as well as absorption, distribution, metabolism, and excretion (pharmacokinetics) along with the adverse effects, clinical uses, interactions, doses, contraindications, and routes of administration of different classes of drugs.

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

CO1: Explain targets and pharmacology of underlying diseases.

CO2: Understand the pharmacological actions of different categories of drugs.

CO3. Apply the basic pharmacological knowledge in the prevention and treatment of various diseases.

CO4: Analyse the effect of drugs on animals by simulated experiments.

CO5: Report the clinical applications, adverse effects and toxicities of drugs used as medicines.

Co-Relationship Matrix

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Indicate the relationships by1- Slight (low) 2- Moderate (Medium) 3-Substantial (high)

Program Outcomes / Course Outcomes	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PSO1	PSO2	PSO3
CO 1	3	-	-	-	-	-	-	-	1	1	-	-
CO 2	3	-	2	-	-	-	-	-	1	1	-	1

CO 3	3	3	2	-	3	-	-	-	1	1	2	1
CO4	3	3	2	2	3	1	1	-	1	1	2	1
CO5	3	3	2	2	3	1	1	1	1	1	2	1
Average	**3**	**3**	**2**	**2**	**3**	**1**	**1**	**1**	**1**	**1**	**2**	**1**

Syllabus **45 Hours**

Unit 1: General Pharmacology **8 Hours**

Introduction to Pharmacology- nature and source of drugs, essential drugs concept and routes of drug administration, Basic terminologies in pharmacology, types of agonists and antagonists. Overview of Pharmacodynamics: Principles and mechanisms of drug action, receptors pharmacology, drug receptors interactions signal transduction mechanisms, dose response relationship, therapeutic index, combined effects of drugs and factors modifying drug action.

Pharmacokinetics- Membrane transport, absorption, distribution, metabolism, and excretion of drugs. Enzyme induction, enzyme inhibition.

Adverse drug reactions. Overview of phases of clinical trials and pharmacovigilance.

Unit 2: Pharmacology of drugs acting on Nervous system **8Hours**

Neurohumoral transmission, co-transmission, and classification of neurotransmitters.

Classification, mechanism, use and adverse effect of drugs in:

a. Parasympathomimetic, Parasympatholytic, Sympathomimetics, sympatholytic.

b. Neuromuscular blocking agents, skeletal muscle relaxants (peripheral), Local anesthetic agents, and glaucoma

c. General anesthetics and pre-anesthetics, Sedatives, hypnotics and centrally acting muscle relaxants, Anti-epileptics, Antipsychotics, antidepressants, anti-anxiety agents, anti-manics, Anti-parkinsonian Anti-Alzheimer's, and Opioid analgesics.

Unit 3: Pharmacology of drugs acting on cardiovascular system and blood: **10 hours**

Classification, mechanism, use and adverse effect of:

Drugs used in congestive heart failure, Anti-hypertensive drugs, Anti-anginal drugs, Anti-arrhythmic drugs, Anti-hyperlipidemic drug, Hematinic, coagulants and anticoagulants. Fibrinolytics and anti-platelet drugs.

Unit 4: Drugs acting on Gastrointestinal tracts and Renal system: **11 hours**

Drugs for Peptic ulcer, diarrhea, and constipation, Antiemetics and Prokinetics.

Physiology of Urine formation, Pharmacology of diuretics and antidiuretics.

Drugs acting on respiratory and NSAIDs:

Expectorants, Antitussives, Drugs for Asthma, Pharmacology of Prostaglandins and NSAIDs. **Chemotherapeutic agents and Immunopharmacology:** General consideration of antimicrobial agents. Pharmacology of antifungal, antibacterial, antiviral, antimalarial and anticancer drugs. Pharmacology of Immunomodulators.

UNIT 5. Toxicology 8 hours

Principles of Toxicology, Introduction to toxicology and toxicokinetic

Routes of exposure and factors influencing toxicity, Mechanisms of toxicity and types of toxicological hazards, Evaluation of Chemical Hazards, Risk assessment and risk management Carcinogenicity, mutagenicity, and teratogenicity, Environmental toxicology, and ecotoxicology

Practical: Pharmacology and Toxicology Lab 45 Hours

1. Introduction to experimental pharmacology, commonly used instruments, and laboratory animals in experimental pharmacology.
2. Common laboratory techniques. Blood withdrawal, serum and plasma separation, anesthetics and euthanasia are used for animal studies.
3. Study of different routes of drugs administration in mice/rats.
4. Effect of drugs on ciliary motility of frog esophagus
5. Effect of drugs on rabbit eye.
6. Effects of skeletal muscle relaxants using rota-rod apparatus.
7. Study of anxiolytic activity of drugs using rats/mice (simulation based)
8. Effect of drugs on locomotor activity using actophotometer.
9. Anticonvulsant effect of drugs by MES and PTZ method (simulation based)
10. Effect of drugs on blood pressure and heart rate of dog.
11. Study of diuretic activity of drugs.
12. Effect of physostigmine and atropine on DRC of acetylcholine using frog rectus abdominis muscle and rat ileum
13. Bioassay Methods of drugs like acetylcholine, adrenaline, insulin, d-tubocurarine
14. Anti-inflammatory activity of drugs using carrageenan induced paw-edema model (simulation based).
15. Estimation of serum biochemical parameters by using semi- autoanalyzer.
16. Study of anti-ulcer activity of a drug using pylorus ligand (SHAY) rat model and NSAIDS induced ulcer model (simulation based).
17. Introduction to basic cell culture technique.

Reference Books (latest edition)

1. Rang, H.P., Dale, M.M., Ritter, J.M. and Moore, P.K., 2003. Pharmacology, Churchill Livingstone. New York, pp.3-4.
2. Katzung, B.G., 2012. Basic and clinical pharmacology.
3. Goodman, L.S., 1996. Goodman and Gilman's the pharmacological basis of therapeutics (Vol. 1549, pp. 1361-1373). New York: McGraw-Hill.
4. Goodman, L.S. and Gilman, A., 1955. The pharmacological basis of therapeutics. The Macmillan.
5. Howland, R.D., and Mycek, M.J., 2006. Lippincotts Illustrated reviews, Pharmacology. Teaching Learning, 5, p.5.
6. Tripathi, K.D., 2003. Essentials of medical pharmacology, Jaypee Brothers. Med Pub Ltd New Delhi Edn, 5, pp.93-94.
7. Kulkarni SK. Handbook of experimental pharmacology. VallabhPrakashan,Dawson, B. and Trapp, R.G. 2019.

Modes of Evaluation: Quiz/Assignment/Presentation/ Written Exam/ Examination Scheme: Continuous Assessment- 50%, mid semester examination- 20% and End term examination- 30%

Theory Assessment:

	Continuous Assessment/Internal Assessment (50)				**Mid Term Exam**	**End Term Exam**	**Total**
Components	Surprise Test/Quiz	Assignments	Group Discussion /Presentations	Project Based Learning/ Tutorials based learning			
Weightage (%)	10	10	10	20	20	30	100

Laboratory Assessment:

	Continuous Assessment/Internal Assessment			**End Term Examination**		
Components	Experimental Performance	Viva voce	Lab record	Major Experiments (Practical)	Viva voce	Total
Weightage (%)	30	20	20	20	10	100

Design and Management of Clinical Trials L-T-P-C:2-1-1.5-4.5

- **COURSE OBJECTIVE**

  This course provides an overview of design, conduct, and management of clinical trials. This course describes the fundamental principles of clinical trial design, ethical considerations, data collection and analysis, regulatory requirements, and trial management strategies. It helps students in developing a strong foundation in planning and executing clinical trials, ensuring patient safety, and generating reliable and valid evidence for healthcare interventions.

➢ **COURSE OUTCOMES**

On completion of this course, the students will be able to

CO1. Explain the purpose and importance of clinical trials in evaluating the safety and efficacy of healthcare interventions.

CO2. Describe the fundamental principles of clinical trial design, including study objectives, endpoints, sample size calculation, randomization, and blinding.

CO3. Identify the ethical considerations and regulatory requirements in clinical trial conduct, including informed consent, data privacy, and institutional review board (IRB) approval.

CO4. Develop skills in data collection, management, and analysis in clinical trials, including case report form (CRF) development and statistical considerations.

CO5. Describe the role of monitoring, quality assurance, and data safety monitoring boards (DSMBs) in ensuring trial integrity and patient safety.

Co-Relationship Matrix

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Indicate the relationships by1- Slight (low) 2- Moderate (Medium) 3-Substantial (high)

Program Outcomes / Course Outcomes	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PSO1	PSO2	PSO3
CO 1	3	-	-	-	-	-	-	-	1	1	-	-
CO 2	3	-	2	-	-	-	-	-	1	1	-	1

CO 3	3	2	2	-	3	-	-	-	1	1	2	1
CO4	3	2	2	2	3	1	2	-	1	1	2	1
CO5	3	2	2	2	3	1	2	-	1	1	2	1
Average	**3**	**2**	**2**	**2**	**3**	**1**	**2**	**-**	**1**	**1**	**2**	**1**

Syllabus **45 Hours**

UNIT 1. Clinical Trial Design **10 Hours**

Study objectives and research questions**,** Selection of study population and eligibility criteria**,** Randomization, blinding, and allocation concealment**,** Endpoints and Sample Size Calculation**,** Selection and measurement of primary and secondary endpoints**,** Power and sample size calculation**,** Considerations for non-inferiority and equivalence trials.

UNIT II. Data Collection and Management **10 Hours**

Case report form (CRF) development and data collection tools, Data validation and quality control, electronic data capture (EDC) systems and data management. Statistical Considerations in Clinical Trials, Overview of statistical concepts and hypothesis testing, Analysis plans and statistical analysis methods, Interim analysis, and adaptive trial design.

UNIT III. Participant Recruitment, Retention, and Adherence **12 Hours**

Strategies for participant recruitment and informed consent, Retention and follow-up of study participants, Adherence monitoring and strategies. Clinical Trial Monitoring and Safety, Role of clinical research monitors, Data safety monitoring boards (DSMBs) and interim analysis, Pharmacovigilance, and adverse event reporting

UNIT IV. Good Clinical Practice (GCP) and Trial Management **8 Hours**

Principles of GCP and regulatory compliance, Responsibilities of sponsors, investigators, and study coordinators, Study site management and coordination.

UNIT V. Virtual and decentralized trials **5 Hours**

Virtual and decentralized trials, Adaptive trial designs and precision medicine approaches, big data, and real-world evidence in clinical research

PRACTICAL **45 HOURS**

1. Hands on training on Protocol Development
2. Hands on training on Study Feasibility Assessment
3. Ethical Considerations and Informed Consent
4. Data Collection and Case Report Form (CRF) Design
5. Randomization and Blinding
6. Study Monitoring and Quality Assurance

7. Data Analysis and Interpretation
8. Safety Monitoring and Adverse Event Reporting
9. Regulatory Compliance and Reporting
10. Case Studies and Practical Scenarios.

REFERENCES

1. Spriet, A., Dupin-Spriet, T. and Simon, P., 1994. Methodology of clinical drug trials. Karger Publishers.
2. Chow, S.C. and Liu, J.P., 2008. Design and analysis of clinical trials: concepts and methodologies (Vol. 507). John Wiley & Sons.
3. EDITION, T., 1988. Principles and Practice of Pharmaceutical Medicine.
4. Rees, J., 2004. The fundamentals of clinical discovery. Perspectives in Biology and Medicine, 47(4), pp.597-607.
5. Spriet, A., Dupin-Spriet, T. and Simon, P., 1994. Methodology of clinical drug trials. Karger Publishers.
6. Chow, S.C. and Liu, J.P., 2008. Design and analysis of clinical trials: concepts and methodologies (Vol. 507). John Wiley & Sons.
7. Karlberg, J.P.E. and Speers, M.A., 2010. Reviewing clinical trials: a guide for the ethics committee. Hong Kong.

Modes of Evaluation: Quiz/Assignment/Presentation/ Written Exam/ Examination Scheme: Continuous Assessment- 50%, mid semester examination- 20% and End term examination- 30%

Theory Assessment:

	Continuous Assessment/Internal Assessment (50)				**Mid Term Exam**	**End Term Exam**	**Total**
Components	Surprise Test/Quiz	Assignments	Group Discussion /Presentations	Project Based Learning/ Tutorials based learning			
Weightage (%)	10	10	10	20	20	30	100

Laboratory Assessment:

	Continuous Assessment/Internal Assessment			**End Term Examination**		
Components	Experimental Performance	Viva voce	Lab record	Major Experiments (Practical)	Viva voce	Total
Weightage (%)	30	20	20	20	10	100

Clinical Sampling and Analytical Techniques L-T-P-C:2-1-2-5

COURSE OBJECTIVE

This course provides an overview of clinical sampling and analytical techniques used in healthcare and biomedical research. It covers the principles and procedures for sample collection, handling, and storage, as well as the analytical techniques used for measuring various clinical parameters. Learners will learn the importance of reliable and accurate hands on performing and analysing clinical samples.

COURSE OUTCOME: Upon the completion of the course the student will be able to

CO1: Explain the principles and importance of clinical sampling in healthcare and biomedical research.

CO2: Describe different types of clinical samples and their collection techniques.

CO3: Demonstrate skills in performing common clinical tests, analytical techniques used for clinical sample analysis.

CO4: Explain quality control and quality assurance measures in clinical sample analysis.

CO5: Discuss the emerging technologies and advancements in clinical sample analysis.

Co-Relationship Matrix

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Indicate the relationships by1- Slight (low) 2- Moderate (Medium) 3-Substantial (high)

Program Outcomes / Course Outcomes	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PSO1	PSO2	PSO3
CO 1	3	-	-	-	-	-	-	-	1	1	-	-
CO 2	3	-	2	-	-	-	-	-	1	1	-	1
CO 3	3	3	2	-	3	-	-	-	1	1	2	1
CO4	3	3	2	2	3	1	1	-	1	1	2	1
CO5	3	-	2	2	3	1	1	1	1	1	2	1
Average	**3**	**3**	**2**	**2**	**3**	**1**	**1**	**1**	**1**	**1**	**2**	**1**

Syllabus **45 Hours**

UNIT I. Introduction to Clinical Sampling and Analysis **10 Hours**

Importance of clinical sampling in healthcare and research, Ethical considerations and informed consent in sample collection, Overview of analytical methods used in clinical sample analysis. Types of Clinical Samples and Collection Techniques, blood, and serum samples: venipuncture, fingerstick, and arterial sampling, Urine, saliva, and other bodily fluid samples: collection methods and considerations, Tissue, and biopsy samples: collection techniques and processing.

UNIT II. Clinical Sample Handling **8 Hours**

Clinical sample handling, storage, and transport, pre-analytical factors: sample collection tubes, anticoagulants, and additives, Sample handling procedures: centrifugation, aliquoting, and labeling, Storage conditions and sample stability, transport considerations and chain of custody. Analytical techniques in clinical sample analysis.

UNIT III. Quality Control and Assurance **8 Hours**

Quality control and assurance in clinical sample analysis, calibration and standardization of analytical instruments used in clinical sample handling. Internal and external quality control measures, Validation and verification of analytical methods, Accreditation, and proficiency testing.

UNIT IV. Common Clinical Tests and Interpretation of Results **8 Hours**

Complete blood count (CBC) and differential analysis, Basic metabolic panel (BMP) and liver function tests, Lipid profile, hormone assays, and therapeutic drug monitoring, Microbiological and molecular diagnostic tests.

UNIT V. Point-of-Care Testing (POCT) and Rapid Diagnostics **11 Hours**

Overview of POCT devices and their applications, Selection and use of POCT devices in different clinical settings, Quality assurance and regulatory considerations for POCT. Emerging Technologies in Clinical Sample Analysis, Advances in molecular diagnostics: PCR, next-generation sequencing (NGS), Point-of-care molecular testing and biosensors, Omics technologies: genomics, proteomics, and metabolomics

Practical: Clinical Sampling and Analytical Lab **60 Hours**

This lab course complements the theoretical knowledge gained in the Clinical Sampling and Analytical course. Students will gain hands-on experience in various clinical sampling techniques and analytical methods used in healthcare and biomedical research.

