GALGOTIAS UNIVERSITY

(Established under Galgotias University Uttar Pradesh Act No. 14 of 2011)

School of Biological and Biomedical Sciences

Course: M. Sc. Clinical Research

Scheme: 2019 – 2021

Curriculum

Semester 1

Sl. No	Course Code	Name of the Course					Assessment Pattern		
			L	T	P	C	IA	MTE	ETE
1	MCRT1001	Clinical Research Overview	3	0	0	3	20	50	100
2	MCRT1002	Pharmacology-1	4	0	0	4	20	50	100
3	MCRT1003	Drug Discovery and Development	3	0	0	3	20	50	100
4	MCRT1004	Therapeutic review of disease	3	0	0	3	20	50	100
5	MCRT1005	Biostatistics -1	3	0	0	3	20	50	100
6	MCRT1006	Advanced Microbiology and Biochemistry	3	0	0	3	20	50	100
7	MCRP1051	Hands-on Training-I	0	0	16	8	20	00	100
		Total	**19**	**0**	**16**	**27**			

Semester II

Sl No	Course Code	Name of the Course					Assessment Pattern		
			L	T	P	C	IA	MTE	ETE
1	MCRT2001	Regulatory affairs and Ethics in Clinical Research	4	0	0	4	20	50	100
2	MCRT2002	Pharmacology-II	4	0	0	4	20	50	100
3	MCRT2003	Biostatistics –II	3	0	0	3	20	50	100
4	MCRT2004	Pharmacovigilance- 1	3	0	0	3	20	50	100
5	MCRT2005	Research Methodology	3	0	0	3	20	50	100
		Elective:							
6	(I)MCRT2006	Epidemiological Principles in Clinical Research (E)	3	0	0	3	20	50	100
7	(II)MCRT2007	Introduction to IPR and Patenting (E)	3	0	0	3	20	50	100
		Total	**23**	**0**	**0**	**23**			

Semester III

Sl No	Course Code	Name of the Course					Assessment Pattern		
			L	T	P	C	IA	MTE	ETE
1	MCRT3001	Pharmacovigilance-II	3	0	0	3	20	50	100
2	MCRT3002	Designing Clinical Trials	4	0	0	4	20	50	100
3	MCRT3003	Clinical Data Management	3	0	0	3	20	50	100
4	MCRT3004	Advance Medical Writing	3	0	0	3	20	50	100
	MCRT3005	Operational aspects of clinical research	3	0	0	3	20	50	100
		Elective							
6	MCRT3006	Management of Clinical Research Project and Outsourcing (E) or	4	0	0	4	20	50	100
7	MCRT3007	Quality Control, Quality Assurance and Total Quality Management in clinical trial (E)	4	0	0	4	20	50	100
		Total	**24**	**0**	**0**	**24**			

Semester IV									
Sl No	**Course Code**	**Name of the Course**					**Assessment Pattern**		
			L	**T**	**P**	**C**	**IA**	**MTE**	**ETE**
1	**MCRT4001**	Clinical project and dissertation	0	0	40	20	20	00	100
		Total	**0**	**0**	**40**	**20**			

List of Electives

Basket-1

Sl No	**Course Code**	**Name of the Electives**					**Assessment Pattern**		
			L	**T**	**P**	**C**	**IA**	**MTE**	**ETE**
1	MCRT 2006	Epidemiological Principles in Clinical Research (E)	3	0	0	3	20	50	100
2	MCRT 2007	Introduction to IPR and Patenting (E)	3	0	0	3	20	50	100

Basket-2

Sl No	**Course Code**	**Name of the Electives**					**Assessment Pattern**		
			L	**T**	**P**	**C**	**IA**	**MTE**	**ETE**
1	MCRT3006	Management of Clinical Research Project and Outsourcing (E) or	4	0	0	4	20	50	100
2	MCRT3007	Quality Control, Quality Assurance and Total Quality Management in clinical trial (E)	4	0	0	4	20	50	100

Detailed Syllabus

Name of The Course	CLINICAL RESEARCH OVERVIEW			
Course Code	MCRT1001			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	3	0	0	3

Course Objectives:

Students will get exposure about the need and scope of clinical research and the areas of clinical research. They will learn about different phases of clinical research.

Course Outcomes

CO1	Understand about basic concepts of Clinical Research.
CO2	understand the historical perspective of clinical research
CO3	understand different phases and types of clinical Trials
CO4	Perform Intellectual property rights with major emphasis on patents for protection of IP
CO5	Understand about the bioequivalence and bioavailability (BA/BE) studies.

Text Book (s)

1. Guide to Clinical Trials (Volume-I &II), ICRI
2. LachmanL,Liberman H.A and Kanig J.L., "Theory and Practice of Industrial Pharmacy", Lea and Febiger.

Reference Book (s)

1. Clinical trials: a practical approach. John Wiley 1983, by Pocock SJ
2. Clinical trials. Remedica 2006, by Wang D and Bakhai A (Ed)

Course Contents

Unit-1: Introduction **9 hours**
Definition of Clinical research, Terminologies & definitions used in Clinical Research, Difference between Clinical Research and Clinical practice, Glossary of GCP. Historical Aspects of clinical research, Brief description of different phases, Stakeholders in clinical research, Need and scope of clinical research, Areas of clinical research, career opportunities in clinical research
Unit-2: The Historical Prospective of Clinical Research **9 hours**
A Brief History of Clinical Research, Sulphanilamide Tragedy, Thalidomide Disaster, Nazi Experiments, Tuskegee Study, Belmont Report, Nuremberg Code, Declaration of Helsinki Principles, ICH guidelines History, Structure, Process.
Unit-3: Types and Phases of Clinical Trial **9 hours**
Introduction to Clinical Trials –Types of Clinical Trial - Randomized trial, open label study double blind, single blind, matched pair study, cross over trial, case control study, cohort study, equivalence trials, superiority trials and non-inferiority trials Phases of developmental clinical trials, Phase 0, Phase I-IV Phase I –aims of phase I – selection of volunteers- informed consent-protocol –design of study;

Phase II- Therapeutic exploratory, objectives of phase II; Phase IIa; Phase IIb; its regulatory requirements. Phase III- Therapeutics confirmatory – Objectives of phase III- design of Phase III, protocol-regulatory requirements; Phase IV – purpose, types, study design for observational studies, PMS Placebo response, advantage and disadvantages of Placebo
Unit-4: Pharmaceutical Industry and Globalization 9 hours
Overview, Opportunities & Career options in Clinical Research, Overview of global and local players, what are the advantages of conducting Clinical Research in India. Intellectual Property Rights: Introduction, Scope, Objectives of IPR in pharmacy, Indian legal system & its role in IPR; Concept of property with respect to intellectual creativity; Tangible & Intangible property, concept of IPR, scope & nature of patents, copyrights, trade mark, geographical limitations; Indian Patent Act 1970, Patenting in India & abroad, practical aspects of patent filing, components of a patent application in India.
Unit-5: BA/BE Studies 9 hours
Bioavailability and Bioequivalence – Definition, Needs, Methods and Procedures, factors affecting Bioavailability Bioequivalence/ Therapeutic Equivalence, Study parameters: Tmax, Cmax, AUC, t1/2, Test method to assess Bioequivalence, Steady State studies, regulatory requirements, planning & design, Protocol/ CRF outline, QA & QC, Drug accountability, Elements of BE study, Facilities for conducting BA-BE study

Continuous Assessment Pattern

Internal Assessment (IA)	Mid Term Test (MTE)	End Term Test (ETE)	Total Marks
20	30	50	100

Name of The Course	Pharmacology -I Theory (40 Hours)			
Course Code	MCRT1002			
Prerequisite				
Corequisite				
Antirequisite				
	L	**T**	**P**	**C**
	4	0	0	4

Course Objectives:

Students will get exposure about the need and scope of clinical research and the areas of clinical research. They will learn about different phases of clinical research.

Course Outcomes

CO1	the definition of pharmaco-therapeutics, clinical pharmacology and nomenclature related to pharmacology
CO2	different routes of drug administration, rational/irrational prescribing and fixed dose combination
CO3	Different dosage forms of drugs, their advantage and disadvantages
CO4	principle and mechanism of drug action, factors modifying drug action
CO5	the concept of ADME, bioavailability of drug, receptor and protein blinding

Text Book (s)

1. Elements of Pharmacology by Dr Ramesh Goyal, Dr. Anita Mehta.
2. Color Atlas of Pharmacology Ebooks by Heinz Lullmann, Kaus Mohr, Luts Hein,
3. Basic and Clinical Pharmacology by Katzung B
4. Pharmaceutical dosage form, YS Tawanr, AS Sharma

Reference Book (s)

1. Pharmacology by Brenner G
2. Principles of Pharmacology by Golan D

Course Contents

Unit-1 Introduction to Pharmacology **8 hour**
Definitions and brief, pharmaco-therapeutics, clinical pharmacology, chemotherapy, pharmacy and toxicology), drug Nomenclature (chemical name, non-proprietary name and proprietary name) and essential drugs concepts.
Unit-2 Drug Administration **8 Hours**
Route of Drug administration- Local routes (topical, deeper tissues and arterial supply etc.), Systemic routes (Oral, sublingual, rectal, cutaneous, inhalation, nasal, parenteral etc.), Novel Drug Delivery System, Sources of Drugs (Natural sources and synthetic sources). Rational prescribing, Irrational prescribing, Instruction to patients, Fixed Drug Combination: Advantages & disadvantages; Drugs used in Special Conditions.
Unit-3 Dosage Forms of Drug **8 Hours**

Definition and brief about the dosage forms – solid dosage forms (powder, tablets, capsules, lozenges, pills, cachets), liquid dosage forms (suspension, emulsion, elixirs, syrups, lotions, inhalations, eye drops, ear drops, enemas, mouth washes etc.), semisolid dosage forms (ointments, creams, pastes, gels, suppositories, etc.), sterile products (Injection, ophthalmic etc.), gas (aerosols, inhalations, sprays etc.) and novel drug delivery system (liposome, nanosome, nanoparticles, microspheres, osmotic pumps, transdermal, implants, intrauterine devices)
Unit-4 Pharmacodynamics 8 Hours
Principles of drug action and mechanism of drug action, dose response curve and adverse drug reaction, Agonists, Antagonists. Therapeutic Index Factors Modifying Drug Action, Body size, age, sex, species and race, genetics, environmental factors, psychological factor, pathological states, other drugs, cummulation, tolerance, etc
Unit-5: Pharmacokinetics 8 Hours
Absorption, Distribution, Metabolism, excretion (ADME), Bioavailability, receptor and Protein binding, Placental and blood brain barrier

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	Drug Discovery and Development Theory (40 Hours)			
Course Code	MCRT1003			
Prerequisite				
Corequisite				
Antirequisite				
	L	**T**	**P**	**C**
	3	0	0	3

Course Objectives:

Students will get exposure about the need and scope of clinical research and the areas of clinical research. They will learn about different phases of clinical research.

Course Outcomes

CO1	Understand about concepts ofDrug Discovery and Development, need for new drug and lead identification
CO2	Understand the concept of pre-clinical evaluation, drug screening type of evaluation
CO3	Clinical safety data management, guidelines on carcinogenicity testing
CO4	Understand about development process of medical device
CO5	Understand about development process of clinical diagnostic, cosmetics and their regulatory aspects

Text Book (s)

1. Pharmaceutical Biotechnology by O Kayser, R H Muller
2. Principles and Practice of Pharmaceutical Medicine, 3rd Edition. Lionel D. Edwards, Anthony W. Fox, Peter D. Stonier. Publisher: Wiley-Blackwell.

Reference Book (s)

1. Methodology of Clinical Drug Trials, 2nd Edition. Spriet A., Dupin-Spriet T., Simon P. Publisher: Karger.
2. Clinical trials. Remedica 2006, by Wang D and Bakhai A (Ed)

Course Contents

Unit-1 Evolution of new drugs **8 Hours**
Need for a new Drug, Lead identification, Sources of new drugs and compounds for screening as a potential drug, Drug development process.Drug design-Ligand based, Structure based, Active site identification, rational drug discovery High throughput screening, Structure Activity Relationship (SAR), Quantitative Structure Activity Relationship (QSAR), Computer assisted drug designing (CADD)
Unit-2: Preclinical evaluation -I **8 Hours**
Drug screening, types of evaluation, animal pharmacology, Non clinical overview and non clinicalsummaries(M4S(R2)), Non clinical safety studies(M3(R1)), Guidance on non clinicalsafety studies for the conduct of Human clinical trials and marketing authorization, Dose response information to support drug registration(E4)
Unit-3: Preclinical evaluation 2 **8 Hours**

Clinical safety data management, guideline on the need of carcinogenicity studies of pharmaceuticals(S1A), Toxicity Studies, Duration of chronic toxicity testing in animals (rodent and non rodent toxicity testing (S4), safety pharmacology studies for human pharmaceuticals (S7A)
Unit-4: Medical Device and Vaccines 8 Hours
Global Regulations for Medical Devices, Classification of medical Devices, Regulatory agencies and regulations, Clinical Trials of Medical Devices; Global Medical Device Nomenclature, Product lifecycle of medical devices. Quality Risk Management of Medical Devices: ISO 14971, Validation and Verification of Medical device
Unit-5: Clinical Diagnostics and Cosmetics 8 Hours
Objective, scope, definitions, clinical diagnostic, cosmetics and regulatory requirement. Global regulation for cosmetics.