1. **Introduction to Clinical Sampling and Laboratory Safety:** To study Clinical sampling techniques, Laboratory safety protocols and practices.
2. **Introduction to laboratory instruments and equipment.**

3. **Blood Sample Collection and Analysis:** To study and understand Venipuncture technique and blood collection, Preparation and analysis of blood smears, Hematology tests: complete blood count (CBC) and differential analysis
4. **Urine Sample Collection and Analysis:** Study Collection methods and considerations for urine samples, Analysis of urine samples using dipstick tests, microscopic examination of urine sediment
5. **Biochemical Analysis of Clinical Samples:** Explain Principles of spectrophotometry and spectrometry, Analysis of clinical samples for biochemical parameters (e.g., glucose, cholesterol, liver enzymes), Use of automated analyzers for biochemical analysis
6. **Immunological and Serological Analysis:** Explain Enzyme-linked immunosorbent assays (ELISA), Rapid diagnostic tests for infectious diseases, Antibody, and antigen detection techniques.
7. **Molecular Diagnostics:** Understand DNA extraction techniques from clinical samples, Polymerase chain reaction (PCR) for molecular diagnostics, Next-generation sequencing (NGS) techniques
8. **Quality Control and Assurance in Clinical Sample Analysis:** Explain Calibration and standardization of instruments, Internal and external quality control measures, Validation of analytical methods
9. **Data Analysis and Interpretation:** Perform Statistical analysis of clinical data, Interpretation of laboratory test results, Reporting and documentation of laboratory findings.
10. **Emerging Technologies in Clinical Sample Analysis:** Introduction to advanced techniques (e.g., mass spectrometry, proteomics, genomics), Hands-on experience with emerging technologies (if available).

REFERENCE and Textbooks

1. Harr, R.R., 2012. Medical laboratory science review. FA Davis.
2. Bishop, M.L., 2020. Clinical Chemistry: Principles, Techniques, and Correlations, Enhanced Edition: Principles, Techniques, and Correlations. Jones & Bartlett Learning.
3. B McKenzie, S., 2015. Clinical laboratory hematology. Lynne Williams.
4. Grody, W.W., Nakamura, R.M., Kiechle, F.L. and Strom, C. eds., 2009. Molecular diagnostics: techniques and applications for the clinical laboratory. Academic Press.
5. Rifai, N., 2017. Tietz textbook of clinical chemistry and molecular diagnostics-e-book. Elsevier Health Sciences.

Modes of Evaluation: Quiz/Assignment/Presentation/ Written Exam/ Examination
Scheme: Continuous Assessment- 50%, mid semester examination- 20% and End term examination- 30%

Theory Assessment:

	Continuous Assessment/Internal Assessment (50)				**Mid Term Exam**	**End Term Exam**	**Total**
Components	Surprise Test/Quiz	Assignments	Group Discussion /Presentations	Project Based Learning/ Tutorials based learning			
Weightage (%)	10	10	10	20	20	30	100

Laboratory Assessment:

	Continuous Assessment/Internal Assessment			**End Term Examination**		
Components	Experimental Performance	Viva voce	Lab record	Major Experiments (Practical)	Viva voce	Total
Weightage (%)	30	20	20	20	10	100

Environmental Science	**Credits :- 4**

Leadership and Teamwork	**Credits :- 2**

Ability Enhancement/Co-curricular	**Qualifying**

SEMESTER IV

Pharmacovigilance L-T-P-C:2-1-1.5-4.5

Course Objective: This course provides an overview of pharmacovigilance, the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. Students will learn about the importance of pharmacovigilance in ensuring drug safety, the global regulatory framework, and the methods used to collect, analyze, and report adverse drug reactions. They will also explore risk management strategies and pharmacovigilance in different populations.

Course Outcome

After the completion of course, the students will be able to:

CO1. Explain the basic principle and importance of pharmacovigilance in drug safety monitoring.
CO2. Describe the global regulatory framework and guidelines for pharmacovigilance.
CO3. Explain the methods and tools used in collection, analysis, and reporting of ADR
CO4. Discuss the role of pharmacovigilance in signal detection and risk management.
CO5. Describe the challenges and future trends in pharmacovigilance and gain insights into pharmacovigilance in special populations.

Co-Relationship Matrix

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)
Indicate the relationships by1- Slight (low) 2- Moderate (Medium) 3-Substantial (high)

Program Outcomes / Course Outcomes	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PSO1	PSO2	PSO3
CO 1	3	-	-	-	-	-	-	-	1	2	-	-
CO 2	3	-	2	-	-	-	-	-	1	2	-	2
CO 3	3	3	2	-	3	-	-	-	1	2	2	2

CO4	3	3	2	2	3	1	1	-	1	2	2	2
CO5	3	3	2	2	3	1	1	1	1	2	2	2
Average	**3**	**3**	**2**	**2**	**3**	**1**	**1**	**1**	**1**	**2**	**2**	**2**

Syllabus **45 Hours**

UNIT 1. Introduction to Pharmacovigilance **8 Hours**

Definition, scope, and objectives of pharmacovigilance

Historical background and milestones in pharmacovigilance, Roles, and responsibilities of stakeholders in pharmacovigilance, Pharmacovigilance databases and information systems, Global Regulatory Framework and Guidelines

International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines, World Health Organization (WHO) guidelines and programs, National regulatory authorities, and their roles in pharmacovigilance.

UNIT 2. Adverse Drug Reaction (ADR) Reporting and Data Collection8 Hours

ADR reporting methods, data collection and sources of ADR reporting: spontaneous reporting, clinical trials, literature, and electronic health records, Signal detection and data mining techniques, Adverse Event Assessment and Causality Assessment.

Causality assessment methods: WHO-Uppsala Monitoring Centre (UMC) criteria, Naranjo algorithm, Severity assessment and seriousness criteria, Quality assessment of ICSR

UNIT 3. Pharmacovigilance in Special Populations **8 Hours**

Pediatric pharmacovigilance: challenges and considerations, Geriatric pharmacovigilance: age-related changes and medication safety, Pharmacovigilance in pregnancy and lactation, Pharmacovigilance in Drug Development and Clinical Trials, Pre-marketing safety assessment and clinical trial safety monitoring, Role of the clinical research team in pharmacovigilance, Reporting of serious adverse events (SAEs) in clinical trials.

UNIT 4. Pharmacovigilance in the Real-World Setting **10 Hours**

Post-marketing surveillance and real-world evidence, Pharmacoepidemiology and observational studies in pharmacovigilance, Role of healthcare professionals and patients in pharmacovigilance, Pharmacovigilance Challenges and Future Trends, Challenges in signal detection and benefit-risk assessment

Pharmacovigilance in the era of big data and artificial intelligence, Emerging trends, and future directions in pharmacovigilance

UNIT 5. Vaccine safety surveillance and Materiovigilance **11 Hours**

Vaccine pharmacovigilance, vaccination failure, adverse events following immunization

Pharmacovigilance methods passive surveillance – spontaneous reports and case series, stimulated reporting, active surveillance – sentinel sites, drug event monitoring and registries, comparative observational studies – cross sectional study, case control study and cohort study, targeted clinical investigations

Materiovigilance, Hemovigilance, Identification and reporting of medication errors, Communication in Pharmacovigilance

Pharmacovigilance Practical **45 Hours**

Practical pharmacovigilance activities aim to provide students with hands-on experience in the implementation of pharmacovigilance principles and processes.

1. **Study and explain Adverse Drug Reaction (ADR): A Case Study Analysis**

2. **Understand and explain pharmacovigilance databases** such as the WHO Global Individual Case Safety Report (ICSR) database or national databases. Report hypothetical or adverse drug reactions using standardized reporting forms.

3. **Explain Signal Detection and Data Analysis:** Use pharmacovigilance data sets to perform spontaneous reporting. Apply signal detection techniques to identify potential safety concerns and generate signal reports.

4. **Risk Management Planning: Develop** risk management plans for selected medications. Identify potential risks, propose risk minimization strategies, and design tools for risk communication to healthcare professionals and patients.

5. **Pharmacovigilance Auditing and Inspection:** Simulation based pharmacovigilance audits or inspections.

Prepare audit/inspection report, review relevant documentation, identify compliance gaps, and propose corrective actions.

6. **Pharmacoepidemiology Study Design: Understand** pharmacoepidemiology study designs, such as cohort studies or case-control studies. Design Pharmacoepidemiologic studies to investigate potential associations between drug exposures and adverse events.

7. **Adverse Event Reporting in Clinical Trials:** Demonstrate Monitoring and reporting serious adverse events (SAEs) occurring during clinical trials.

8. **Role-Playing Exercises: Simulate** interactions between healthcare professionals, patients, and pharmacovigilance professionals.

Practice counseling patients on ADR reporting, handling queries from healthcare professionals, or conducting medication safety presentations.

References and Textbooks

1. Mann, R.D., and Andrews, E.B. eds., 2007. Pharmacovigilance. John Wiley & Sons.
2. Waller, P. and Harrison-Woolrych, M., 2017. An introduction to pharmacovigilance. John Wiley & Sons.

3. Andrews, E.B. and Moore, N. eds., 2014. Mann's pharmacovigilance. John Wiley & Sons.
4. Nour, S. and Plourde, G., 2018. Pharmacoepidemiology and pharmacovigilance: Synergistic tools to better investigate drug safety. Academic Press.
5. Plotkin, S.A., Orenstein, W. and Offit, P.A., 2012. Vaccines E-book. Elsevier Health Sciences.
6. Mal, D.K., Ehsan, I. and Mukherjee, B., MATERIOVIGILANCE and HAEMOVIGILANCE.

Modes of Evaluation: Quiz/Assignment/Presentation/ Written Exam/ Examination Scheme: Continuous Assessment- 50%, mid semester examination- 20% and End term examination- 30%

Theory Assessment:

	Continuous Assessment/Internal Assessment (50)				**Mid Term Exam**	**End Term Exam**	**Total**
Components	Surprise Test/Quiz	Assignments	Group Discussion /Presentations	Project Based Learning/ Tutorials based learning			
Weightage (%)	10	10	10	20	20	30	100

Laboratory Assessment:

	Continuous Assessment/Internal Assessment			**End Term Examination**		
Components	Experimental Performance	Viva voce	Lab record	Major Experiments (Practical)	Viva voce	Total
Weightage (%)	30	20	20	20	10	100

Clinical Pharmacokinetics L-T-P-C:2-1-1.5-4.5

COURSE OBJECTIVES:

This course is intended to teach students the fundamental principles and applications of pharmacokinetics in designing the individualized dosage regimen, to interpret the plasma drug concentration profile in altered pharmacokinetics, drug interactions and in therapeutic drug monitoring processes to optimize the drug dosage regimen.

COURSE OUTCOMES:

Upon completion of this course, it is expected that students shall be able to:

CO1: Define pharmacokinetic drug interactions

CO2: Discuss pharmacokinetic parameters in clinical settings

CO3: Recommend dosage adjustment for pediatric and geriatric populations

CO4: Design the drug dosage regimen for individual patients; recommend dosage adjustment for patients with renal/hepatic impairment

Co-Relationship Matrix

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Indicate the relationships by1- Slight (low) 2- Moderate (Medium) 3-Substantial (high)

Program Outcomes / Course Outcomes	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PSO1	PSO2	PSO3
CO 1	3	-	-	-	-	-	-	-	1	1	-	-
CO 2	3	-	2	-	-	-	-	-	1	1	-	1
CO 3	3	-	2	-	3	-	-	-	1	1	2	1
CO4	3	3	2	2	3	1	1	-	1	1	2	1
Average	**3**	**3**	**2**	**2**	**3**	**1**	**1**	**1**	**1**	**1**	**2**	**1**

Syllabus **45 Hours**

UNIT I:

Introduction to clinical pharmacokinetics10 Hours

Compartmental and non-compartmental models, renal and non-renal clearance, models of hepatic clearance, estimation of bioavailability, multiple dosing, calculation of loading and maintenance doses. Designing of dosage regimens - determination of dose and dosing intervals, conversion from intravenous to oral dosing, nomograms, and tabulations in designing dosage regimen.

UNIT II: Pharmacokinetics of Drug Interaction 6 Hours

Pharmacokinetic drug interactions, inhibition and induction of drug metabolism, inhibition of biliary excretion.

UNIT III Non-Linier Mixed Effects Modelling 10 Hours

Structural or base model, modeling random effects, modeling covariate relationships, mixture model, estimation methods, model building techniques, covariate screening methods, testing the model assumptions, precision of the parameter estimates and confidence intervals, model misspecification and violation of the model assumptions, model validation, simulation of dosing regimens and dosing recommendations.

UNIT III: Altered Pharmacokinetics8 Hours

Drug dosing in the elderly, pediatrics, obese patients, and during pregnancy and lactation, drug dosing in renal failure and extracorporeal removal of drugs, drug dosing in hepatic failure.

UNIT IV: Therapeutic Drug Monitoring: 11 Hours

Introduction, individualization of drug dosage regimen (variability – genetic, age, weight, disease and interacting drugs). TDM protocol, pharmacokinetic/pharmacodynamic correlation in drug therapy. TDM in Cardiovascular disease - lidocaine, digoxin, and amiodarone; Antibiotics - gentamicin, vancomycin, and meropenem; Seizure disorders - carbamazepine, phenytoin, and sodium valproate; Psychiatric conditions - fluoxetine, lithium, and amitriptyline; Organ transplantation - cyclosporine; Cytotoxic agents - 5-fluorouracil, methotrexate, and cisplatin.

Practical: Clinical Pharmacokinetics Lab 30 Hours

1. To determine Ka, pKa, and partition coefficient (PC) of Salicylic acid and study their relationship.
2. To study *in vitro* drug release of the given compressed tablet of Paracetamol.

3. To study *in vitro* drug release of the given fast release tablet.
4. To perform *in vitro* absorption-permeation study of marketed tablet.
5. To study the protein binding of salicylic acid by equilibrium dialysis method.
6. To determine various pharmacokinetic parameters from given blood data of IV bolus injection (one compartment model).
7. To determine the area under the curve for the given data by Trapezoidal method.
8. To determine the area under the curve for the given data by counting squares method and cutting & weighing method.
9. Determine the pharmacokinetic model from the given plasma concentration verses time data following 250 mg rapid intravenous bolus dose of a drug.

REFERENCES

1. Gibaldi, M., 1991. Biopharmaceutics and clinical pharmacokinetics.
2. Shargel, L., Andrew, B.C. and Wu-Pong, S., 1999. Applied biopharmaceutics & pharmacokinetics (Vol. 264). Stamford: Appleton & Lange.
3. Huang, X.H. and Li, J., 2007. PETER L. BONATE. Pharmacokinetic-Pharma-codynamic Modeling and Simulation. New York: Springer, 2005. 387 ISBN: 038727197X.
4. Burton, M.E. ed., 2006. Applied pharmacokinetics & pharmacodynamics: principles of therapeutic drug monitoring. Lippincott Williams & Wilkins.
5. Wong, S.H. and Sunshine, I., 1996. Handbook of analytical therapeutic drug monitoring and toxicology. CRC Press.
6. Dhillon, S. and Kostrzewski, A. eds., 2006. Clinical pharmacokinetics. Pharmaceutical Press.
7. Notari, Robert E. Biopharmaceutics and clinical pharmacokinetics: an introduction. Routledge, 2017.
8. Doogue, M.P. and Polasek, T.M., 2013. The ABCD of clinical pharmacokinetics. Therapeutic advances in drug safety, 4(1), pp.5-7.