Continuous Assessment Pattern

Internal Assessment (IA)	Mid Term Test (MTE)	End Term Test (ETE)	Total Marks
20	30	50	100

Name of The Course	**Therapeutic Review of Disease**				
Course Code	MCRT1004				
Prerequisite					
Corequisite					
Antirequisite					
		L	**T**	**P**	**C**
		3	0	0	3

Course Objectives:

Student will get knowledge about therapeutic review of different diseases and its management

Course Outcomes

CO1	Understand about basic concepts of Gastrointestinal diseases
CO2	understand the Respiratory system and diseases associated with it
CO3	understand the cardiovascular system and associated diseases
CO4	Understand the endocrine system
CO5	Understand about the Nervous System and musculoskeletal system

Text Book (s)

1. Handbook of Pathophysiology by Joan P Frizzell
2. Anatomy and Physiology in Health and Illness by Anne Waugh, Allison Grant

Reference Book (s)

1. Principles of Pharmacology by Golan D
2. Pharmacology for the Health Care Professions Ebook by Christine M Thorp

Course Contents

Unit-1: GIT	**8 Hours**
Hyperacidity, peptic ulcer, GERD, Chrohn's disease, Jaundice, Hepatitis	
Unit-2 Respiratory system	**8 Hours**
Introduction to upper and lower respiratory disorder, Asthma, COPD, Tuberculosis, Pneumonia, DIPD	
Unit-3: Cardiovascular System	**8 Hours**
Hypertension, Angina, Ischemic heart Disease, MI, Congestive heart failure, Arrhythmia	
Unit-4: Endocrine System	**8 Hours**
Diabetes, Hypo/hyper Thyrodism, Cushings syndrome	
Unit-5: Nervous System and musculoskeletal system	**8 Hours**
Epilepsy, Parkinson, Alzheimer's, Migraine, Anxiety	

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	**Biostatistics-I**			
Course Code	MCRT1005			
Prerequisite				
Corequisite				
Antirequisite				
	L	**T**	**P**	**C**
	3	0	0	3

Course Objectives:

Students will get exposure about the knowledge of Biostatistics and its application in clinical research. Student will be able to understand the concept of presentation of Data

Course Outcomes

CO1	Understand about concepts of Biostatistics and its application in the clinical research
CO2	Understand the concept of sampling
CO3	Understand about presentation and uses and presentation of Data
CO4	Understand the measure of central tendency and dispersion
CO5	Know and understand correlation, regression and time series analysis

Text Book (s)

1. Biostatistics: The Bare Essentials by Norman G
2. Introduction to Statistics in Pharmaceutical Clinical Trials by Todd A Durham & J Rick Turner

Reference Book (s)

1. Pharmaceutical statistics; Practical and Clinical Application by Sanford Bolton

Course Contents

Unit-1: Introduction to Biostatistics & its role in Clinical Research 8 Hours
Objectives, scope, Introduction biostatistics, terminology and application in research studies
Unit-2: Basic knowledge about presentation of Data 8 Hours
Type of diagram, one dimensional diagram, two dimension diagram, three dimensional, pie diagram and pictogram, Histogram, frequency, polygon and frequency curve
Unit-3: Sampling 7 Hours
Definition, selection of samples, merit and limitation of sampling, methods of sampling.
Unit-4: Measures of central tendency and Dispersion 9 Hours
Mean, median, mode and relation between arithmetic mean, geometric mean and harmonic mean, Mean deviation, advantage and disadvantage of mean deviation, coefficient of mean deviation, standard deviation, application of standard deviation and coefficient of variation.
Unit-5: Correlation, Regression and Time Series Analysis 8 Hours
Definitions: Correlation, Regression, Correlation analysis, estimation of regression line. Time series analysis: Variations in time series, trend analysis, cyclical variations, seasonal variations and irregular variations.Chi-square test and t-test

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	Advanced Microbiology and Biochemistry			
Course Code	MCRT1006			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	3	0	0	3

Course Objectives:

Students will get exposure about the knowledge of clinical aspect of Microbiology and Biochemistry

Course Outcomes

CO1	about concepts of Microbiology, growth and control of microbes
CO2	the clinical aspect of clinical Microbiology, Host parasite interaction: Microorganisms
CO3	the clinical aspect of clinical Microbiology
CO4	carbohydrate, lipid and protein, their biomedical importance
CO5	importance of micronutrients, Glycemicstatus, biochemical evaluation of different diseases

Text Book (s)

1. Medical Microbiology, Edited by Greenwood, D, Slack, R and Peutherer, J, ELST Publishers

Reference Book (s)

1. Bailey & Scott's Diagnostic Microbiology, Betty A. Forbes , Daniel F. Sahm, Alice S. Weissfeld , Ernest A. Trevino, Published by C.V. Mosby

Course Contents

Unit-1 : Basic Microbiology **8 Hours**
Science of Microbiology, Structure of Prokaryotic cell and virus, methods in Microbiology viewing, measuring, culturing and preservation of microorganisms. Grwoth of microbes: Growth type/rate/Phases, Nutrients for microbes and their transfer Control of microorganism: Death rate, sterilization, Physical control, Chemical control
Unit-2: Clinical Microbiology **8 Hours**
Host parasite interaction: Microorganisms, and human diseases-properties and capacities of selected pathogens, basic aspects of immune systems, Diagnostic immunology, and prevention of microbial diseases
Unit-3: Chemistry of Bio-organic Molecules **8 Hours**
Carbohydrates: Definition, biological importance and classification. Monosaccharides – isomerism, anomerism. Sugar derivatives, Disaccharides. Polysaccharides. Structures of starch and glycogen. Lipids: Definition, biological importance and classification. Fats and fatty acids. Introduction to compound lipids. Hydrophobic and hydrophilic groups. Cholesterol. Bile salts. Micelle. Bimolecular leaflet. Proteins: Biological importance. Aminoacids: Classification. Introduction to peptides, Proteins: Simple and conjugated; globular and fibrous. Charge properties. Buffer action. Introduction to

protein conformation: Denaturation. Nucleic acids: Building units. Nucleotides. Outline structure of DNA and RNA. High energy compounds: ATP, Phosphorylamidines, Thiolesters, Enol phosphates.
Unit-4: Micronutrients 10 Hours
Vitamins: Definition, classification, daily requirement, sources and deficiency symptoms. Brief account of water-soluble vitamins with biochemical functions. Vitamins A functions including visual process. Vitamin D and its role in calcium metabolism. Vitamin E. Vitamin K and gamma carboxylation. Introduction to antivitamins and hypervitaminosis. Minerals: Classification, daily requirement. Calcium and phosphate: sources, uptake, excretion, function. Serum calcium regulation. Iron: sources, uptake and transport. Heme and nonheme iron functions; deficiency. Iodine: Brief introduction to thyroxine synthesis. General functions of thyroxine. Fluoride: function, deficiency and excess. Indications of role of other minerals.
Unit-5: Clinical Biochemistry 6Hours
Glycemicstatus. Hyperthyroidism and hypothyroidism: Biochemical evaluation. Hyperlipoproteinemias and atherosclerosis, Approaches to treatment. Jaundice: Classification and evaluation. Liver function tests: Plasma protein pattern,serum enzymes levels. Brief introduction to kidney function tests and gastric function tests. Acid base imbalance

Continuous Assessment Pattern

Internal Assessment (IA)	Mid Term Test (MTE)	End Term Test (ETE)	Total Marks
20	30	50	100

Name of The Course	Practical and Hands-on Training-I			
Course Code	MCRP1051			
Prerequisite				
Corequisite				
Antirequisite				
	L	**T**	**P**	**C**
	0	0	16	8

Course Objectives:

Students will get practical exposure of a clinical set up, record keeping and bioethics

Course Outcomes

CO1	about basic instruments and laboratory equipment
CO2	Students will have some hands on training on blood and tissue sample collection,
CO3	Student will be exposed to some pharmacological and biochemical laboratory exercises relevant to clinical research
CO4	have exposure to biological sample handling, transport, storage, and archiving
CO5	have exposure to biological sample handling, transport, storage, and archiving

Course Contents

Unit-1: Visit to Hospital **8 Hours**
Patient's history and demographics, Medical record keeping, Bio-ethics –do's, don't's, confidentiality, cultural/social ethic
Unit-2: Visit to a Laboratory **8Hours**
Basic learning of operation of common laboratory equipment
Unit-3: Pre-clinical screening of drug **8 Hours**
Demonstration of routes of administration of drugs, Demonstration of some non-invasive techniques in pre-clinical screening of drug
Unit-4: Visit to Clinical trial site **8 Hours**
Visit to clinical trial site /SMO/National Medical library
Unit-5: Visit to clinical research organization **8 Hours**
Visit to sponsors companies-Pharmaceutical /Medical /Diagnostical/ surgical

Continuous Assessment Pattern

Internal Assessment (IA)	Mid Term Test (MTE)	End Term Test (ETE)	Total Marks
20	00	80	100

Name of The Course	Regulatory Affairs and Ethics in Clinical Research			
Course Code	MCRT2001			
Prerequisite				
Corequisite				
Antirequisite				
	L	**T**	**P**	**C**
	4	0	0	4

Course Objectives:

Students will get exposure about the ethical concepts clinical research and the process of evolution of regulatory control in clinical trial

Course Outcomes

CO1	about the ethical aspects important to sound clinical research
CO2	importance of IRB/IEC, Independent Ethic committees, Ethic review
CO3	Understand the operational imperatives of Good Clinical Practices
CO4	Evolution of regulatory control, ICH-GCP, ICMR requirement
CO5	international regulatory bodies and guidelines

Text Book (s)

1. Guide to Clinical Trials (Volume-I &II), ICRI
2. Good Clinical Practice by Josef Kolman, Paul Meng

Reference Book (s)

1. Guideline for Drug Regulatory Submissions by Sandy Welnberg
2. International Pharmaceutical Registration by Alan A Chalmers

Course Contents

Unit-1: Ethic in clinical research **8Hours**
Evolution of ethic in clinical research, Tuskegee experiment, Nuremberg code, Declaration of Helsinki, Belmont report, Establishment of CIOMS, NIH, and ICMR guidelines, Legal liability in clinical research, negligence, strict liability, criminal liability, legal obligations of a investigator, compensation to subjects/patients for clinical trial related injuries
Unit-2; Overview of IRB/IEC/ERB **8Hours**
Independent Ethic committees, Ethic review procedures, importance of inform consent document, patient information sheet, and inform consent form, Fraud and misconduct, detection of fraud in clinical research. Ethics in academia, violation of ethic in clinical research, HIPAA
Unit-3: Evolution of regulatory control **8 Hours**
Evolution of regulatory control: An international comparison, Pure food and drug act, drug and cosmetic act 1945, thalidomide disaster, Kafauvers Harris amendment act, Waxman hatch act, Evolution of ICH, NICE. Introduction to ICH-International Conference on Harmonization of technical requirements for registration of Pharmaceuticals for human use guidelines Milestones in the evaluation of GCP
Unit-4: Applicable GCP Guidelines, IND and NDA **8 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

IND Application :requirements forms , contents, application , Investigator IND, Treatment IND , Emergency use of IND. NDA application: contents , forms , review process, actions, Guidance documents for IND and NDA, Common Technical Document: Purpose , structure and contents
Unit-5: International Regulatory bodies and Guidelines: 8 Hours
US Food and Drug Administration(USFDA): 21CFR 50,316,314The FDA and Food Drug and Cosmetics Act, New drug development and approval : the principal steps. India: Regulatory laws, Schedule Y, registration of new drugs, requirements for registration, regulatory environment and practices, Indian GCP, CTRI Medicines and Healthcare Products Regulatory Agency (MHRA): Overview of regulatory environment/ background, regulatory authorities, regulatory requirements and procedures. European Agency for Evaluation of medicinal Products(EMEA): National registration , the decentralized procedures, mutual recognition procedures. Brazil: Overview of regulatory affairs.

Continuous Assessment Pattern

Internal Assessment (IA)	Mid Term Test (MTE)	End Term Test (ETE)	Total Marks
20	30	50	100

Name of The Course	Pharmacology -II			
Course Code	MCRT2002			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	4	0	0	4

Course Objectives:

Students will get exposure about the drugs and their mechanism of action acting on different body organ system

Course Outcomes

CO1	different drugs acting on central nervous system
CO2	different drugs acting on autonomic nervous system
CO3	different drugs acting on cardiovascular system
CO4	Anti-hypertensive drugs and their mechanism of action
CO5	Drugs acting on respiratory system

Text Book (s)

1. Essentials of Medical Pharmacology, K.D Tripathi
2. The Pharmacological Basics of Therapeutics, 5th edition, Goodman and Gillman

Reference Book (s)

1. Basic and Clinical Pharmacology, Bertram G. Katzung

Course Contents

Unit-1: Drugs acting Central Nervous System(CNS) 8 Hours
General anesthetics, anxiolytics and hypnotics drugs, anti depressants, CNS stimulants and psychotomimetic drugs, Opioid analgesics and opioid anatagonists, Drug dependence and drug abuse, Antiepileptic drugs, Drug therapy for neurodegenerative disorders like parkinson's disease and schizophrenia.
Unit-2: Drugs acting on Autonomic Nervous System (ANS) 8Hours
General introduction, Parasympathomimetic, parasympatholytic, Sympathomimetic, sympatholytic agents, Ganglionic stimulants, blockers and adrenergic neuron blocking drugs, local anesthetics
Unit-3: Drugs acting on Cardiovascular System (CVS) 8 Hours
Cardiac glycosides and positive ionotropic agents, Anti-arrhythmic drugs, Antihypertensive drugs, Coronary vasodilators and drugs used in angina, Anti-hyperlipidemic drugs, Fibrinolytic agents, Cardioprotective agents, Anti-anginal agents.
Unit-4: Antihypertensives: 8 Hours
Overview, classification of antihypertensive drugs- Diuretics, Sympatholytics, angiotensin inhibitors, vasodilator, dopamine agonists
Unit-5: Drugs acting on Respiratory System and NSAIDS 8 Hours
Expectorants, Anti-tussive bronchodilators, Drugs used in common cold. Classification of NSAIDS, Mechanism of action , NSAIDSwhich do not inhibit prostaglandin synthesis.

Continuous Assessment Pattern

Internal Assessment (IA)	Mid Term Test (MTE)	End Term Test (ETE)	Total Marks
20	30	50	100

Name of The Course	Biostatistics -II			
Course Code	MCRT2003			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	3	0	0	3

Course Objectives:

Students will get exposure about the definition and rules for different statistical technique and its application in clinical research

Course Outcomes

CO1	Basic definition and rules for probability
CO2	Definition and Application Analysis of variance
CO3	different drugs acting on cardiovascular system
CO4	sampling distributions, sampling techniques
CO5	Hypothesis testing

Text Book (s)

1. Biostatistics, 1st Edition. Sai Subramanian. Publisher: Career Publications.

2. Pharmaceutical Biostatistics, 1st Edition. Shadab Ahmed Khan, Ismali, Ahmed and Husain. Publisher: Birla Publications.