Modes of Evaluation: Quiz/Assignment/Presentation/ Written Exam/ Examination
Scheme: Continuous Assessment- 50%, mid semester examination - 20% and End term examination - 30%

Theory Assessment:

	Continuous Assessment/Internal Assessment (50)			**Total**

Components	Surprise Test/Quiz	Assignments	Group Discussion /Presentations	Project Based Learning/ Tutorials based learning	**Mid Term Exam**	**End Term Exam**	
Weightage (%)	10	10	10	20	20	30	100

Laboratory Assessment:

	Continuous Assessment/Internal Assessment			**End Term Examination**		
Components	Experimental Performance	Viva voce	Lab record	Major Experiments (Practical)	Viva voce	Total
Weightage (%)	30	20	20	20	10	100

Bioethics and Drug Safety	L-T-P-C:2-1-1.5-4.5

Course Description: This course describes the ethical considerations and principles about the development, regulation, and use of pharmaceutical drugs. Students will understand the fundamentals of bioethics and drug safety, addressing ethical issues related to clinical trials, informed consent, access to medications, off-label use, adverse events, and post-marketing surveillance.

Course Outcome: Upon the completion of the course the student will be able to

CO1: Explain the principles of bioethics and their application to drug safety.
CO2: Describe the ethical considerations in the design, conduct, and reporting of clinical trials.
CO3: Discuss the concept of informed consent and its importance in drug research and use.
CO4. Analyze the ethical dimensions of access to medications, including affordability and availability.

Co-Relationship Matrix

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)
Indicate the relationships by1- Slight (low) 2- Moderate (Medium) 3-Substantial (high)

Program Outcomes / Course Outcomes	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PSO1	PSO2	PSO3
CO 1	3	-	-	-	3	-	-	-	2	1	-	2
CO 2	3	-	2	-	3	-	-	-	2	1	-	2
CO 3	3	-	2	-	3	-	-	-	2	1	2	2
CO4	3	3	2	2	3	1	1	-	2	1	2	2
Average	**3**	**3**	**2**	**2**	**3**	**1**	**1**	**1**	**2**	**1**	**2**	**2**

Syllabus **45 Hours**

UNIT I. Introduction to Bioethics and Drug Safety **8 Hours**

Overview of bioethics and its relevance to drug safety, Ethical frameworks and principles in healthcare, Historical perspective on drug safety and regulation, Ethical Considerations in Clinical Trials, Ethical guidelines, and regulations for clinical trials.

UNIT II. **Informed consent and participant autonomy** **8 Hours**

Elements of informed consent, consent process and documentation, special considerations for vulnerable populations, Balancing risks and benefits in trial design and recruitment, Informed Consent in Drug Research and Use, Elements and challenges of informed consent, Ethics of placebo-controlled trials and equipoise. Participant Recruitment and Retention in clinical trials.

UNIT III. Access to Medications: Ethics and Equity **8 Hours**

Ethical issues in medication affordability and accessibility**,** Global health disparities and access to essential medicines**,** pharmaceutical industry practices and drug pricing. Off-label prescribing: benefits and risks**,** Compassionate use programs and expanded access**,** Informed decision-making and patient autonomy**,** Ethics of Adverse Event Reporting and Patient Safety

UNIT IV. Ethical Issues in Drug Safety **11 Hours**

Ethical considerations in monitoring drug safety post-approval, ethical case studies in drug safety, analysis of real-life case studies involving ethical issues in drug safety, Ethical reasoning, and decision-making in complex scenarios. Discussion and debate on different perspectives and ethical frameworks

UNIT V. Ethical Issues in Emerging Technologies and Innovative Therapies 10 Hours

Ethical considerations in clinical trials for modern technologies, New Drugs in Clinical Trials 2019, Emerging Ethical Issues in Drug Safety, Exploration of emerging ethical challenges in drug safety, Ethical considerations in personalized medicine and gene therapy, Ethical implications of emerging technologies in drug development.

Practical: Bioethics and Drug Safety Lab **45 Hours**

Practical activities in a course on Bioethics and Drug Safety provide students with opportunities to apply ethical principles and analyze real-world scenarios related to drug development, regulation, and use.

1. Perform Case Study Analysis: Analyze the case, identify the ethical issues involved, and propose ethical solutions or actions.
2. Evaluate the informed consent process, risk-benefit assessment, and protection of vulnerable populations.

3. Prepare ethical review reports highlighting any concerns or recommendations
   Simulation based demonstration of informed consent process, including communication, comprehension, and documentation.
4. Demonstrates the roles of investigators, research participants, and ethics committee members (simulation based), discuss ethical issues and challenges encountered.
5. Ethics Committee Meeting Simulation: Mock research proposal involving ethical considerations.
   Review the proposal, discuss the ethical aspects, and reach a consensus decision.
   Encourage thoughtful deliberation and ethical reasoning during the simulation.
6. Debate on Access to Medications: Discussion based activity on for and against different perspectives, such as affordability, intellectual property rights, and global health equity. Students should present evidence-based arguments and engage in constructive discussions.
7. Field Visit to Regulatory Agencies or Ethics Committees:
   Visits to local regulatory agencies or ethics committees involved in drug safety and research oversight.
8. Guest Speakers from Bioethical Organizations: Discuss and learn about the practical challenges and ethical considerations in drug safety.

REFERENCE and Textbooks

1. Rozovsky, F.A. and Adams, R.K., 2003. Clinical trials and human research: A practical guide to regulatory compliance.

2. Evans, B.J. and Meslin, E.M., 2006. Encouraging translational research through harmonization of FDA and common rule informed consent requirements for research with banked specimens. The Journal of Legal Medicine, 27(2), pp.119-166.

3. Gallin, J.I. and Ognibene, F.P. eds., 2012. Principles and practice of clinical research. Academic Press.

4. Karlberg, J.P.E. and Speers, M.A., 2010. Reviewing clinical trials: a guide for the ethics committee. Hong Kong.

5. Cartwright, A.C. and Matthews, B.R. eds., 2016. International pharmaceutical product registration (Vol. 200). CRC Press.

6. Beecher, H.K., 2001. Ethics and clinical research. Bulletin of the World Health Organization, 79, pp.367-372.

7. Angell, M., 1997. The ethics of clinical research in the Third World. New England journal of medicine, 337(12), pp.847-849.

8. Wendler, D., 2009. The ethics of clinical research.

Modes of Evaluation: Quiz/Assignment/Presentation/ Written Exam/ Examination
Scheme: Continuous Assessment- 50%, mid semester examination- 20% and End term examination- 30%

Theory Assessment:

	Continuous Assessment/Internal Assessment (50)				**Mid Term Exam**	**End Term Exam**	**Total**
Components	Surprise Test/Quiz	Assignments	Group Discussion /Presentations	Project Based Learning/ Tutorials based learning			
Weightage (%)	10	10	10	20	20	30	100

Laboratory Assessment:

	Continuous Assessment/Internal Assessment			**End Term Examination**		
Components	Experimental Performance	Viva voce	Lab record	Major Experiments (Practical)	Viva voce	Total
Weightage (%)	30	20	20	20	10	100

Working with Data	Credits-02

Ability Enhancement/Co-curricular	Credits-Qualifying

Minor elective **L-T-P-C:2-1-1.5-4.5**

Regulatory Aspects in Clinical Research L-T-P-C:2-1-1.5-4.5

COURSE OBJECTIVES

This course will cover on understanding the importance of Good Clinical Practices (GLP) aspects, regulations governing the conduct of Clinical Trials and the Intellectual Property Rights

COURSE OUTCOMES: Upon completion of this course the student will be able to

CO1. Explain about the conduct of Clinical Trials and understanding of ethical principles underlined research involving human subjects.

CO2. Improves ideas and updating information on the current trend in Good Clinical Practices

CO3. Explain the role of global as well as Indian regulatory authorities, guidelines while conducting clinical trials

CO4. Apply the Information of IPR and GCP guidelines for conducting clinical trials

Co-Relationship Matrix

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Indicate the relationships by1- Slight (low) 2- Moderate (Medium) 3-Substantial (high)

Program Outcomes / Course Outcomes	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PSO1	PSO2	PSO3
CO 1	3	-	-	-	3	-	-	-	1	1	-	-
CO 2	3	-	2	-	3	-	-	-	1	1	-	1
CO 3	3	-	2	-	3	-	-	-	1	1	2	1
CO4	3	3	2	2	3	1	1	-	1	1	2	1
Average	**3**	**3**	**2**	**2**	**3**	**1**	**1**	**1**	**1**	**1**	**2**	**1**

Syllabus **45 Hours**

UNIT-I Ethical Aspects **10 Hours**

Ethical principles underlined research involving human subjects, legal authorities for Institutional Review Board (IRB), Health 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-II Applicable GCP Guidelines **10 Hours**

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.

Regulatory guidelines for Biomaterials and Medical Devices

UNIT-III Council for International Organizations of Medical Science (CIOMS) guidelines **10 Hours**

CIOMS International Ethical guidelines for biomedical research involving human subjects. Principles 0f Medical Ethics Relevant to the Protection of Prisoners Against Torture (1983), Intellectual Property Rights: Terminology, Patent Laws, TRIPS (Trade Related Intellectual Property Rights) Agreement, Trademarks, copyrights, Clinical Trial Application Requirements:

UNIT-IV Investigational New drug (IND) **5 Hours**

Classifications, IND application submission, check list, FDA IND review check list, IND application process, Information for sponsors-investigator submitting IND, IND forms and instructions

UNIT- V New Drug Application (NDA) **10 Hours**

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

Practical- Regulatory Aspects in Clinical Research Lab **45 Hours**

1. Understanding the role of regulatory authorities and importance of regulatory guidelines.
2. Declaration of Helsinki and the Belmont Report
3. Informed Consent
4. Investigational New Drug/Device Application
5. Institutional Review Board/Ethics Committee
6. Good Clinical Practice (GCP)
7. Safety Reporting
8. Data Management and Quality Assurance
9. Regulatory Inspections
10. Reporting and Documentation

Recommended Books:

1. The Fundamentals of Clinical Research: A Universal Guide for Implementing Good Clinical Practice, by P. Michael Dubinsky, Karen A. Henry Wiley; 1st edition (1 February 2022).
2. Clinical Trials Audit Preparation - A Guide for Good Clinical Practice (GCP) Inspections – Illustrated, 18 June 2010, John Wiley & Sons Inc; 1st edition (18 June 2010).
3. Good Clinical Practice - Standard Operating Procedures for Clinical Researchers Paperback – 27 March 1998, John Wiley & Sons Inc; 1st edition (27 March 1998); 01149344934
4. Principles of Good Clinical Practice (Pharmacy Business Administration) Paperback – Pharmaceutical Press; 1st edition (3 August 2010)
5. Guide for Clinical Trial Staff: Implementing Good Clinical Practice Spiral-bound – Import, S Karger AG (14 October 2003)

Modes of Evaluation: Quiz/Assignment/Presentation/ Written Exam/ Examination Scheme: Continuous Assessment- 50%, mid semester examination- 20% and End term examination- 30%

Theory Assessment:

	Continuous Assessment/Internal Assessment (50)				Mid Term Exam	End Term Exam	Total
Components	Surprise Test/Quiz	Assignments	Group Discussion /Presentations	Project Based Learning/ Tutorials based learning			
Weightage (%)	10	10	10	20	20	30	100

Laboratory Assessment:

	Continuous Assessment/Internal Assessment			End Term Examination		
Components	Experimental Performance	Viva voce	Lab record	Major Experiments (Practical)	Viva voce	Total
Weightage (%)	30	20	20	20	10	100

SEMESTER V

Global Regulations of Clinical Trials L-T-P-C:2-1-1.5-4.5

COURSE OBJECTIVES: This course is designed to impart the fundamental knowledge on the clinical development process of drugs, pharmaceuticals and medical devices, regulations and guidance governing the conduct of clinical research in India, USA, and EU.

COURSE OUTCOME On completion of this course, the students will be able to

CO1: Discuss global regulations in clinical research, medical device development process and different types and phases of Clinical trials.

CO2: Describe different regulations governing clinical trials in India as well as USA and EU.

CO3: Explore the ethical considerations and principles underlying clinical trial regulations.

CO4: Examine the processes involved in clinical trial approval, monitoring, and reporting.

CO5. Analyze the challenges and harmonization efforts in global clinical trial regulations.

Co-Relationship Matrix

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Indicate the relationships by1- Slight (low) 2- Moderate (Medium) 3-Substantial (high)

Program Outcomes / Course Outcomes	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PSO1	PSO2	PSO3
CO 1	3	-	-	-	3	-	-	-	1	1	-	2
CO 2	3	-	2	-	3	-	-	-	1	1	-	2
CO 3	3	-	2	-	3	-	-	-	1	1	2	2
CO4	3	3	2	2	3	1	1	-	1	1	2	2
CO5	3	3	2	2	3	1	1	-	1	1	2	2
Average	**3**	**3**	**2**	**2**	**3**	**1**	**1**	**1**	**1**	**1**	**2**	**2**

Syllabus 45 Hours

UNIT I. Regulatory Authorities and Roles 8 Hours

International regulatory bodies: ICH, WHO, and their guidelines, Regional regulatory authorities: FDA, EMA, PMDA, and others, Roles, and responsibilities of regulatory agencies in clinical trial oversight.

UNIT II. Clinical Research Regulations 11 Hours

a. Clinical research regulations in India – Schedule Y, New Drugs in Clinical Trials 2019 & Medical device guidelines-ISO14155. Guidance USA: Regulations to conduct drug studies in USA (FDA)
b. NDA 505(b) (1) of the FD&C Act (Application for approval of a new drug)
c. NDA 505(b) (2) of the FD&C Act (Application for approval of a new drug that relies, at least in part, on data not developed by the applicant)
d. ANDA 505(j) of the FD&C Act (Application for approval of a generic drug products
e. Biosimilar Guidelines

UNIT III. Clinical Research Related Guidelines: 8 Hours

a. E4 – Dose Response Information to support Drug Registration
b. E7 – Studies in support of General Population: Geriatrics
c. E8 – General Considerations of Clinical Trials
d. E10 – Choice of Control Groups and Related Issues in Clinical Trials,
e. E11 – Clinical Investigation of Medicinal Products in the Pediatric Population

UNIT IV. Code of federal regulations related to clinical trials. 10 Hours

a. CFR 21Part 50: Protection of Human Subjects
b. CFR 21Part 54: Financial Disclosure by Clinical Investigators
c. CFR 21Part 312: IND Application
d. CFR 21Part 314: Application for FDA Approval to Market a New Drug
e. CFR 21Part 320: Bioavailability and bioequivalence requirements
f. CFR 21Part 812: Investigational Device Exemptions
g. CFR 21Part 822: post-market surveillance

UNIT V. Harmonization Efforts and Future Trends 8 Hours

Global harmonization initiatives in clinical trial regulations, international collaboration and mutual recognition agreements, Emerging trends, and future directions in global clinical trial regulations

Practical: Global Regulations of Clinical Trials Lab

1. Regulatory Authority Case Studies: Prepare presentations or reports highlighting key aspects and differences in regulations.
2. Mock Clinical Trial Approval Process: Prepare an Investigational New Drug (IND) application or Clinical Trial Authorization (CTA) submission.
3. Mock ethics committee or regulatory review board, addressing ethical and regulatory considerations.
4. Ethical Review Board Simulation: Conduct a simulation where students take on the roles of ethics committee members or regulators.
5. Regulatory Compliance Audits: Mock clinical trial documentation, such as protocols, informed consent forms, and case report forms.
6. Reporting and Documentation Exercise: Reporting process, prepare adverse event reports, and document the necessary information following regulatory requirements.
7. Analyze the impact of their reporting on patient safety and trial conduct.
8. Data Management and Quality Assurance: Mock clinical trial datasets or case studies.
9. Perform data quality checks, assess data integrity, and ensure compliance with regulatory requirements for data collection and management.
10. Site Inspection Preparation
11. Prepare for a mock regulatory inspection by reviewing their site's documentation, ensuring compliance with regulations, and addressing potential compliance gaps.
12. Regulatory Updates and Emerging Trends.