Reference Book (s)

1. Biostatistics for Pharmacy, 1st Edition. Khan and khanum. Publisher: Ukaaz Publication.

2. Basic & Clinical Biostatistics, 4th Edition. Beth Dawson, Robert G. Trapp. Publisher: Lange

Course Contents

Unit-1:Probability **8 Hours**
Basic definitions and rules for probability, conditional probability Independent of events, Baye's Theorem, random variables, Probability distributions: Binomial, Poisson, Uniform and Normal Distributions.
Unit-2: Parametric tests **8 Hours**
Definition and Application Analysis of variance-One Way and Two Way a) McNemar's test b) Exact probability test
Unit-3: Non-Parametric tests **8 Hours**
Definition and Application Sign test for paired data. Rank sum test: Mann –Whitney U test and Kruskal Wallis test. One sample run test, Rank correlation. Chi-square tests for independence of attributes and goodness of fit Rank score tests:a) Wilcoxon signed rank test, b) Wilcoxon two sample rank test, c) The Mann Whitney Test, d) The Spearman Test, e) The Friedman Test. F-test – testing of two population variances, Study design and choosing a statistical test Design
Unit-4: Sampling Distribution and Estimation **8 Hours**
Introduction to sampling distributions, sampling techniques, sampling distribution of mean and proportion, application of central limit theorem. Estimation: Point and Interval estimates for population parameters of large sample and small samples, determining the sample size.

Unit-5: Testing of Hypothesis	**8 Hours**
Hypothesis testing: one sample and two samples tests for means and proportions of large samples (z-test), one sample and two sample tests for means of small samples (t-test), F-test for two sample standard deviations.	

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	**Pharmacovigilance -I**

Course Code	MCRT2004				
Prerequisite					
Corequisite					
Antirequisite					
	L	**T**	**P**	**C**	
	3	0	0	3	

Course Objectives:

Students will get exposure about the need and scope of drug safety reporting.

Course Outcomes

CO1	Need and scope of Pharmacovigilance, historical aspect of Pharmacovigilance, thalidomide tragedy
CO2	Adverse drug reaction, different classification of ADR, severity and seriousness criteria
CO3	ADR reporting, spontaneous/solicited reporting system, advantages and disadvantages
CO4	Different Pharmacovigilance method, Active and passive surveillance
CO5	Risk benefit assessment of drug, Actual v/s perceived Risk and benefits, Factors affecting benefit risk balance

Text Book (s)

1. Pharmacovigilance for Beginners –Dr. S. Gunasakaran and R.Salhesh Kumar TatamaniMagalirCo-Operative Press, 2010 edition.

2. Textbook of Pharmacovigilance ICRI Institute of Clinical Research (India)

Reference Book (s)

1. Highlights of Pharmacovigilance – P.G Yeolo ,DhanalakshmiIyer, 2013 edition.

Course Contents

Unit-1: Introduction to Pharmacovigilance 6 Hours
Definitions, Overview and Scope, Importance, History: Pre Thalidomide era, Thalidomide Disaster and Post Thalidomide Era; Pharmacovigilance Current Status and Systems; Pharmacovigilance need and Objectives; Drugs withdrawn from the Market; Vioxx saga. WHO Drug monitoring Programme and Uppsala Monitoring centre. Pharmacovigilance Regulations in India and national PV policy and programme. National and international scenario, Pharmacovigilance global perspective
Unit-2: Introduction to adverse drug reaction 8 Hours
Definitions and classification of ADRs Detection and reporting, Causality assessment, Severity and seriousness assessment, Predictability and preventability assessment, Management of adverse drug reactions
Unit-3: Adverse drug reaction reporting 8 Hours
Introduction to reporting systems; Spontaneous reporting system; Reporting to regulatory authorities; Guidelines for reporting ADRs in biomedical literature.
Unit-4: Pharmacovigilance Methods 8 Hours
Passive Surveillance, Active Surveillance and Stimulated Reporting. PMS Methodologies - Comparative Observational studies, Descriptive Studies, Drug Utilization Studies, Case studies, Cohort studies, Vaccine safety surveillance studies
Unit-5: Benefit Risk Assessment 8 Hours

Actual v/s perceived Risk and benefits, Factors affecting benefit risk balance; Methods of Risk Minimization, Pharmacovigilance Planning. International Expedited reporting ; Pharmacovigilance Planning Guideline

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	Research Methodology			
Course Code	MCRT2005			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	3	0	0	3

Course Objectives:

Students will get exposure about the different research methodology

Course Outcomes

CO1	Methodology and types of research, Types of research- Descriptive vs. Analytical, Applied vs. Fundamental, Quantitative vs. Qualitative
CO2	Sampling and analysis, Discourse analysis, Biographical Data Analysis, Primary and secondary data, Collection and validation
CO3	Experimental design and hypothesis, Factorial experimental design, Designing experiments, Basic principles- replication,randomization
CO4	Computer application in research, Introduction to spread sheet application, Features and functions, Using formulas and functions, Data storing, Features for Statistical data analysis
CO5	Research report writing, Type of research report- contents, Steps in drafting, Editing and evaluating the final draft

Text Book (s)

1. Research Methodology, CR Kothari

Reference Book (s)

1.. Responsible Conduct of Research, Adil E. Shamoo

Course Contents

Unit-1: Introduction to Research **8 Hours**
Methodology and Method, Types of research- Descriptive vs. Analytical, Applied vs. Fundamental, Quantitative vs. Qualitative, Conceptual vs. Empirical, Concept of Interdisciplinary Research, Procedures in research, Identification of the problem-Literature survey, Experimental methods, Quasi-experimental studies- Survey, Types of surveys- CATI, CAPI, Mail, Email, Face-to-face, Questionnaire
Unit-2: Sampling and Analysis **8 Hours**
Discourse analysis, Biographical Data Analysis, Primary and secondary data, Collection and validation, Methods of sampling- Simple random sampling, Stratified random sampling and Systematic sampling, Attitude Measurement- land Scales, Scaling of attitude, Deterministic attitudes, Measurement models, Summative models.
Unit-3: Experimental design and Hypothesis **8 Hours**
Factorial experimental design, Designing experiments, Basic principles- replication,randomization, blocking. Single Factor Experiment: Hypothesis design, Hypothesis testing using z- test, t-test, ANOVA etc., Analysis of Variance Components (ANOVA) for fixed effect model, Sum of squares of treatments (SST), Sum of squares of error (SSE),Degrees of freedom, Confidence interval, ANOVA for random effects model, Model adequacy checking.
Unit-4: Computer Application **8 Hours**

Introduction to spread sheet application, Features and functions, Using formulas and functions, Data storing, Features for Statistical data analysis, Generating charts/ graph and other features, Power point presentation, Use of software for statistical analysis such as SPSS
Unit-5: Research Report **8 Hours**
Type of research report- contents, Steps in drafting, Editing and evaluating the final draft,Styles for figures, tables, text, quoting of reference and bibliography, Use and format of appendices- Indexing, Structure and presentation of research report, Research ethics, plagiarism, Reading and writing research paper

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	Epidemiological principles in clinical research			
Course Code	MCRT2006			
Prerequisite				
Corequisite				
Antirequisite				
	L	**T**	**P**	**C**
	3	0	0	3

Course Objectives:

Students will get exposure about the need and scope of Epidemiology in clinical research

Course Outcomes

CO1	Scope of epidemiology, Definition, descriptive and analytical epidemiology, contribution to population health
CO2	Measures of association: definition and calculation of risk ratio, Measures of association: definition and calculation of risk ratio, Measures of population impact
CO3	about ecological and geographical studies, Uses and interpretation of ecological studies, advantages and disadvantages of ecological investigation
CO4	Routine data source, Registries and record linkage, mortality, socio-demographic information
CO5	Human genome project, Introduction to the concepts, principles, and use of molecular and genetic methods in epidemiology genetic methods in epidemiology

Text Book (s)

1. Text Book of Preventive and Social Medicine — Park

2. Epidemiology & Management of Health Care for all-P.V. Sathe& A.P. Sathe

3. Biostatistics for Pharmacy, 1st Edition. Khan and khanum. Publisher: Ukaaz Publication.

4. Basic & Clinical Biostatistics, 4th Edition. Beth Dawson, Robert G. Trapp. Publisher: Lange.

Reference Book (s)

1. Element of Health Statistics-Rao NSN

Course Contents

Unit-1: Scope of epidemiology **6 Hours**
Definition, descriptive and analytical epidemiology, contribution to population health, Measures of disease frequency: definition and calculation of prevalence, incidence, risk, rate, basic and net reproductive rate, choosing suitable measures, limitations of case and population definitions, and their impact on measures of disease frequency
Unit-2: Measures of disease occurrence and association **9 Hours**
Measures of association: definition and calculation of risk ratio, rate ratio, odds ratio, absolute risk and rate differences, choosing suitable measures. Measures of population impact: definition and calculation of population attributable risk and fraction, assumptions and limitations of these measures.

Measures of dynamics of infectiousness: transmissibility of infectious disease, definition and calculation of the net reproduction rate and the basic reproduction rate, infection and transmissibility periods, general dynamics of infection
Unit-3: Ecological/geographical studies 9 Hours
Uses and interpretation of ecological studies, advantages and disadvantages of ecological investigation, ecological fallacy and ecological bias. Case control studies: retrospective, prospective/nested study design. Cohort studies: cross-sectional, retrospective and prospective cohort study design. Intervention studies and RCTs: characteristics, confounding and bias, randomization. Migrant studies: design strategies
Unit-4: Routine data sources 8Hours
Registries and record linkage, mortality, socio-demographic information Disease trends and standardization: direct and indirect, standardised mortality ratio, proportional mortality ratio. Random error/chance: samples size and statistical power, type I and II errors, regression dilution, confidence intervals
Unit-5: Human Genome Project 8 Hours
Introduction to the concepts, principles, and use of molecular and genetic methods in epidemiology and clinical research, Human Genome Project, Framework for interpreting, assessing, and incorporating molecular and genetic measures in research, Meaning of race, ethnicity, social class, and culture, their effects on the conduct and interpretation of clinical research, Pharmacogenomics and its application in clinical research, GWA

Continuous Assessment Pattern

Internal Assessment (IA)	Mid Term Test (MTE)	End Term Test (ETE)	Total Marks
20	30	50	100

Name of The Course	Introduction to IPR and Patenting			
Course Code	MCRT2007			
Prerequisite				
Corequisite				
Antirequisite				
	L	**T**	**P**	**C**
	3	0	0	3

Course Objectives:

Students will get exposure about basic and general concept of Intellectual property, patent laws copy right and trademarks.

Course Outcomes

CO1	Basic and general concept of Intellectual property
CO2	Requirement for Protecting Intellectual Property
CO3	Patent Laws Introduction to Copyrights and Trademarks
CO4	International copyright lawsoutine data source, Registries and record linkage, mortality, socio-demographic information
CO5	Trademark, Types of trademark and Laws

Text Book (s)

1. Text Book of Preventive and Social Medicine — Park

2. Epidemiology & Management of Health Care for all-P.V. Sathe& A.P. Sathe

3. Biostatistics for Pharmacy, 1st Edition. Khan and khanum. Publisher: Ukaaz Publication.

4. Basic & Clinical Biostatistics, 4th Edition. Beth Dawson, Robert G. Trapp. Publisher: Lange.

Reference Book (s)

1. Element of Health Statistics-Rao NSN

Course Contents

Unit-1: General concepts Intellectual Property Rights & International Institution (8Hours)
Intellectual Property overview and its theory, Requirement for Protecting Intellectual Property- a national and international comparison, Types of Intellectual Property- Origin and Development- An Overview,World Intellectual Property Organization (WIPO), Role of WIPO and its association with WTO, Commercialization of Intellectual Property Rights by Licensing, Financial values of IPR
Unit-2: Intellectual Property Rights (8 Hours)
Intellectual property rights-TRIPS, GATT-International conventions patents and methods of application of patents-Legal implications-Biodiversity and farmer rights Intellectual property rights-TRIPS, GATT-International conventions patents and methods of application of patents-Legal implications-Biodiversity and farmer rights
Unit-3: Patent Laws Introduction to Copyrights (8Hours)

Indian Patent Law, The Patents Act, 1970 and its amendments, Criteria for Patentability, Filing Patent Applications and its Granting procedure and Patent Infringement
Unit-4: International Laws (8Hours)
International Laws, Paris Convention and Patent Cooperation Treaty, WTO- TRIPS agreement, CBD, Indian copyright law, types of copyright etc., Types of trademarks, Indian trademark law etc
Unit-5: Trademarks (8Hours)
Types of trademarks, Indian trademark law etc

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	Pharmacovigilance-II			
Course Code	**MCRT3001**			
Prerequisite				
Corequisite				
Antirequisite				
	L	**T**	**P**	**C**
	3	0	0	3

Course Objectives:
Students will get exposure about the safety processing guidelines

Course Outcomes

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

CO1	Global safety monitoring system, Drug Safety Guidelines: ICH, WHO etc .PV in Europe, US, India, China
CO2	Case processing operation, Life cycle of a case – Data entry to evaluation, report generation, triage
CO3	Risk benefit assessment of drug, Actual Vs perceived Risk and benefits, Factors affecting benefit risk balance
CO4	Signal Management process, Signal generation, Sources and methods of Signal Detection
CO5	the process of setting up a Pharmacovigilance center

Text Book (s)

1. Highlights of Pharmacovigilance – P.G Yeolo ,DhanalakshmiIyer, 2013 edition

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Reference Book (s)

1. Textbook of Pharmacovigilance ICRI Institute of Clinical Research (India), 2011 April edition

Course Contents

Unit-1: Global Safety Monitoring Systems **9 hours**
Drug Safety Guidelines: ICH, WHO etc .PV in Europe, US, India, China, Australia, Japan. Regulations and guidelines of these countries .US FDA medwatch, UK Yellow card System. Adverse Event Case Processing; Case Processing Principles; Sources of Individual Case Safety Reports; format and content and compilation of PSURS worldwide, PBRER, PDUR
Unit-2: Case Processing Operations **9 hours**
Life cycle of a case – Data entry to evaluation, report generation, triage, case review and narrative writing. Case studies. Data entry terminology MEDRA, WHO ART , WHO DD, M1
Unit-3: Benefit Risk Assessment **9 hours**
Actual Vs perceived Risk and benefits, Factors affecting benefit risk balance; Methods of Risk Minimization, Pharmacovigilance Planning. International Expedited Reporting, Pharmacovigilance Planning Guidelines
Unit-4 : Signal Detection **9 hours**
Signal generation, Sources and methods of Signal Detection, Automated quantitative Signal Detection.UMC signaling Process. PV data base software (Aris, Argus etc for case report Management.
Unit-5: Setting up a Pharmacovigilance Centre **9 hours**
Initiation of Drug monitoring centre- challenges and Practicalities; Pharmacovigilance Centres in India; Crisis management for Pharmacovigilance.