References and RECOMMENDED BOOKS

1. Chin, R. and Bairu, M. eds., 2011. Global clinical trials: effective implementation and management. Academic Press.
2. Gallin, J.I. and Ognibene, F.P. eds., 2012. Principles and practice of clinical research. Academic Press.
3. Gad, S.C. ed., 2009. Clinical trials handbook. John Wiley & Sons.
4. Plomer, A., 2013. The law and ethics of medical research: international bioethics and human rights. Routledge.
5. Chow, S.C. and Liu, J.P., 2008. Design and analysis of clinical trials: concepts and methodologies (Vol. 507). John Wiley & Sons.
6. Lang, T. and Siribaddana, S., 2012. Clinical trials have gone global: is this a good thing? PLoS medicine, 9(6), p.e1001228.

7. Weigmann, K., 2015. The ethics of global clinical trials: In developing countries, participation in clinical trials is sometimes the only way to access medical treatment. What should be done to avoid exploitation of disadvantaged populations? EMBO reports, 16(5), pp.566-570.

Modes of Evaluation: Quiz/Assignment/Presentation/ Written Exam/ Examination
Scheme: Continuous Assessment- 50%, mid semester examination- 20% and End term examination- 30%

Theory Assessment:

	Continuous Assessment/Internal Assessment (50)				**Mid Term Exam**	**End Term Exam**	**Total**
Components	Surprise Test/Quiz	Assignments	Group Discussion /Presentations	Project Based Learning/ Tutorials based learning			
Weightage (%)	10	10	10	20	20	30	100

Laboratory Assessment:

	Continuous Assessment/Internal Assessment			**End Term Examination**		
Components	Experimental Performance	Viva voce	Lab record	Major Experiments (Practical)	Viva voce	Total
Weightage (%)	30	20	20	20	10	100

Epidemiology and Global Health L-T-P-C:2-1-1.5-4.5

Course Objectives

The course objective of this course helps student to describe the science of epidemiology and the etiology of specific diseases, interpret epidemiological information contained in scientific literature and design interventions for treating and preventing ill health.

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

CO1 Describe the evolution of epidemiology.

CO2 Discuss various types of epidemiological studies and ethical considerations involving human subjects.

CO3 Evaluate the process of investigation of an outbreak and causation in Epidemiology.

CO4 Plan research project and critical reading of published reports.

CO5 Develop analytical approaches to monitoring and evaluation.

Co-Relationship Matrix

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Indicate the relationships by1- Slight (low) 2- Moderate (Medium) 3-Substantial (high)

Program Outcomes / Course Outcomes	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PSO1	PSO2	PSO3
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CO 3	-	-	-	-	3	-	-	-	1	-	-	-
CO4	-	3	-	2	-	1	1	-	1	-	-	-
CO5	-	3	2	2	3	1	1	3	1	-	2	-
Average	**3**	**3**	**2**	**2**	**1**	**1**	**1**	**3**	**1**	**-**	**2**	**-**

Syllabus **45 Hours**

Unit I: Epidemiology: Laying the Foundations **8 Hours**

Definitions: Epidemiology, Public Health, and Health. Uses of Epidemiology, evolving patterns of morbidity and mortality-Demographics and disease patterns, mortality, and life expectancy trends. Roots of Epidemiology-John Graunt, Germ theory, The London Epidemiological Society, John Snow and William Farr. Global Health and Sustainable Development Goals.

Unit II: Epidemiological Study Designs **8 Hours**

Etiologic research- Hypothesis statement**,** Epidemiological variables-Person, place, time, and data. Descriptive versus Analytical, Longitudinal versus cross-sectional. Epidemiological studies. Experimental versus observational, cohort versus case-control. Ethical conduct of studies involving human subjects.

Unit III: Outbreak Investigation and Causation **10 Hours**

Background-Initial detection of Outbreaks, goals, and methods. CDC prescribed investigatory steps. Case study on the outbreak investigation of Covid 19 and Foodborne outbreak. Causation in Epidemiology-Natural history of the disease, Variability in the expression of disease, causal models, Concept of cause, Establishing the cause of a disease.

Unit IV: Health Services and Health Policy **8 Hours**

Healthcare planning and evaluation, Measuring the quality of healthcare, the planning cycle, health public policy in practice, Planning a research project, and critical reading of published reports.

Unit V: Monitoring and Evaluation **11 Hours**

Monitoring Health Care Systems, Organizations, and Programs

Surveillance, Health services information and Evaluation.

Dimensions of Evaluation, The Evaluation Process, Conceptual Framework for Specifying Evaluation Criteria, and Analytical Approaches to Evaluation.

Practical- Epidemiology and Global Health Lab **45 Hours**

The course will also extend students' practical skills and ability to critically review the existing public health policies and Programs. Emphasis will be placed on epidemiological reasoning principles and findings interpretation. At the end of this course, students can apply quantitative and qualitative approaches to address population health challenges and interpret

epidemiological information in scientific literature. It encompasses planning an epidemiological study and encouraging the publication of the results.

1. Write a critical review of any one theory of Disease.
2. Introduction to case study on Covid 19 (Region specific/Uttarakhand)
3. Give a summary of the recommended health strategy and an assessment of whether the health strategy was successful.
4. Project proposal on any one identified public health issue in a selected community.
5. Evaluation of the three articles and recommendation for an effective public health intervention
6. Community Screening: Framing open-ended and close-ended questionnaires/Probing.
7. Development of tools to assess knowledge, attitudes, and practices
8. Report on a Community Visit/Transect walk and social mapping.
9. Seminar
10. Peer reviews

Practical hours include one seminar in which students will give presentations. The project proposal plan of the study will be presented in the seminar and discussed with other students. Students will also be engaged in peer reviews of one another's research plans.

Reference Books

1. Beaglehole, R. et al. (1993): *Basic Epidemiology*. Geneva, WHO.
2. Lilienfeld's Foundations of Epidemiology (Fourth Edition) Dona Schneider, David E. Lilienfeld
3. B. Burt Gerstman, Epidemiology Kept Simple: An Introduction to Traditional and Modern Epidemiology (3rd Edition)
4. Applied Epidemiology: Theory to Practice edited by Ross C. Brownson, Diana B. Petitti
5. Lilienfeld, Abraham M. (1994): *Foundations of Epidemiology*. New York, Oxford University Press, (Chapter 2)
6. Denise M. Oleske: Epidemiology and the Delivery of Health Care Services (Third edition): Methods and Applications, Springer.

Suggested Readings

1. Pawson, R. & Tilley, N. (2008): *Realistic Evaluation*, Sage Pub. London. Ch. 3, pp. 55-82.
2. Doll R. & Hill A.B. (1950): Smoking and Cancer of the Lung – A Preliminary Report. *BMJ*, Sept. 30. pp.739 – 748.

3. Doll R. and Hill A. B. (1964): Mortality, Relation to Smoking - Ten Years Observation of British Doctors, British *Medical Journal,* 30th May, pp. 1300-1410.
4. Ritu Priya, Atul Kotwal & Imrana Qadeer (2009): 'Towards an Eco-social Epidemiology Approach to Goitre and Other Iodine Deficiency Disorders: A Case study of India's Technocratic Programme for Universal Iodisation of Salt'. *IJHS,* Vol. 39, No.2. pp: 343-362.
5. Susser M. & E. (1996): Choosing a Future for Epidemiology – Parts I and II. *AJPH* 86 (5) pp. 668-673 and 674-677.
6. Int J Infect Dis. 2022 Sep; 122:669-675. doi: 10.1016/j.ijid.2022.07.010. Epub 2022 Jul 8. PMID: 35811075; PMCID: PMC9263687.
7. Technical Focus: COVID-19 Early Epidemiologic and Clinical Investigations for public health response.
8. https://sdgs.un.org/goals

Modes of Evaluation: Quiz/Assignment/Presentation/ Written Exam/ Examination Scheme: Continuous Assessment- 50%, mid semester examination- 20% and End term examination- 30%

Theory Assessment:

	Continuous Assessment/Internal Assessment (50)				**Mid Term Exam**	**End Term Exam**	**Total**
Components	Surprise Test/Quiz	Assignments	Group Discussion /Presentations	Project Based Learning/ Tutorials based learning			
Weightage (%)	10	10	10	20	20	30	100

Laboratory Assessment:

	Continuous Assessment/Internal Assessment			**End Term Examination**		
Components	Experimental Performance	Viva voce	Lab record	Major Experiments (Practical)	Viva voce	Total
Weightage (%)	30	20	20	20	10	100

XXXXXXXX **Immunology** **L-T-P-C: 2-1-1.5-4.5**

COURSE OBJECTIVE

This course's main objective is to introduce the basic concepts of immunology and its application in disease diagnosis. This course addresses immunological disorders and discusses the techniques to be employed in diagnostic laboratories. This will also enable the students to know about the different cells which are associated with the body's defense mechanism against pathogens and cancer.

COURSE OUTCOMES

Upon completion of the course, the student should be able to:

THEORY

CO1: Outline the history of scientists who contributed to immunology.

CO2: Explain types of cells and organs that participate in defense mechanisms against pathogens and other foreign particles.

CO3: Discuss the defense mechanism through Antibodies, Major histocompatibility complex and Complement systems.

CO4: Apply advanced technologies in immunology to diagnose different diseases.

PRACTICAL

CO5: Demonstrate basic skills of total Leukocyte Count and differential Leukocyte Count of the given blood sample

Co-Relationship Matrix

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Indicate the relationships by1- Slight (low) 2- Moderate (Medium) 3-Substantial (high)

Program Outcomes / Course Outcomes	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PSO1	PSO2	PSO3
CO 1	3	-	-	-	-	-	-	-	1	-	-	-
CO 2	3	-	-	-	-	-	-	-	1	-	-	-
CO 3	-	-	-	-	3	-	-	-	1	-	-	-

CO4	-	3	-	2	-	1	1	-	1	-	-	-
CO5	-	3	2	2	3	1	1	3	1	-	2	-
Average	**3**	**3**	**2**	**2**	**1**	**1**	**1**	**3**	**1**	**-**	**2**	**-**

Syllabus **45 Hours**

Unit I: History of immunology **8 Hours**

Introduction to Innate and Adaptive immunity; Contributions of scientists to the development of the field of immunology - Edward Jenner, Karl Landsteiner, Robert Koch, Paul Ehrlich, Elie Metchnikoff, Peter Medawar, MacFarlane Burnet, Neils K Jerne, Rodney Porter, and Susumu Tonegawa.

Unit II: Immunity: Cells, organs, and Antigen-Antibody Interaction **11 Hours**

(a) Structure, and Functions of: Immune Cells – Stem cell, T cell, B cell, NK cell, Macrophage, Neutrophil, Eosinophil, Basophil, Mast cell, Dendritic cell; and Immune Organs – Bone Marrow, Thymus, Lymph Node, Spleen, GALT, MALT, CALT.

(b) Characteristics of antigens (Foreignness, Molecular size, and Heterogeneity); Haptens; Epitopes (T & B cell epitopes); T-dependent and T-independent antigens; Adjuvants; Structure, Types, Functions and Properties of antibodies; Antigenic determinants on antibodies (Isotypic, allotypic, idiotypic); VDJ rearrangements; Monoclonal and Chimeric antibodies.

Unit III: Immune responses **8 Hours**

Primary and Secondary Immune Response; Generation of Humoral Immune Response (Plasma and Memory cells); Generation of Cell Mediated Immune Response (Self MHC restriction, T cell activation, Co- stimulatory signals).

Unit IV: Major Histocompatibility Complex and Complement System **8 Hours**

Organization of MHC locus (Mice & Human); Structure and Functions of MHC I & II molecules; Antigen processing and presentation (Cytosolic and Endocytic pathways); Components of the Complement system; Activation pathways (Classical, Alternative and Lectin pathways).

Unit V: Immunological dysregulation and immunity in tumour **10 Hours**

Types of Autoimmunity and Hypersensitivity with examples; Immunodeficiencies - SCID, DiGeorge syndrome, Chediak- Higashi syndrome, Leukocyte adhesion deficiency; Types of tumors, tumor Antigens, causes and therapy for cancers.

Immune technology

Principles of Precipitation, Agglutination, Immunodiffusion, Immunoelectrophoretic, ELISA, Western blotting, Immunofluorescence, Flow cytometry, Immunoelectron microscopy.

PRACTICALS 45 Hours

1. Identification of human blood groups.
2. Perform Total Leukocyte Count of the given blood sample.
3. Perform Differential Leukocyte Count of the given blood sample.
4. Separate serum from the blood sample (demonstration).
5. Perform immunodiffusion by Ouchterlony method.
6. Perform DOT ELISA.
7. Perform immunoelectrophoretic.

REFERENCES

1. Abbas AK, Lichtman AH, Pillai S. (2007). Cellular and Molecular Immunology. 6th edition Saunders Publication, Philadelphia.
2. Delves P, Martin S, Burton D, Roitt IM. (2006). Roitt's Essential Immunology.11th edition Wiley Blackwell Scientific Publication, Oxford.
3. Goldsby RA, Kindt TJ, Osborne BA. (2007). Kuby's Immunology. 6th edition W.H. Freeman and Company, New York.
4. Murphy K, Travers P, Walport M. (2008). Janeway's Immunobiology. 7th edition Garland Science Publishers, New York.
5. Peakman M, and Vergani D. (2009). Basic and Clinical Immunology. 2nd edition Churchill Livingstone Publishers, Edinberg.
6. Richard C and Geiffrey S. (2009). Immunology. 6th edition. Wiley Blackwell Publication.

Modes of Evaluation: Quiz/Assignment/Presentation/ Written Exam/ Examination Scheme: Continuous Assessment- 50%, mid semester examination- 20% and End term examination- 30%

Theory Assessment:

	Continuous Assessment/Internal Assessment (50)				Mid Term Exam	End Term Exam	Total
Components	Surprise Test/Quiz	Assignments	Group Discussion /Presentations	Project Based Learning/ Tutorials based learning			
Weightage (%)	10	10	10	20	20	30	100

Laboratory Assessment:

	Continuous Assessment/Internal Assessment			End Term Examination		
Components	Experimental Performance	Viva voce	Lab record	Major Experiments (Practical)	Viva voce	Total
Weightage (%)	30	20	20	20	10	100

Course Objectives

This course is introduced with an idea to fill the gap between academia and research. This course introduces analytical techniques along with working principles, common instrumentation, and their applications. This course engenders students with the fundamental knowledge of analytical techniques required for research careers in allied health fields.

Course Outcomes

After the completion of course, the students will be able to:

CO1: Outline different analytical techniques and their instrumentation, and operation.

CO2: Demonstrate skill in carrying out research projects by employing centrifugation, and chromatographic and electrophoresis-based separation techniques.

CO3: Describe the terms, principle, instrumentation, operation, and applications of molecular spectroscopic and microscopic techniques.

CO4: Apply appropriate bioanalytical techniques for identification, separation, isolation, and purification of biomolecules.

CO5: Apply principles of various analytical devices used in research and enhance problem solving techniques.

Co-Relationship Matrix

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Indicate the relationships by1- Slight (low) 2- Moderate (Medium) 3-Substantial (high)

Program Outcomes / Course Outcomes	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PSO1	PSO2	PSO3
CO 1	3	-	-	-	-	-	-	-	1	-	-	-
CO 2	3	-	-	-	-	-	-	-	1	-	-	-
CO 3	3	3	2	-	3	-	-	-	1	-	2	-

CO4	3	3	2	2	-	1	1	-	1	-	2	-
CO5	3	3	2	2	3	1	1	3	1	-	2	-
Average	**3**	**3**	**2**	**2**	**1**	**1**	**1**	**3**	**1**	**-**	**2**	**-**

Syllabus **45 Hours**

Unit-I Centrifugation **6 Hours)**

Basic principles of centrifugation, standard sedimentation coefficient, types of centrifuges based on speed, different types of rotors, principles and applications of differential, rate zonal and density gradient centrifuge.

Unit-II Chromatography **(10 Hours)**

Introduction to chromatography, principle and applications of paper chromatography, thin layer chromatography, column chromatography (adsorption, gel filtration, ion exchange, and affinity) and high-performance liquid chromatography (HPLC).