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	DESIGNING OF CLINICAL TRIALS			
Course Code	**MCRT3002**			
Prerequisite				
Corequisite				
Antirequisite				
	L	**T**	**P**	**C**
	4	0	0	4

Course Objectives:
Students will get exposure about the designing of clinical trial, methodology of designing and importance of designing.

Course Outcomes

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

CO1	about basic concepts of designing & development
CO2	about mechanism and type of designing
CO3	Impact of designing in outcomes of clinical trials.
CO4	Importance of different tools used in designing
CO5	the importance of evaluation of outcome

Text Book (s)

3. Guide to Clinical Trials (Volume-I &II), DCGI
4. Modules of Clinical trial methodology and management, RHE Life Science (CRO)

Reference Book (s)

1. Clinical trials: a practical approach. John Wiley 1983, by Pocock SJ
2. Clinical trials. Remedica 2006, by Wang D and Bakhai A (Ed)

Course Contents

Unit-1: Introduction to clinical trial design **9 hours**
Overview and importance of clinical trial designing, title of study, terminologies, regulatory requirement for trial design, ethical consideration to develop clinical trial design.

Unit-2: Fundamentals of clinical trial design **9 hours**
Objectives of clinical trial design, types of designs- observational, interventional, prospective, retrospective, single and multicentric, randomization, nonrandomization, crossover design, parallel design, comparative design, non-comparative design, single arm, multiple arm, appropriate hypotheses(superiority, inferiority, non-inferiority, equivalency).
Unit-3: Planning & strategy of clinical trial design **9 hours**
Subject's recruitment, recruitment advertisement, and rule for subject withdrawal, eligibility of subject (inclusion and exclusion criteria), study procedure, recruitment period, treatment period, follow-up period, types of control groups including no control, placebo control, and active control, concomitant treatment, various way of randomization, various way of bias, blinding (open label, single blind, double blind, triple blind).
Unit-4 : Efficacy and safety assessment mechanisms **9 hours**
Objectives, definitions, Importance, description of efficacy methods and assessment parameters, baseline and endpoint measurements, description of safety and assessment methods, adverse event, serious adverse event, suspected adverse event, unexpected adverse event and reporting mechanisms.
Unit-5: Outcomes and analysis **9 hours**
Definition, scope, checklist, Scientifically sound study hypotheses, influence on design, intention to treat, subgroup analysis, interim analysis, scientific misconduct, description of access control, publication policy.

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	**Clinical Data Management**			
Course Code	**MCRT3003**			
Prerequisite				
Corequisite				
Antirequisite				
	L	**T**	**P**	**C**
	3	0	0	3

Course Objectives:
Students will get exposure about the need and scope of Clinical Data Management in Clinical Research

Course Outcomes

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

CO1	Basic concept of clinical data management
CO2	Quality control of clinical data
CO3	Data lock and Data base transfer
CO4	Query Management
CO5	Electronic data and lab data locking

Text Book (s)

1. Good Clinical Data Management Practices Committee, ICRI.

Reference Book (s)

1. Clinical Data Management, ICRI

Course Contents

Unit-1: Introduction to Clinical Data Management **9 hours**
Introduction to CDM, Computer system validation (CSV), Clinical Data Management flow, Data Management team, Roles and responsibilities of key team members and sponsor, SOPs of data Management, review and authorization. CRF design , Procedure for CRF design, elements of CRF, data points to be captured in individual CRFs. Database design and build ,Introduction to data base design and build, data base design, data base validation. Clinical data entry process, Data entry screen

validation, data entry process, symbols, data entering. Guidelines and regulations in Clinical Trial data.
Unit-2: Quality control of clinical data 9 hours
Terminology and definitions, quality control process, data errors and quality measurement, responsibilities, operational QC, data management matrix, QA in Clinical data management.
Unit-3: Database lock and data transfer 9 hours
Introduction to data base lock, minimum standards, procedure, errors found after database closure, freezing the data base, best practices, recommended Standard Operating Procedures. Introduction to data transfer, procedure, best practices.
Unit-4 : Query Management 9 hours
Role plays of real clinical research stake holders like Clinical research associate, investigator, project manager, volunteer, clinical research coordinator, auditor etc
Unit-5: Electronic data and lab data loading 9 hours
Electronic data interchange-Architecture for EDI, Advantages of using EDI, barriers to implementation, positives and negatives, Lab data loading -Roles and responsibilities of lab loader technician, helpdesk, study coordinator, -loading lab data, electronic/lab file contents, typical problems, lab data findings, Quality Assurance, SOPs for processing lab data, taking lab data seriously.

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	**Advance Medical Writing**			
Course Code	**MCRT3004**			
Prerequisite				
Corequisite				
Antirequisite				
	L	**T**	**P**	**C**
	3	0	0	3

Course Objectives:
Students will get exposure about the need and scope of Medical Writing and its importance in clinical research

Course Outcomes

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

CO1	Basic concept of evidence based medicine
CO2	Importance of medical writing in clinical research
CO3	Regulation and ethic in Medical writing
CO4	Types of medical writing and methodology
CO5	Documentation in Medical writing

Text Book (s)

1. Mastering Scientific and medical writing- Silvia M. Rogers , 2nd Edition.

2. Medical Writing: A Brief guide for beginners- Carol Scott-Conner ,Nov 2015.3. Biostatistics for Pharmacy, 1st Edition. Khan and khanum. Publisher: Ukaaz Publication.

Reference Book (s)

1. The Complete Guide to Medical Writing- Mark Stuart, 2007
2. Medical Writing, A guide for Clinicians, Educators, and Researchers-Robert B. Taylor, 3rd Edition.

Course Contents

Unit-1: Introduction to Medical Writing **9 hours**
Introduction to Medical Writing, Epidemiology and Evidence based medicine, Roles and Responsibilities of a medical Writer, Importance of Medical Writing in Clinical Research, Basic principles of Clinical trials, basics of medical writing.
Unit-2: Regulations and Ethics in Medical Writing **9 hours**

Introduction to Indian regulations governing clinical trials, Schedule Y, Introduction to Judicial systems in India and D&C ACT, Medical Devices, Veterinary products and biosimilar, Regulatory Regime – FDA, EMA and Japan, Overview of the regulatory, marketing, and drug promotion processes, IND and NDA requirements.
Unit-3: Types of Medical Writing methodology 9 hours
Publication writing- Writing for academic Publication; Writing a Literature Review; Biomedical research Course; Abstract; Grant proposal for Clinical Research; Evidence-Based Clinical Review Article, Medico-marketing writing- Patient Education resources; Resources for pharma sales Training; Medical content development; Web based learning
Unit-4 : Documentation in Medical Writing 9 hours
Regulatory writing- Protocol; ICF and Patient Information Sheet; Feasibility Report; Sops; Clinical Study Report; Survey Questionnaires; Patient Diary Cards; Regulatory writing for medical devices
Unit-5: Peer Review Process 9 hours
Discussion: Understanding how to review a paper - and applying those same practices and principles to own papers, principles of conducting reviews followed by several hands-on examples

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	Operational aspects of clinical research			
Course Code	**MCRT3005**			
Prerequisite				
Corequisite				
Antirequisite				
	L	**T**	**P**	**C**
	3	0	0	3

Course Objectives:
Students will get exposure about the need and scope of clinical research and the areas of clinical research. They will learn about different phases of clinical research.