Unit-III Electrophoresis **(8 Hours)**

Introduction to electrophoresis, polyacrylamide, and agarose gel electrophoresis SDS and Native-PAGE, isoelectric focusing (IEF) and 2-D gel electrophoresis.

Unit-IV Spectroscopy **(11 Hours)**

Introduction to spectroscopy, electromagnetic spectrum, Jablonski's diagram, Lambert-Beer law, principle, instrumentation, and applications of UV-visible, fluorescence, Fourier-transform infrared (FT-IR) and nuclear magnetic resonance (NMR). Introduction, principle and applications of mass spectrometry, types of ionization methods (Electron impact, chemical ionization, ESI, MALDI).

Unit-V Microscopy **(10 Hours)**

Principle of microscopy, resolving powers of different microscopes, magnification, principle, and applications of: Compound microscopy, dark field microscopy, fluorescent microscopy, phase contrast microscopy, confocal and electron microscopy (SEM & TEM), Fixation and staining.

Practical **(45 Hours)**

[1]. Separation of components of a given mixture using a laboratory scale centrifuge.

[2]. Separation of mixtures by paper / thin layer chromatography.

[3]. Separation of mixtures of molecules by any form of chromatography.

[4]. Separation of protein mixtures by sodium-dodecyl sulphate-polyacrylamide gel electrophoresis (SDS-PAGE).

[5]. Quantification of carbohydrates by DNS/Anthrone method using UV-Visible spectrophotometer.

[6]. Determination of fluorescence in bovine serum albumin.

[7]. Fluorescence spectroscopy-based confirmational analysis of protein molecules.

[8]. To perform simple direct staining to study the morphology of bacterial culture.

Reference Books

1. Principles and Techniques of Biochemistry and Molecular Biology (2018) 8th ed., Wilson, K. and Walker, J. Cambridge University Press, ISBN 13: 978-1316614761.
2. Introduction to Practical Biochemistry (2009) Sawhney, S.K. and Singh R. Narosa Publishing House (New Delhi), ISBN-13: 978-8173193026.
3. Biophysical Chemistry: Principles and Techniques (2016) Upadhyay A., Upadhyay K. and Nath N. Himalaya Publishing House, ISBN 13: 978-8183188654.
4. Principles of Fluorescence Spectroscopy (2010) 5th ed. Lakowicz J.R. Springer, ISBN 13: 978-0387312781.

Modes of Evaluation: Quiz/Assignment/Presentation/ Written Exam/ Examination Scheme: Continuous Assessment- 50%, mid semester examination- 20% and End term examination- 30%

Theory Assessment:

	Continuous Assessment/Internal Assessment (50)				**Mid Term Exam**	**End Term Exam**	**Total**
Components	Surprise Test/Quiz	Assignments	Group Discussion /Presentations	Project Based Learning/ Tutorials based learning			

Weightage (%)	10	10	10	20	20	30	100

Laboratory Assessment:

	Continuous Assessment/Internal Assessment			**End Term Examination**		
Components	Experimental Performance	Viva voce	Lab record	Major Experiments (Practical)	Viva voce	Total
Weightage (%)	30	20	20	20	10	100

Design Thinking	**Credits 2**

Ability Enhancement/Co-curricular	**Qualifying**

Industrial Training/Survey/Project Qualifying

SEMESTER VI

Pharmacotherapeutics **L-T-P-C:4-1-1-6**

Course Objectives

This course is designed to impart a thorough knowledge of the relevant aspects of pharmacotherapy of various conditions with reference to its pharmacological approaches and understanding of basic pathophysiological mechanisms. Hence, it will help study the syllabus of pharmacotherapeutic approaches and get baseline knowledge required to practice medicine safely, confidently, rationally, and effectively.

Course outcomes: After the completion of course, the students will be able to:

CO1: Understand the etiology and pathogenesis of the disease states and basic mechanism of the disease.

CO2: Explain the functions of different drugs used in the mitigation of the diseased condition.

CO3: Identify the signs and symptoms of the diseases.

CO4: Describe various therapeutic approaches and the importance of individualized therapeutic plans based on diagnosis.

CO5: Create a plan of rational medicine therapy for common diseases and design and deliver discharge counselling for patients.

Co-Relationship Matrix

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Indicate the relationships by1- Slight (low) 2- Moderate (Medium) 3-Substantial (high)

Program Outcomes / Course Outcomes	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PSO1	PSO2	PSO3
CO 1	3	-	-	-	-	-	-	-	1	1	-	-
CO 2	3	-	2	-	-	-	-	-	1	1	-	1
CO 3	3	3	2	-	3	-	-	-	1	1	2	1
CO4	3	3	2	2	3	1	1	-	1	1	2	1
CO5	3	3	2	2	3	1	1	1	1	1	2	1
Average	**3**	**3**	**2**	**2**	**3**	**1**	**1**	**1**	**1**	**1**	**2**	**1**

Syllabus **75 Hours**

Unit I: Introduction to Pharmacotherapeutics **12 Hours**

Pharmacotherapeutics – Introduction, scope, and objectives. Rational use of Medicines, Evidence Based Medicine, Essential Medicines List, Standard Treatment Guidelines (STGs). Basic principles of Cell injury and Adaptation: Introduction, definitions, Homeostasis, Components and Types of Feedback systems, Causes of cellular injury, Pathogenesis (Cell membrane damage, Mitochondrial damage, Ribosome damage, Nuclear damage), Morphology of cell injury – Adaptive changes (Atrophy, Hypertrophy, hyperplasia, Metaplasia, Dysplasia), Cell swelling, Intra cellular accumulation, Calcification, Enzyme leakage and Cell Death Acidosis & Alkalosis, Electrolyte imbalance

Unit II Basic mechanism involved in the process of inflammation **12 Hours**

Basic mechanism involved in the process of inflammation and repair: Introduction, Clinical signs of inflammation, Different types of Inflammation, Mechanism of Inflammation – Alteration in vascular permeability and blood flow, migration of WBC's, Mediators of inflammation, Basic principles of wound healing in the skin, Pathophysiology of Atherosclerosis

Unit III Etiopathogenesis and treatment of cardiovascular disorders **13 Hours**

Definition, etiopathogenesis, clinical manifestations, nonpharmacological and pharmacological management of the diseases associated with Cardiovascular System: Hypertension, congestive heart failure, ischemic heart disease (angina, myocardial infarction, atherosclerosis, and arteriosclerosis)

Unit IV Etiopathogenesis and treatment of respiratory, kidney and blood related disorders **13 Hours**

Definition, etiopathogenesis, clinical manifestations, nonpharmacological and pharmacological management of the diseases associated with Respiratory system: Asthma, Chronic obstructive airways diseases. Renal system: Acute and chronic renal failure. Hematological Diseases: Iron deficiency, megaloblastic anemia (Vit B12 and folic acid), sickle cell anemia, thalassemia, hereditary acquired anemia, hemophilia.

Unit V Etiopathogenesis and treatment of nervous, endocrine, and gastrointestinal disorders **12 Hours**

Definition, etiopathogenesis, clinical manifestations, nonpharmacological and pharmacological management of the diseases associated with Endocrine system: Diabetes, thyroid diseases, disorders of sex hormones. Nervous system: Epilepsy, Parkinson's disease, stroke. Psychiatric disorders: depression, schizophrenia, and Alzheimer's disease. Gastrointestinal system: Peptic Ulcer

Unit VI Etiopathogenesis and treatment of cancer, infectious diseases, bone, and joint disorders. 13 Hours

Principles of Cancer: Classification, etiology, and pathogenesis of Cancer. Infectious diseases: Meningitis, Typhoid, Leprosy, Tuberculosis Urinary tract infections. Sexually transmitted diseases: AIDS, Syphilis, Gonorrhea.

Definition, etiopathogenesis, clinical manifestations, nonpharmacological and pharmacological management of the diseases associated with diseases of bones and joints: Rheumatoid Arthritis, Osteoporosis, Gout.

Practical: Pharmacotherapeutics 30 Hours

1. Preparation and discussion of SOAP (Subjective, Objective, Assessment and Plan) notes for at least SIX clinical cases (real / hypothetical) of the following disease conditions: Hypertension and Angina Pectoris
2. Preparation and discussion of SOAP (Subjective, Objective, Assessment and Plan) notes for at least SIX clinical cases (real / hypothetical) of the following disease conditions: Myocardial Infarction and Hyperlipidemia
3. Preparation and discussion of SOAP (Subjective, Objective, Assessment and Plan) notes for at least SIX clinical cases (real / hypothetical) of the following disease conditions: Rheumatoid arthritis and Asthma
4. Preparation and discussion of SOAP (Subjective, Objective, Assessment and Plan) notes for at least SIX clinical cases (real / hypothetical) of the following disease conditions: Diabetes and Epilepsy
5. Preparation and discussion of SOAP (Subjective, Objective, Assessment and Plan) notes for at least SIX clinical cases (real / hypothetical) of the following disease conditions: Stroke and Depression
6. Preparation and discussion of SOAP (Subjective, Objective, Assessment and Plan) notes for at least SIX clinical cases (real / hypothetical) of the following disease conditions: Tuberculosis and Anemia
7. Preparation and discussion of SOAP (Subjective, Objective, Assessment and Plan) notes for at least SIX clinical cases (real / hypothetical) of the following disease conditions: Dermatological condition s and Viral Infection
8. Patient counselling exercises using role plays based on the real / hypothetical clinical case scenarios
9. Simulated cases to enable dose calculation of selected drugs in pediatrics under various pathological conditions

10. Simulated cases to enable dose calculation of selected drugs in geriatrics under various pathological conditions

Reference Books

1. Rang, H.P., Dale, M.M., Ritter, J.M. and Moore, P.K., 2003. Pharmacology, Churchill Livingstone. New York, pp.3-4.
2. Katzung, B.G., 2012. Basic and clinical pharmacology.
3. Goodman, L.S., 1996. Goodman and Gilman's the pharmacological basis of therapeutics (Vol. 1549, pp. 1361-1373). New York: McGraw-Hill.
4. Goodman, L.S. and Gilman, A., 1955. The pharmacological basis of therapeutics. The Macmillan.
5. Howland, R.D., and Mycek, M.J., 2006. Lippincotts Illustrated reviews, Pharmacology. Teaching Learning, 5, p.5.
6. Tripathi, K.D., 2003. Essentials of medical pharmacology, Jaypee Brothers. Med Pub Ltd New Delhi Edn, 5, pp.93-94.
7. Kulkarni SK. Handbook of experimental pharmacology. Vallabh Prakashan, Dawson, B. and Trapp, R.G. 2019.

Modes of Evaluation: Quiz/Assignment/Presentation/ Written Exam/ Examination Scheme: Continuous Assessment- 50%, mid semester examination- 20% and End term examination- 30%

Theory Assessment:

	Continuous Assessment/Internal Assessment (50)				**Mid Term Exam**	**End Term Exam**	**Total**
Components	Surprise Test/Quiz	Assignments	Group Discussion /Presentations	Project Based Learning/ Tutorials based learning			
Weightage (%)	10	10	10	20	20	30	100

Laboratory Assessment:

	Continuous Assessment/Internal Assessment			**End Term Examination**		
Components	Experimental Performance	Viva voce	Lab record	Major Experiments (Practical)	Viva voce	Total
Weightage (%)	30	20	20	20	10	100

Biopharmaceutics L-T-P-C:4-1-1-6

Course Objective: This course provides an in-depth understanding of the principles and applications of biopharmaceutics, which is the study of the relationship between the physicochemical properties of drugs, their formulation, and their pharmacological and therapeutic effects. The course covers topics such as drug absorption, distribution, metabolism, and excretion, as well as drug delivery systems and bioavailability**.**

Course Outcome Upon the completion of the course the student will be able to

CO1 Understand biopharmaceutical, physiological, biochemical and cell biology-related aspects on the transport and metabolism of drugs in the gastrointestinal tract and in the liver

CO2 Explain mechanisms behind the transport of drug and metabolism and how drugs can interact with other drugs and food and methods to study these interactions.

CO3 Describe the role of biopharmaceutics in clinical research within the pharmaceutical industry.

CO4 Apply regulatory requirements within the biopharmaceutical area.

CO5 Compile the findings of biopharmaceutical studies in clinical research.

Co-Relationship Matrix

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Indicate the relationships by1- Slight (low) 2- Moderate (Medium) 3-Substantial (high)

Program Outcomes / Course Outcomes	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PSO1	PSO2	PSO3
CO 1	3	-	-	-	-	-	-	-	1	1	-	-
CO 2	3	-	2	-	-	-	-	-	1	1	-	1
CO 3	3	3	2	-	3	-	-	-	1	1	2	1
CO4	3	3	2	2	3	1	1	-	1	1	2	1
CO5	3	3	2	2	3	1	1	1	1	1	2	1
Average	**3**	**3**	**2**	**2**	**3**	**1**	**1**	**1**	**1**	**1**	**2**	**1**

Syllabus **75 Hours**

Unit1 Introduction to Biopharmaceutics **12 Hours**

Overview of biopharmaceutics and its significance in drug development and delivery. Basic concepts of drug absorption, distribution, metabolism, and elimination (ADME). Physiological, biochemical and cell biology-related background to the physiology of the gastrointestinal tract and the liver and different pathophysiological conditions associated with gastrointestinal tract and the liver.

Unit 2 Drug Delivery Systems 12 Hours

Routes of administration: oral, parenteral (intravenous, intramuscular, subcutaneous), topical, transdermal, inhalation, etc. Formulation considerations for different drug delivery systems. Drug release kinetics and mechanisms.

Unit 3Drug Absorption and Distribution13 Hours

Absorption: Mechanisms of drug absorption through GIT, factors influencing drug absorption though GIT, absorption of drug from Non per oral extra-vascular routes.

Tissue permeability of drugs, binding of drugs, apparent, volume of drug distribution, plasma and tissue protein binding of drugs, factors affecting protein-drug binding. Kinetics of protein binding, Clinical significance of protein binding of drugs.

Unit 4Drug metabolism and elimination 12 Hours

Drug metabolism and basic understanding metabolic pathways Microsomal oxidation. Phases of biotransformation of Drugs and endogenous toxic compounds. Microsomal oxidation reactions. II phase of biotransformation of medicines. Conjugation reactions in the liver.

Renal excretion of drugs, factors affecting renal excretion of drugs, renal clearance, non-renal routes of drug excretion of drugs

Unit 5 Bioavailability and Bioequivalence13 Hours

Definition and Objectives of bioavailability, absolute and relative bioavailability, measurement of bioavailability, in-vitro drug dissolution models, in-vitro-in-vivo correlations, bioequivalence studies. Regulatory aspects on the absorption, bioavailability, and bioequivalence of drug.

UNIT 6 Biopharmaceutics and Pharmacokinetics Modeling 13 Hours

Mathematical models for drug absorption, distribution, and elimination.PK/PD (pharmacokinetic/pharmacodynamic) modeling and simulation, Application of modeling in drug development and dosage regimen optimization.

Practical – Biopharmaceutics Lab 30 Hours

Basic understanding of in silico, in vitro, in situ and in vivo methods that have been used to study dissolution, permeability, transit times, stability, metabolism, bioavailability, and bioequivalence.

1. To use open-source platforms such as Swiss dock for prediction of ADMET parameters and their comparison with the practical values.
2. Use of Nomograms to adjust dose for persons having renal impairment.
3. Use of Nomograms to adjust dose for persons having hepatic impairment.
4. Study of Protein Binding of ciprofloxacin hydrochloride by Enhancing the concentration of Egg Albumin.
5. To study the effect of solubility of drug on dissolution and absorption.
6. To study the effect of stability on absorption of the drugs.
7. To study the effect of pH on dissolution of marketed enteric coated tablets.
8. To study the effect of pH on dissolution of diclofenac sodium.
9. Calculation of bioequivalence of different dosage forms.
10. Effect of transit times on dissolution of tablets.

Recommended books:

1. Shargel, L., Andrew, B.C. and Wu-Pong, S., 1999. Applied biopharmaceutics & pharmacokinetics (Vol. 264). Stamford: Appleton & Lange.

2. Notari, R.E., 1975. Biopharmaceutics and pharmacokinetics: an introduction. (No Title).

3. Gibaldi, M., 1971. Introduction to biopharmaceutics.

4. Wagne, J.G., 1970. Biopharmaceutics and relevant pharmacokinetics. Drug Information Bulletin, 4(2), pp.226-226.

5. Niazi, S., 1979. Textbook of biopharmaceutics and clinical pharmacokinetics.

6. Handbook of Bioequivalence Testing, by Niazi, S. K.

7. Macheras, P. and Iliadis, A., 2016. Modeling in biopharmaceutics, pharmacokinetics, and pharmacodynamics: homogeneous and heterogeneous approaches (Vol. 30). Springer.

8. Riviere, J.E. ed., 2011. Comparative pharmacokinetics: principles, techniques, and applications. John Wiley & Sons.

Modes of Evaluation: Quiz/Assignment/Presentation/ Written Exam/ Examination Scheme: Continuous Assessment- 50%, mid semester examination- 20% and End term examination- 30%

Theory Assessment:

	Continuous Assessment/Internal Assessment (50)				Mid Term Exam	End Term Exam	Total
Components	Surprise Test/Quiz	Assignments	Group Discussion /Presentations	Project Based Learning/ Tutorials based learning			
Weightage (%)	10	10	10	20	20	30	100

Laboratory Assessment:

	Continuous Assessment/Internal Assessment			End Term Examination		
Components	Experimental Performance	Viva voce	Lab record	Major Experiments (Practical)	Viva voce	Total
Weightage (%)	30	20	20	20	10	100

Data Management Technologies L-T-P-C:4-1-1-6

Course Objective: This course introduces data management technology focused on its applications in clinical research. Students will learn about the principles and techniques involved in managing clinical research data effectively and ensuring data quality and integrity. The course covers both theoretical concepts and practical skills necessary for data management in clinical research settings.

Course Outcome:

CO1: Explain and understand the importance of data management, regulatory requirements, and guidelines for data management in clinical research.

CO2: Develop skills in designing and implementing databases for clinical research studies.

CO3: Explain data entry, validation, and cleaning techniques specific to clinical research.

CO4: Apply knowledge and hands-on on electronic data capture (EDC) systems and understand the principles of data security and privacy in clinical research.

CO5: Explore emerging trends and technologies in data management for clinical research.

Co-Relationship Matrix

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Indicate the relationships by1- Slight (low) 2- Moderate (Medium) 3-Substantial (high)

Program Outcomes / Course Outcomes	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PSO1	PSO2	PSO3
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CO 2	3	-	2	-	-	-	-	-	1	1	-	2
CO 3	3	3	2	-	3	-	-	-	1	1	2	2
CO4	3	3	2	2	3	1	1	-	1	1	2	2
CO5	3	3	2	2	3	1	1	1	1	1	2	2
Average	**3**	**3**	**2**	**2**	**3**	**1**	**1**	**1**	**1**	**1**	**2**	**2**

Syllabus **75 Hours**

UNIT I Introduction to Data Management in Clinical Research **15 Hours**

Overview of data management in the clinical research process, Role of data management in ensuring data integrity and regulatory compliance, Types of Clinical data including image data, tabular data, EM waves data, Bio signal data.

UNIT II Designing Databases for Clinical Research Studies **15 Hours**

Study database architecture and design considerations, Electronic Case Report Forms (eCRFs) and data collection instruments, Data entry best practices and techniques, Data validation checks and edit checks, Double data entry and reconciliation. Identification and resolution of

data discrepancies, Query management and resolution process, Data quality assessment and monitoring

UNIT III. Electronic Data Capture (EDC) Systems 15 Hours

Introduction to EDC systems and their features, EDC system implementation and user training, Data extraction and reporting from EDC systems, Data Security and Privacy, Protection of personal health information (PHI), Data encryption and anonymization techniques, Compliance with Health Insurance Portability and Accountability Act (HIPAA)

UNIT IV. Data Integration and Interoperability 15 Hours

Data standards in clinical research (e.g., CDISC standards), Data integration techniques for multi-site studies, Electronic Health Records (EHR) integration

Risk Based Monitoring, statistical monitoring, central monitoring, involvement of real time data monitor, data visualization and monitoring.

UNIT V. Emerging Trends in Data Management for Clinical Research 15 Hours

Use of artificial intelligence and machine learning in data management, Mobile health (mHealth) technologies and their impact on data collection, AI based Healthcare applications, Challenges and Benefits of using AI in healthcare applications.

Practical: - Data Management Technologies Lab 30 Hours

In a clinical research lab, effective data management is crucial to ensure the integrity, accuracy, and security of research data.

1. Electronic Data Capture (EDC) Systems: EDC systems are software applications designed to collect, manage, and store clinical research data electronically.
2. Clinical Trial Management Systems (CTMS): CTMS platforms are used to manage various aspects of clinical trials, including participant enrollment, study timelines, documentation, and communication.
3. Laboratory Information Management Systems (LIMS): LIMS software is specifically designed to manage laboratory workflows and data in research and healthcare settings.
4. Data Warehousing and Integration: Data warehousing and integration technologies play a crucial role in consolidating and integrating data from multiple sources.
5. Data Security and Privacy Measures: Data security is paramount in clinical research labs to protect participant confidentiality and comply with regulatory requirements.
6. Statistical Analysis Software: Statistical analysis software packages like SAS (Statistical Analysis System), R, or SPSS are commonly used in clinical research labs for data analysis and statistical modeling.

7. Electronic Medical Records (EMR) Systems: In some cases, clinical research labs may integrate with hospital or clinic EMR systems to access relevant patient data for research purposes.
8. Data Backup and Disaster Recovery: To ensure data integrity and prevent loss, clinical research labs implement data backup and disaster recovery solutions.

References and Textbooks

1. Rondel, R.K., Varley, S.A. and Webb, C.F. eds., 2000. Clinical data management. New York: Wiley.
2. Prokscha, S., 2011. Practical guide to clinical data management. CRC Press.
3. Ngari, M.M., Waithira, N., Chilengi, R., Njuguna, P., Lang, T. and Fegan, G., 2014. Experience of using an open-source clinical trials data management software system in Kenya. BMC research notes, 7(1), pp.1-8.
4. Huberman, A.M., and Miles, M.B., 1994. Data management and analysis methods.
5. "Schadt, E.E., Linderman, M.D., Sorenson, J., Lee, L. and Nolan, G.P., 2010. Computational solutions to large-scale data management and analysis. Nature reviews genetics, 11(9), pp.647-657.
6. Callahan, S.P., Freire, J., Santos, E., Scheidegger, C.E., Silva, C.T. and Vo, H.T., 2006, June. VisTrails: visualization meets data management. In Proceedings of the 2006 ACM SIGMOD international conference on Management of data (pp. 745-747).

Modes of Evaluation: Quiz/Assignment/Presentation/ Written Exam/ Examination Scheme: Continuous Assessment- 50%, mid sem examination- 20% and End term examination- 30%

Theory Assessment:

	Continuous Assessment/Internal Assessment (50)				**Mid Term Exam**	**End Term Exam**	**Total**
Components	Surprise Test/Quiz	Assignments	Group Discussion /Presentations	Project Based Learning/ Tutorials based learning			

Weightage (%)	10	10	10	20	20	30	100

Laboratory Assessment:

	Continuous Assessment/Internal Assessment			**End Term Examination**		
Components	Experimental Performance	Viva voce	Lab record	Major Experiments (Practical)	Viva voce	Total
Weightage (%)	30	20	20	20	10	100

Start Your Startup	**Credits 2**

Ability Enhancement/Co-curricular	**Qualifying**

Industrial Training/Survey/Project	**Qualifying**

SEMESTER VII

Health Economics and Outcome Research	**L-T-P-C:4-1-0-5**

COURSE OBJECTIVES

This course provides an overview of the structure of health care markets and its economy. Students will understand the impact of the health care system on the competing goals of broad access, high quality, and affordability. Identify how consumers and providers respond to changes in incentives and develop an appreciation for opposing views on health care reform.

COURSE OUTCOME

CO1. Explain the use of central ethical principles that are considered when government makes decisions and influence public health.

CO2. Summarize which health indices can be used to combine different aspects of health and explain how to derive the cost of illnesses.

CO3. Describe how government insurance programs affect participants, medical providers, and private insurance markets.

CO4. Distinguish the different types of medical care data and how those measurements are driven by reimbursement and quality measurement needs.

CO5. Evaluate the impact of health care reform from both the free-market and government-interventionist perspectives.

Co-Relationship Matrix

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Indicate the relationships by1- Slight (low) 2- Moderate (Medium) 3-Substantial (high)

Program Outcomes / Course Outcomes	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PSO1	PSO2	PSO3
CO 1	3	-	-	-	-	-	-	-	1	1	-	-
CO 2	3	-	2	-	-	-	-	-	1	1	-	1
CO 3	3	3	2	-	3	-	-	-	1	1	2	1
CO4	3	3	2	2	3	1	1	-	1	1	2	1
CO5	3	3	2	2	3	1	1	1	1	1	2	1
Average	**3**	**3**	**2**	**2**	**3**	**1**	**1**	**1**	**1**	**1**	**2**	**1**

Syllabus **75 Hours**

UNIT I Introduction to Health Economics10Hours

Introduction to Health Economics, Demand; Supply; Market Equilibrium; Elasticity; Market Efficiency; Ethical principles in health economic analysis; Measuring status of health and cost of illness. Introduction to outcome research and its role in evaluating healthcare interventions.

UNIT II Economic Evaluation Methods **15 Hours**

Cost-effectiveness analysis (CEA): principles, measures of effectiveness, and cost-effectiveness ratios.

Cost-utility analysis (CUA): quality-adjusted life years (QALYs) and utility measures.

Cost-benefit analysis (CBA): monetizing health outcomes and interpreting benefit-cost ratios.

Budget impact analysis (BIA): assessing the financial implications of healthcare interventions.

UNIT III Health Technology Assessment (HTA) and Health Outcomes Measurement 15 Hours

Overview of HTA and its role in evaluating the value of healthcare technologies.

HTA agencies, guidelines, and processes in different countries.

Conducting economic evaluations for HTA purposes.

Health Outcomes Measurement: Patient-reported outcomes (PROs) and quality of life assessments. Health-related quality of life instruments and utility measurement.

Preference-based valuation methods (e.g., time trade-off, standard gamble).

UNIT IV Economic Evaluation in Pharmaceutical Industry 12 Hours

Economic Evaluation in Pharmaceutical Industry:

Economic considerations in pharmaceutical product development.

Pricing and reimbursement strategies.

Real-world evidence (RWE) and its role in economic evaluations.

UNIT V Health Policy and Health Economics 13Hours

Health policy analysis and its relationship with health economics.

Economic evaluation in healthcare policy decision-making.

The role of economic evaluations in healthcare resource allocation.

Ethical and Methodological Issues:

Ethical considerations in health economic research.

Methodological challenges and limitations in conducting economic evaluations.

Interpretation and reporting of health economic analyses.

UNIT VI Advanced Topics in Health Economics and Outcome Research 10 Hours

Value-based pricing and value frameworks.

Economic evaluations in specific disease areas.

Emerging trends and methodologies in HEOR research.

Recommended books/ References

1. Health Economics, Jay Battacharya, Timothy Hyde, and Peter Tu, 1st Edition, Palgrave Macmillan,

2014.

2. Health Care Reform: What It Is, Why It is Necessary, How It Works, Jonathan Gruber, 2012.

3. An Introduction to Health Economics (Pharmacoeconomics & outcomes research). Brookwood Medical Publications Ltd (1 January 1995). M.F. Drummond.

4. https://www.econ.berkeley.edu/undergrad/home/learning-goals

Modes of Evaluation: Quiz/Assignment/Presentation/ Written Exam/ Examination
Scheme: Continuous Assessment- 50%, mid semester examination - 20% and End term examination - 30%

Theory Assessment:

	Continuous Assessment/Internal Assessment (50)				**Mid Term Exam**	**End Term Exam**	**Total**
Components	Surprise Test/Quiz	Assignments	Group Discussion /Presentations	Project Based Learning/ Tutorials based learning			
Weightage (%)	10	10	10	20	20	30	100

Emerging Technologies in Clinical Trials L-T-P-C:3-1-1-5

Course Objective The objective of the course on Emerging Technologies in Clinical Research is to provide students with an in-depth understanding of the latest technological advancements and their applications in the field of clinical research. The course aims to familiarize students with the potential benefits, challenges, and regulatory considerations associated with adopting emerging technologies in clinical trials.

Course Outcome Upon the completion of this course the student will be able to

CO1. Evaluate the impact of wearable devices, sensors, and other data collection technologies on clinical trial design and data quality.

CO2. Analyze the potential applications and benefits of electronic health records (EHR) and real-world data (RWD) in clinical research.

CO3. Assess the role of mobile health (mHealth) technologies in patient recruitment, remote monitoring, and data collection in clinical trials.

CO4. Examine the use of artificial intelligence (AI) and machine learning (ML) in clinical trial design, patient stratification, and adverse event detection.

CO5. Explain the principles and challenges of virtual and decentralized clinical trials and their impact on trial design and patient engagement.

Co-Relationship Matrix

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Indicate the relationships by1- Slight (low) 2- Moderate (Medium) 3-Substantial (high)

Program Outcomes / Course Outcomes	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PSO1	PSO2	PSO3
CO 1	3	-	-	-	-	-	-	-	1	1	-	2
CO 2	3	-	2	-	-	-	-	-	1	1	-	2
CO 3	3	3	2	-	3	-	-	-	1	1	2	2
CO4	3	3	2	2	3	1	1	-	1	1	2	2
CO5	3	3	2	2	3	1	1	1	1	1	2	2
Average	**3**	**3**	**2**	**2**	**3**	**1**	**1**	**1**	**1**	**1**	**2**	**2**

Syllabus **60 Hours**

UNIT 1. Introduction to Emerging Technologies in Clinical Trials. **10 Hours**

Overview of clinical trials and their importance in medical research, Introduction to emerging technologies and their impact on clinical trials, Ethical and regulatory considerations for adopting emerging technologies, Wearable Devices and Sensors in Clinical Trials, Introduction

to wearable devices and sensors, Applications of wearables and sensors in data collection, Data integration and analysis from wearables and sensors, Challenges and considerations in using wearable devices in clinical trials

UNIT 2Electronic Health Records (EHR) and Real-World Data (RWD) in Clinical Trials

10 Hours

Utilizing electronic health records in clinical trial design and recruitment; Leveraging real-world data for trial feasibility, patient selection, and outcomes assessment; Ensuring data quality and privacy in the use of EHR and RWD; Regulatory considerations and guidelines for utilizing EHR and RWD in clinical trials; Mobile Health (mHealth) Technologies in Clinical Trials

UNIT 3. Introduction to mobile health technologies and applications 10 Hours

Mobile apps for patient recruitment, informed consent, and study participation, Remote monitoringand telemedicine in clinical trials, Data security and privacy considerations in mHealth technologies,

UNIT 4Artificial Intelligence (AI) and Machine Learning (ML) in Clinical Trials 10 Hours

Overview of AI and ML techniques in clinical trial design and analysis, Predictive modeling and patient stratification using AI and ML, Adverse event detection and signal identification using AI and ML, Ethical considerations and challenges in adopting AI and ML in clinical trials

UNIT 5.Blockchain Technology in Clinical Trials 10 Hours

Introduction to blockchain technology and its potential in clinical trials, Enhancing data integrity, transparency, and security with blockchain, Introduction to virtual and decentralized clinical trials, Remote patient monitoring and virtual visits, Data collection and management in virtual trials, Regulatory considerations and emerging best practices for virtual trials

UNIT 6. Data Analytics and Big Data in Clinical Trials 10 Hours

Introduction to big data and its applications in clinical trials, Predictive analytics for patient recruitment and trial outcomes, Real-time monitoring and adaptive trial design using big data. Digital Biomarkers and Endpoint Assessment

Practical: Emerging Technologies in Clinical Trials Lab 30 Hours

- Introduction to the lab environment and tools used in emerging technologies in clinical trials
- Familiarization with software applications and platforms relevant to data collection, analysis, and management
- Hands-on experience with wearable devices and sensors commonly used in clinical trials
- Data collection and integration from wearable devices and sensors
- Accessing and working with electronic health records and real-world data sources

- Data extraction, transformation, and integration from EHR and RWD platforms
- Analyzing and visualizing clinical data from EHR and RWD using statistical software or programming languages
- Exploring mobile health applications and platforms for clinical trials
- Hands-on experience with mHealth tools for patient recruitment, data collection, and remote monitoring
- Integration and analysis of data obtained from mHealth technologies
- Hands-on experience with blockchain platforms and tools used in clinical trials
- Simulation of virtual and decentralized clinical trial scenarios
- Hands-on experience with virtual trial platforms and remote monitoring tools
- Working with large-scale clinical trial datasets. Exploratory data analysis and visualization using big data tools and platforms
- Digital Biomarkers and Endpoint Assessment Lab
- Identification and evaluation of digital biomarkers in clinical trial datasets and implementing algorithms for digital endpoint assessment

Textbooks and References

1. Cortez, N., 2018. Digital Health: Scaling Healthcare to the World. Cham, Switzerland: Springer, Cham, pp.249-269.
2. Rosa, C., Campbell, A.N., Miele, G.M., Brunner, M. and Winstanley, E.L., 2015. Using e-technologies in clinical trials. Contemporary clinical trials, 45, pp.41-54.
3. Gresham, G., Schrack, J., Gresham, L.M., Shinde, A.M., Hendifar, A.E., Tuli, R., Rimel, B.J., Figlin, R., Meinert, C.L. and Piantadosi, S., 2018. Wearable activity monitors in oncology trials: current use of an emerging technology. Contemporary clinical trials, 64, pp.13-21.
4. "mHealth: Multidisciplinary Verticals" edited by SasanAdibi
5. "Real-World Evidence Generation and Evaluation of Therapeutics: Proceedings of a Workshop" by the National Academies of Sciences, Engineering, and Medicine
6. "Blockchain in Healthcare: Innovations that Empower Patients, Connect Professionals and Improve Care" by Corey Todaro and John D. Halamka
7. "Artificial Intelligence in Healthcare: A Comprehensive Guide" edited by Shailendra Singh and Rajendra Akerkar
8. "Chang, H., 2015. Book review: Data-driven healthcare & analytics in a big data world. Healthcare informatics research, 21(1), pp.61-62.
9. Manogaran, G., Lopez, D., Thota, C., Abbas, K.M., Pyne, S. and Sundarasekar, R., 2017. Big data analytics in healthcare Internet of Things. Innovative healthcare systems for the 21st century, pp.263-284.

10. Cagnan, H., Denison, T., McIntyre, C. and Brown, P., 2019. Emerging technologies for improved deep brain stimulation. Nature biotechnology, 37(9), pp.1024-1033.
11. Ristevski, B. and Chen, M., 2018. Big data analytics in medicine and healthcare. Journal of integrative bioinformatics, 15(3), p.20170030.

Modes of Evaluation: Quiz/Assignment/Presentation/ Written Exam/ Examination
Scheme: Continuous Assessment- 50%, mid semester examination- 20% and End term examination- 30%

Theory Assessment:

	Continuous Assessment/Internal Assessment (50)				**Mid Term Exam**	**End Term Exam**	**Total**
Components	Surprise Test/Quiz	Assignments	Group Discussion /Presentations	Project Based Learning/ Tutorials based learning			
Weightage (%)	10	10	10	20	20	30	100

Laboratory Assessment:

	Continuous Assessment/Internal Assessment			**End Term Examination**		
Components	Experimental Performance	Viva voce	Lab record	Major Experiments (Practical)	Viva voce	Total
Weightage (%)	30	20	20	20	10	100

Research Methodology	L-T-P-C:3-1-1-5

Course Objectives

This course is designed to enable students to:

- understand basic concepts of research and its methodologies
- identify and define a research problem, state a hypothesis, select an appropriate research design, and implement research project
- discuss the concepts and procedures of sampling, ethical considerations, data collection, analysis, and reporting
- review literature, collect and analyze data, and write a report / dissertation

Course Outcomes

Upon completion of the course, the student should be able to:

CO1: Understand the basics of research, types, steps, and application.

CO2: Collect, review, and analyze literature and data

CO3: Identify and define a research problem, set hypothesis, and select an appropriate research design

CO4: Demonstrate the ability to choose methods appropriate to research aims and objectives

CO5: Compile and Communicate research findings

Co-Relationship Matrix

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Indicate the relationships by1- Slight (low) 2- Moderate (Medium) 3-Substantial (high)

Program Outcomes / Course Outcomes	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PSO1	PSO2	PSO3
CO 1	3	-	-	-	-	-	-	-	1	1	-	-
CO 2	3	-	2	-	1	-	-	-	1	1	-	1
CO 3	3	3	2	-	1	-	-	-	1	1	2	1
CO4	3	3	2	2	1	1	1	-	1	1	2	1
CO5	3	3	2	2	1	1	1	1	1	1	2	1
Average	**3**	**3**	**2**	**2**	**1**	**1**	**1**	**1**	**1**	**1**	**2**	**1**

Syllabus

Unit I: Introduction to Research **14 hrs**

Definition of research, objectives of research, applications and types of research, research process and steps involved. Collecting and reviewing literature, types of literature review (survey, systematic, meta-analysis), conceptualization, and formulation of a research problem, constructing hypothesis, identifying variables, Synopsis.

Unit II: Design of Research and Sample Survey or Experiments **12 hrs**

Research Design-Selecting and defining a research problem, need for research design, features of a good research design, different research designs (exploratory, descriptive experimental and diagnostic research); Design of Sample Survey or Experiments; Census V/s

Sample enumerations, objectives and principles of sampling, Types of sampling, Sampling and Non-sampling errors. Designing Questionnaires and interviews. Determination of the sample size.

Unit III: Measurement of Scaling Concepts **9 hrs**

Scales of measurements, nominal, ordinal, internal and ratio scales, Errors in measurements. Validity and Reliability in measurement, Scale Construction Techniques.

Unit IV: Data Collection & Analysis **16 hrs**

Primary & secondary data, Validity and Reliability of data collection procedures, data preparation, exploratory data analysis, parametric and nonparametric tests, correlation and regression analysis, ANOVA, Multivariate Techniques, Introduction to data representation methods/tools. Like SAS, SPSS, R, etc.

Unit V: Research Ethics & Scientific Communication **9 hrs**

Ethical conduct of research, Introduction to scientific misconduct, repeatability and reproducibility of research, Ethics, and plagiarism in publication, Art of Communicating Scientifically – formats for scientific presentation and writing, conclusion, referencing and, Bibliography; journal publications, Impact factor, Citation index, Research related Software - references management, Plagiarism detection etc.

Recommended Books/ Resources:

1. Kothari C.R., “Research Methodology, Methods, and Techniques, Second edition, (2008), New Age International Publication.
2. Krishna Swamy K.N., Siva Kumar A.I., Mathirajan M., “Management Research Methodology (2006), Pearson Education, New Delhi.
3. Ranjit Kumar: Research Methodology, A step by step guide for beginners, Pearson Education, Sixth Edition 2009.
4. Mark Saunders, Philip Lewis, AdrainThornhiu: Research Methods for Business Students, Pearson Education.
5. Ram Ahuja, “Research Methods,” (2001), Rawat Publications, New Delhi. 6. Cooper D., Schindler P., Business research methods,” (2003) Tata Mc-Graw Hill, New Delhi
6. https://apps.who.int/iris/bitstream/handle/10665/206929/929061157X_eng.pdf?sequence=1&isAllowed=y

Practicals **30 hrs**

1) **Literature review**

Detailed review of literature on the chosen topic

2) **Reference management tools (Mendeley, EndNote, etc.)**

Use of reference management tools and integration into MS office

3) **Setting research question**

Identify the research area/topic of interest, review the research trends, write about significance of the chosen topic/area, set research question(s), and develop hypothesis.

4) **Setting objectives and protocols (methods)**

Write specific objectives and design research methods for each objective.

5) **Data collection, analysis, and representation**

6) **Report writing and communication**

Finalize the report based on the collected and analyzed data, communicate for peer-review, etc.

Modes of Evaluation: Quiz/Assignment/Presentation/ Written Exam/ Examination
Scheme: Continuous Assessment- 50%, mid semester examination- 20% and End term examination- 30%

Theory Assessment:

	Continuous Assessment/Internal Assessment (50)				**Mid Term Exam**	**End Term Exam**	**Total**
Components	Surprise Test/Quiz	Assignments	Group Discussion /Presentations	Project Based Learning/ Tutorials based learning			
Weightage (%)	10	10	10	20	20	30	100

Laboratory Assessment:

	Continuous Assessment/Internal Assessment	**End Term Examination**	

Components	Experimental Performance	Viva voce	Lab record	Major Experiments (Practical)	Viva voce	Total
Weightage (%)	30	20	20	20	10	100

Good Laboratory and Manufacturing Practices L-T-P-C: 3-1-1-5

COURSE OBJECTIVE

The main objective of this course is to introduce the basic concepts of Quality assurances in Good Laboratory Practices. This course addresses Federal Food and Drug Law and discusses the Trade and Company Standards Control by National, International. This will also enable the students to know about the Scope and importance of GLP and GMP.

COURSE OUTCOMES

Upon completion of the course, the student should be able to:

CO1: To know about the detailed guidelines on GLP and GMP.
CO2: To study the trade standards of quality Federal Food and Drug Law FDA.
CO3: Understand the concept of Regulatory requirements and approval procedures for New Drugs and technologies.
CO4: Identify and understand the GLP and GMP
CO5: Describe the procedures and importance of GLP and GMP.

Co-Relationship Matrix

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Indicate the relationships by1- Slight (low) 2- Moderate (Medium) 3-Substantial (high)

Program Outcomes / Course Outcomes	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PSO1	PSO2	PSO3
CO 1	3	-	-	-	-	-	-	-	1	1	-	-
CO 2	3	-	2	-	1	-	-	-	1	1	-	1
CO 3	3	3	2	-	1	-	-	-	1	1	2	1
CO4	3	3	2	2	1	1	1	-	1	1	2	1
CO5	3	3	2	2	1	1	1	1	1	1	2	1
Average	**3**	**3**	**2**	**2**	**1**	**1**	**1**	**1**	**1**	**1**	**2**	**1**

Syllabus **60 Hours**

Unit I: Good Laboratory Practices **10 Hours**

Introduction to GLP, WHO guidelines on GLP and GMP, Quality assurances in Good Laboratory Practices and Quality Standards. Advantages and Disadvantages, Concept of Quality Control. Government and trade standards of quality Federal Food and Drug Law FDA Action BSTI Laws, BSTI action and activities other food laws (Legalization).

Unit II: Validation of Analytical Procedures **15 Hours**

Implications of cGMP and Food plant sanitation. The regulations of cGMPs Planning of Plant Sanitation Programs and Construction factors Hygienic design of food plants and equipment Sanitation in warehousing, storage, shipping, receiving, containers and packaging materials Control of rats, rodents, birds, insects, and microbes. Cleaning and Disinfection: Physical and Microbiological Approach. Food Quality and Quality control including the HACCP system

(Critical quality control points in different stages of production including raw materials and processing materials)

Unit III: Good Manufacturing Practice **10 Hours**

Good Manufacturing Practice: definitions, requirements, and historical background. Quality assurance, quality management, design of quality systems. Principles for documentation in GMP, Site Master File, SMF, Monographs, Protocols (production protocols, standard operating procedures, SOP).

Unit IV: Risk Analysis and Precautions **10 Hours**

Risk analysis and risk assessment, Clinical trials, Qualification and validation, Microbiological test and quality control, Aseptic production, localities, clothing, Audit, monitoring, internal and external inspections

Unit V: Sampling **15 Hours**

Sampling: Introduction, WHO guidelines, sampling plans and techniques, operating characteristics curves, maintenance of sampling records of finished product and packaging material

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

PRACTICALS **30 Hours**

1. Basic procedures and precautions for working in a Laboratory
2. Pre-analysis preparations and management of materials.
3. Describe Sampling techniques and perform a sampling of raw materials
4. Accuracy and Precision of analysis method.
5. Validate the analysis metho
6. Basic procedures to produce hygiene food and drugs.
7. Procedure to produce a Food product.
8. Storage stability tests for Developed products.
9. Packaging and transportation requirements for a product.

REFERENCES

1. cGMP starter guide: Principles in Good Manufacturing Practices for Beginners, Emmet P. Tobin, Createspace Independent Publishing Platform, April 2016.

2. Good Manufacturing Practices for Pharmaceuticals: GMP in Practice, B Cooper, Createspace Independent Publishing Platform, July 2017.

3. Sarwar Beg and Md Saquib Hasnain, Pharmaceutical Quality by design: Principles and application, Academic press, March 2019.

4. Ron S. Kenett, Shelemyahu Zacks, Daniele Amberti, Modern Industrial Statistics: with applications in R, MINITAB and JMP, 2nd Edition, Wiley, January 2014.

5. N Politis S, Colombo P, Colombo G, M RekkasD.Design of experiments (DoE) in pharmaceutical development, Drug Dev Ind Pharm. 2017 Jun;43(6):889-901. doi: 10.1080/03639045.2017.1291672.

6. Andrew Teasdale, David Elder, Raymond W. Nims, ICH quality guidelines- An implementation guide, Dec 2017.

7. Singh, G., Agarwal, G. and Gupta, V. Drug regulatory affairs, CBS publication, 2005.

8. Marc P. Mathieu, New Drug Development: A regulatory overview, Nov 2000.

9. ICH guidelines available in the official website “https://www.ich.org”. Course Outcomes: Understand that the areas that come under the Good Laboratory Practices are personnel and organizational, testing facilities, equipment, testing and controls, records, reports, and protocol for and conduct of non-clinical labs.

Modes of Evaluation: Quiz/Assignment/Presentation/ Written Exam/ Examination Scheme: Continuous Assessment- 50%, mid semester examination - 20% and End term examination - 30%

Theory Assessment:

	Continuous Assessment/Internal Assessment (50)				**Mid Term Exam**	**End Term Exam**	**Total**
Components	Surprise Test/Quiz	Assignments	Group Discussion /Presentations	Project Based Learning/ Tutorials based learning			

Weightage (%)	10	10	10	20	20	30	100

Laboratory Assessment:

	Continuous Assessment/Internal Assessment			**End Term Examination**		
Components	Experimental Performance	Viva voce	Lab record	Major Experiments (Practical)	Viva voce	Total
Weightage (%)	30	20	20	20	10	100

Industrial Internship/Startup - BSc Honours students Research Project-BSc Honours with Research studentsCredits-15

Elective Course L-T-P-C: 3-2-0-5

Ayush and Lifestyle	L-T-P-C:3-2-0-5

Course Objective: The objective of the course on Ayush and Lifestyle is to provide students with a comprehensive understanding of the principles, practices, and applications of Ayurveda, Yoga & Naturopathy, Unani, Siddha, and Homeopathy, along with the significance of lifestyle factors in promoting health and well-being. The course aims to equip students with the knowledge and skills to integrate Ayush principles and lifestyle practices into their personal lives and professional healthcare settings.

Course Outcome: Upon the completion of this course the student will be able to

CO1. Explain the fundamental principles, philosophies, and concepts of Ayurveda, Yoga & Naturopathy, Unani, Siddha, and Homeopathy.

CO2. Analyze and apply diagnostic methods and assessment tools used in Ayush systems to evaluate individual constitution and health conditions.

CO3. Demonstrate the use of Ayush therapies, treatments, and lifestyle interventions to promote health, prevent diseases, and manage common health conditions.

CO4. Evaluate and apply principles of nutrition, dietetics, and herbal medicine in the context of Ayush and lifestyle practices.

CO5. Apply the principles of lifestyle medicine in addressing chronic diseases and health promotion.

Co-Relationship Matrix

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Indicate the relationships by1- Slight (low) 2- Moderate (Medium) 3-Substantial (high)

Program Outcomes / Course Outcomes	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PSO1	PSO2	PSO3
CO 1	3	-	-	-	-	-	-	-	1	-	-	-
CO 2	3	-	2	-	1	-	-	-	1	-	-	-
CO 3	3	3	2	-	1	-	-	-	1	-	2	-
CO4	3	3	2	2	1	1	1	-	1	-	2	-
CO5	3	3	2	2	1	1	1	1	1	-	2	-
Average	**3**	**3**	**2**	**2**	**1**	**1**	**1**	**1**	**1**	**-**	**2**	**-**

Syllabus **75 Hours**

UNIT 1. Introduction to Ayush and Lifestyle **15 Hours**

Overview of Ayush systems (Ayurveda, Yoga & Naturopathy, Unani, Siddha, and Homeopathy), Principles and philosophies underlying Ayush practices, Importance of lifestyle factors in maintaining health and well-being **Ayurveda:** Fundamental principles and concepts of Ayurveda**,** Doshas (Vata, Pitta, Kapha) and their role in health and disease**,** Ayurvedic diagnostic techniques and assessment of prakriti (individual constitution)**,** Ayurvedic therapies and treatment modalities**,** Ayurvedic diet and nutrition.

Concept of Dincharya and how its related to modern times Circadian rhythm, Ritu Charya - Seasonal Cycles as per Ayurveda.

Yoga & Naturopathy: Introduction to yoga and its philosophy**,** Asanas (physical postures) and pranayama (breathing techniques)**,** Yogic relaxation techniques and meditation**,** Naturopathic principles and therapies for health promotion and disease prevention**,** Mind-body connection, and stress management

UNIT 2. Unani Medicine, Sidhdha and Homeopathy Medicine **15 Hours**

Introduction to Unani medicine and its historical background**,** Concepts of temperament (Mizaj) and humors (Akhlat)**,** Unani diagnostic methods and approaches to treatment**,** Unani pharmacology and herbal medicine**,** Unani dietetics and lifestyle recommendations.

Siddha Medicine: Overview of Siddha medicine and its principles, Concepts of doshas (Vata, Pitta, Kapha) and seven humors (Dhatus), Siddha diagnostic methods and assessment of disease, Siddha treatment modalities, including herbal medicines and therapies, Siddha lifestyle practices for maintaining health and wellness

Homeopathy: Introduction to homeopathy and its fundamental principles**,** Law of similar and principles of potentization**,** Homeopathic material medica and remedy selection**,** Homeopathic case taking and individualization of treatment**,** Homeopathic management of common health conditions

UNIT 3. Lifestyle Medicine 13 Hours

Importance of lifestyle factors in health and disease prevention, Role of nutrition, physical activity, and stress management in promoting health, Lifestyle interventions for chronic diseases such as diabetes, cardiovascular diseases, and obesity, Integrating Ayush principles and practices into a healthy lifestyle, Evidence-based approaches to lifestyle medicine, Research and Evidence in Ayush and Lifestyle. Traditional food recipes from Ayush Systems, Ayurveda based diet and lifestyle guidelines.

UNIT 4. Introduction to research methodologies in Ayush and lifestyle medicine 12 Hours

Critical appraisal of Ayush and lifestyle research studies, Evaluation of evidence-based practices in Ayush and lifestyle interventions, Ethical considerations in Ayush and lifestyle research, Public Health Perspectives in Ayush and Lifestyle, Ayush, and lifestyle interventions for community health promotion**.**

UNIT 5. Ayurveda as a curative and restorative science 10 Hours

Public health challenges and opportunities in integrating Ayush practices, Role of Ayush and lifestyle approaches in preventive healthcare**,** Health policy considerations in the Ayush and lifestyle sector**,** Emerging Trends and Future Directions in Ayush and Lifestyle

UNIT 6. Innovations and advancements in Ayush practices 10 Hours

Integration of Ayush and lifestyle approaches into mainstream healthcare systems**,** Global perspectives and collaborations in Ayush and lifestyle medicine**,** Potential challenges, and opportunities in the field.

Textbooks and References

1. "Ayurveda: The Science of Self-Healing" by Dr. Vasant LadLotus Press; 2nd edition (28 July 1993).
2. "The Complete Book of Ayurvedic Home Remedies" by Dr. Vasant Lad, Little, Brown Book Group (2 November 2006).
3. "The Yoga Bible" by Christina Brown, Krause Publications; 39820th edition (29 May 2003)
4. Naturopathic Medicine: Treating the Whole Person, Health Advisory Lectures & Literature; 3rd Revised edition (1 November 2000)
5. "Unani Medicine: Towards a Global Approach" by Hakeem Syed Zillur Rahman Betascript Publishing, 2011
6. Rasayana: Ayurvedic Herbs for Longevity and Rejuvenation, H.S. Puri · 2002
7. Tridosha Made Easy: The Basic Ayurvedic Principle, Janardhana V Hebbar, Raghuram YS, Manasa S · 2019
8. "Lifestyle Medicine: Lifestyle, the Environment, and Preventive Medicine in Health and Disease" edited by James M. Rippe.

Modes of Evaluation: Quiz/Assignment/Presentation/ Written Exam/ Examination Scheme: Continuous Assessment- 50%, mid semester examination- 20% and End term examination- 30%

Theory Assessment:

	Continuous Assessment/Internal Assessment (50)				**Mid Term Exam**	**End Term Exam**	**Total**
Components	Surprise Test/Quiz	Assignments	Group Discussion /Presentations	Project Based Learning/ Tutorials based learning			
Weightage (%)	10	10	10	20	20	30	100

Site Management Operations	L-T-P-C: 3-2-0-5

Course Objective: This course will provide information on clinical research services, clinical research organization, clinical investigator, and pharmaceutical or Biotechnology Company, hospitals, or medical device company. An SMO specializes in managing clinical research sites.

Course Outcome: Upon the completion of this course the student will be able to

CO1: Explain about the functions of monitor, investigator, sponsor in Clinical Research Organization

CO2: Demonstrate knowledge of good clinical practice (GCP) guidelines and regulatory requirements for conducting clinical research.

CO3. Apply site selection criteria and conduct feasibility assessments for clinical trial participation.

CO4. Demonstrate Effective management of site documentation and ensure compliance with regulatory standards.

CO5. Describe study start-up activities, including site initiation visits and investigator meetings.

Co-Relationship Matrix

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)

Indicate the relationships by1- Slight (low) 2- Moderate (Medium) 3-Substantial (high)

Program Outcomes / Course Outcomes	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PSO1	PSO2	PSO3
CO 1	3	-	-	-	-	-	-	-	1	1	-	-
CO 2	3	-	2	-	1	-	-	-	1	1	-	1
CO 3	3	3	2	-	1	-	-	-	1	1	2	1
CO4	3	3	2	2	1	1	1	-	1	1	2	1
CO5	3	3	2	2	1	1	1	1	1	1	2	1
Average	**3**	**3**	**2**	**2**	**1**	**1**	**1**	**1**	**1**	**1**	**2**	**1**

Syllabus **75 Hours**

UNIT 1. Introduction to Site Management Operations **12 Hours**

Overview of site management operations in clinical research, Roles and responsibilities of site managers and clinical research coordinators, Importance of good clinical practice (GCP) and regulatory compliance, Contract Research Organizations (CRO), their functions and importance in clinical trials, Difference between Site Management Organization (SMOs) and CROs, General comments on the site's status and GCP compliance, using company- or trial-specific checklists.

Visit details – who was seen by whom, what was discussed, the date of the next planned visit.

UNIT 2. Site Documentation and Regulatory Compliance **12 Hours**

Essential documents in clinical research and their management, Regulatory requirements and submissions for site approval, Compliance with local, national, and international regulations and guidelines

UNIT 3. Study Start-up and Site Initiation **13 Hours**

Study start-up activities and timelines, Site initiation visits and investigator meetings, Study-specific training and site staff qualification, Subject Recruitment and Enrollment, Strategies for subject recruitment and retention, Informed consent process and documentation, Screening, eligibility criteria, and subject enrollment procedures

UNIT 4. Site Monitoring and Quality Assurance 12 Hours

Role of site monitors and clinical research associates (CRAs), Monitoring visits, source data verification, and compliance checks, Quality assurance processes and corrective actions, Investigational Product Management, Handling and accountability of investigational products, Drug storage, dispensing, and reconciliation, Adherence to Good Manufacturing Practice (GMP) guidelines

UNIT 5Global Site Management Organizations (SMO) Markets 12 Hours

Global Site Management Organizations Market (2021 to 2035) - by Therapeutic Areas, Trial Phases, Clinical Trial Components, Type of Interventions and Key Geographies. Site Management Operations in Specialized Settings, Considerations for site management operations in specialized trials (e.g., pediatric, oncology, global trials), Site management in decentralized and virtual trials, Ethical considerations in site management operations

UNIT 6: Study Close-out and Archiving, Study close-out activities and timelines. 12 Hours

Documentation completion and final reporting, archiving and retention of study records Emerging Trends and Future Directions in Site Management Operations, Advances in technology and their impact on site operations, Risk-based monitoring and remote monitoring approaches, Innovations, and challenges in site management operations.

References

1. https://www.insightaceanalytic.com/report/global-site-management-organizations-smo-market/1191

2. https://www.prnewswire.com/news-releases/global-site-management-organizations-market-2021-to-2035---by-therapeutic-areas-trial-phases-clinical-trial-components-type-of-interventions-and-key-geographies-301446900.html

Textbooks

1. Swink, M., Melnyk, S.A., Cooper, M. and Hartley, J., 2014. Managing operations (Vol. 1260547639). New York: McGraw-Hill/Irwin.
2. The CRA's Guide to Monitoring Clinical Research, Fourth Edition Perfect Paperback – 1 June 2016.
3. "Site Management Handbook: An Operational Guide for Investigators, Sponsors, and Site Personnel" by Gregory K. Mislick and Laura C. Bonifacio

4. "Good Clinical Practice Guide" by Medicines and Healthcare products Regulatory Agency (MHRA)
5. "Clinical Trials Handbook: Design and Conduct" by Curtis L. Meinert
6. "Managing the Investigational Product Supply Chain: Ensuring Effective Distribution in Clinical Trials" by Nigel Rulewski
7. "Risk-Based Monitoring and Fraud Detection in Clinical Trials Using JMP and SAS" by Richard C. Zink and Christi Lalanne.

Modes of Evaluation: Quiz/Assignment/Presentation/ Written Exam/ Examination Scheme: Continuous Assessment- 50%, mid semester examination - 20% and End term examination - 30%

Theory Assessment:

	Continuous Assessment/Internal Assessment (50)				**Mid Term Exam**	**End Term Exam**	**Total**
Components	Surprise Test/Quiz	Assignments	Group Discussion/Presentations	Project Based Learning/ Tutorials based learning			
Weightage (%)	10	10	10	20	20	30	100

Pharmacovigilance L-T-P-C:3-2-0-5

Course Objective: This course provides an overview of pharmacovigilance, the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems. Students will learn about the importance of pharmacovigilance in ensuring drug safety, the global regulatory framework, and the methods used to collect, analyze, and report adverse drug reactions. They will also explore risk management strategies and pharmacovigilance in different populations.

Course Outcome

After the completion of course, the students will be able to:

CO1. Explain the basic principle and importance of pharmacovigilance in drug safety monitoring.
CO2. Describe the global regulatory framework and guidelines for pharmacovigilance.
CO3. Explain the methods and tools used in collection, analysis, and reporting of ADR
CO4. Discuss the role of pharmacovigilance in signal detection and risk management.
CO5. Describe the challenges and future trends in pharmacovigilance and gain insights into pharmacovigilance in special populations.

Co-Relationship Matrix

Relationship between the Course Outcomes (COs) and Program Outcomes (POs)
Indicate the relationships by1- Slight (low) 2- Moderate (Medium) 3-Substantial (high)

Program Outcomes / Course Outcomes	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9	PSO1	PSO2	PSO3
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CO 2	3	-	2	-	1	-	-	-	1	1	-	1
CO 3	3	3	2	-	1	-	-	-	1	1	2	1
CO4	3	3	2	2	1	1	1	-	1	1	2	1
CO5	3	3	2	2	1	1	1	1	1	1	2	1
Average	**3**	**3**	**2**	**2**	**1**	**1**	**1**	**1**	**1**	**1**	**2**	**1**

Syllabus **75 Hours**

UNIT 1. Introduction to Pharmacovigilance **15 Hours**

Definition, scope, and objectives of pharmacovigilance

Historical background and milestones in pharmacovigilance, Roles, and responsibilities of stakeholders in pharmacovigilance, Pharmacovigilance databases and information systems, Global Regulatory Framework and Guidelines

International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines, World Health Organization (WHO) guidelines and programs, National regulatory authorities, and their roles in pharmacovigilance.

UNIT 2. Adverse Drug Reaction (ADR) Reporting and Data Collection 15 Hours

ADR reporting methods, data collection and sources of ADR reporting: spontaneous reporting, clinical trials, literature, and electronic health records, Signal detection and data mining techniques, Adverse Event Assessment and Causality Assessment.

Causality assessment methods: WHO-Uppsala Monitoring Centre (UMC) criteria, Naranjo algorithm, Severity assessment and seriousness criteria, Quality assessment of ICSR

UNIT 3. Pharmacovigilance in Special Populations **15 Hours**

Pediatric pharmacovigilance: challenges and considerations, Geriatric pharmacovigilance: age-related changes and medication safety, Pharmacovigilance in pregnancy and lactation, Pharmacovigilance in Drug Development and Clinical Trials, Pre-marketing safety assessment and clinical trial safety monitoring, Role of the clinical research team in pharmacovigilance, Reporting of serious adverse events (SAEs) in clinical trials.

UNIT 4. Pharmacovigilance in the Real-World Setting 15 Hours

Post-marketing surveillance and real-world evidence, Pharmacoepidemiology and observational studies in pharmacovigilance, Role of healthcare professionals and patients in pharmacovigilance, Pharmacovigilance Challenges and Future Trends, Challenges in signal detection and benefit-risk assessment

Pharmacovigilance in the era of big data and artificial intelligence, Emerging trends, and future directions in pharmacovigilance

UNIT 5. Vaccine safety surveillance and Materiovigilance 15 Hours

Vaccine pharmacovigilance, vaccination failure, adverse events following immunization

Pharmacovigilance methods passive surveillance – spontaneous reports and case series, stimulated reporting, active surveillance – sentinel sites, drug event monitoring and registries, comparative observational studies – cross sectional study, case control study and cohort study, targeted clinical investigations

Materiovigilance, Hemovigilance, Identification and reporting of medication errors, Communication in Pharmacovigilance

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References and Textbooks

1. Mann, R.D., and Andrews, E.B. eds., 2007. Pharmacovigilance. John Wiley & Sons.
2. Waller, P. and Harrison-Woolrych, M., 2017. An introduction to pharmacovigilance. John Wiley & Sons.
3. Andrews, E.B. and Moore, N. eds., 2014. Mann's pharmacovigilance. John Wiley & Sons.
4. Nour, S. and Plourde, G., 2018. Pharmacoepidemiology and pharmacovigilance: Synergistic tools to better investigate drug safety. Academic Press.
5. Plotkin, S.A., Orenstein, W. and Offit, P.A., 2012. Vaccines E-book. Elsevier Health Sciences.
6. Mal, D.K., Ehsan, I. and Mukherjee, B., MATERIOVIGILANCE and HAEMOVIGILANCE.

Modes of Evaluation: Quiz/Assignment/Presentation/ Written Exam/ Examination Scheme: Continuous Assessment- 50%, mid semester examination - 20% and End term examination - 30%

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