Course Outcomes

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

CO1	Operational aspects in CRO and SMO, Site Selection Criteria- Site Selection parameters
CO2	Function of IRB/IEC, responsibility and composition of IRB/IEC
CO3	Roles and responsibility of clinical research players
CO4	Clinical trial documentation, study protocol, CRF, SOPs
CO5	Procedures in clinical trial, Quality Assurance and Quality Control in Clinical Research

Text Book (s)

1. Guide to Clinical Trials,Bert Spilker, 1991 (Now 3rd edition).

2. Ethical guidelines for Biomedical Research on Human Subject, ICRI Government Published 2000

Reference Book (s)

1. Clinical trials: a practical approach. John Wiley 1983, by Pocock SJ
2. Clinical trials. Remedica 2006, by Wang D and Bakhai A (Ed)

Course Contents

Unit-1: Operation in CRO & SMO	**9 hours**
Site Selection Criteria- Site Selection parameters: Location, Staffing, Qualifications, History, Clinical trial experience, Area of therapeutic experience, Investigational pharmacy, ICH-GCP compliance, Patient enrollment, Site Selection Check list, Site Initiation Visit (SIV) Single Centre/Multi Centre Trial- Definition, benefits of Single centre and or Multi centre, Differences between Single centre & Multi centre Trial Investigator Selection	

Investigator qualification and agreement, duties delegation, Undertaking by the Investigator, Feasibility study, Other functions-Central lab, Shipment and shipping records, meetings with Sponsor, analysis & interpretation of results etc Operation of Institutional Review Board (IRB)/ Independent Ethics Committee (IEC) - Defining Scope of IRB/IEC Authority, Responsibilities of IRB/IEC, Composition of IRB/IEC, Basic Functions, Operation and Procedure of IRB/IEC, Communication with IRB, IRB/IEC Records, Documents for submission to IRB/IEC, Difference between IRB and IEC
Unit-2: Operation of Institutional Review Board (IRB)/ Independent Ethics Committee 9 hours
Defining Scope of IRB/IEC Authority, Responsibilities of IRB/IEC, Composition of IRB/IEC, Basic Functions, Operation and Procedure of IRB/IEC, Communication with IRB, IRB/IEC Records, Documents for submission to IRB/IEC, Difference between IRB and IEC
Unit-3: Roles & Responsibilities of Clinical Trial Personnel 9 hours
Roles & Responsibilities of Sponsor, Investigator, CRO/SMO, CRA/Monitor, Auditor, Clinical Research co-coordinator, Clinical Data Manager, Clinical Biostatistician
Unit-4 : Clinical Trial Documentation 9 hours
Investigator's Brochure- Confidentiality Statement, Summary, Introduction, structure and content Study Protocol – Structure and content Case Report Forms (CRF) & e-CRF-Structure and content Informed Consent Form/Assent Form- structure and content Clinical Study Report-structure and content Standard Operating Procedures (SOP) in Clinical Trials-Need of SOPs, What is SOPs, Benefits of SOPs, different types of SOPs, SOP Writing SOPs and Guideline, Implementation and monitoring of SOPs, Change control. Essential Documents-Importance of Essential Documents, Pre-study/during and post study documents
Unit-5: Procedures in Clinical Trial 9 hours
Quality Assurance and Quality Control in Clinical Research –Introduction, Regulatory requirement of quality Assurance (QA) and Quality Control (QC) in Clinical Research, Role and Responsibilities of QA personnel, Different types of Audit, Quality System and Quality Policy, Continual Process Improvement Interventions, Study Drug Packaging and Distribution of Study Drug Receipt, Dispensing, Accountability, Storage, Disposal, Regulatory Requirement. Monitoring in Clinical Trials: Purpose of monitoring & Monitor's responsibilities, Monitoring procedures, Monitoring report, Audit, Extent and nature of monitoring, Medical Monitoring, Query Resolution

Continuous Assessment Pattern

Internal Assessment (IA)	Mid Term Test (MTE)	End Term Test (ETE)	Total Marks
20	30	50	100

Name of The Course	MANAGEMENT OF CLINICAL RESEARCH PROJECT AND OUTSOURCING			
Course Code	**MCRT3006**			
Prerequisite				
Corequisite				
Antirequisite				
	L	**T**	**P**	**C**
	4	0	0	4

Course Objectives:
Students will get exposure about the management of clinical trial and outsourcing

Course Outcomes

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

CO1	about basic concepts of project mile stones and their management, Overview of project, planning, scope, checklist
CO2	about checklist of budgeting and vendor selection, terminologies, specific item, agreements, payment planning and controls
CO3	about feasibility of project and outsourcing, Introduction, Essential clinical trial documents, development, regulatory aspects
CO4	Methodology of clinical trial operation
CO5	Investigations product management

Text Book (s)

1. Guide to Clinical Trials (Volume-I &II), ICRI

2. LachmanL, Liberman H.A and Kanig J.L., "Theory and Practice of Industrial Pharmacy", Lea and Febiger.

Reference Book (s)

1. Clinical trials: a practical approach. John Wiley 1983, by Pocock SJ
2. Clinical trials. Remedica 2006, by Wang D and Bakhai A (Ed)

Course Contents

Unit-1: Overview of Project mile stones and Management **9 hours**
Overview of project, mile stones, planning, scope, checklist, terminologies & definitions used in clinical research project management, project forecast.

Unit-2: Budgeting and outsourcing of Clinical Research Project 9 hours
Objectives and scope, definition and types of costs, procedures and checklist, terminologies, specific item, agreements, payment planning and controls, cost measures, Insurance, complexity, Indemnification. Outsourcing- overview, concepts, definition, planning, partnership, future trends.
Unit-3: Clinical Trial Documents and development 9 hours
Introduction, Essential clinical trial documents, development, regulatory aspects, documents before the clinical trial commence, during clinical trial conduct and post-trial or termination of the trial, forms, logs, Patient diary, source document, questionnaires.
Unit-4 : Clinical Trial Monitoring and Audit 9 hours
Overall objectives, Importance, personnel, types of monitoring, pre-study, initiation study, periodic, close-out visits and their purpose, checklist, monitoring report, procedure, audit, type of audit, purpose of audit.
Unit-5: Investigational Product (IP) Management 9 hours
Definition, management plan, checklist, packaging, labeling, storage, transport, receipt, certificate of analysis (COA), customs, dispensing, accountability, disposition.

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	**Quality control, Quality assurance and Total Quality Management in clinical trial**				
Course Code	**MCRT3007**				
Prerequisite					
Corequisite					
Antirequisite					
	L	**T**	**P**	**C**	
	4	0	0	4	

Course Objectives:
Students will get exposure about the need and scope of quality control and quality assurance in clinical research and the details about audit and inspection.

Course Outcomes

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

CO1	Overview of quality control, quality assurance and total quality management
CO2	Audit and inspection, types of audit, source data verification
CO3	Good manufacturing practices
CO4	Good laboratory practices
CO5	Process validation

Text Book (s)

1. Willig SW & Stoker JW, "Good manufacturing practices for pharmaceuticals", Marcel Dekker, New York
2. Drugs & Cosmetics Act.

Reference Book (s)

1. Environment Protection Act.
2. Federal Food, Drugs & Cosmetic

Course Contents

Unit-1: QC, QA and TQM overview **9 hours**
Relevance of QA and QC in clinical trials and their comparison, Importance of Clinical Quality Assurance department in industry, Total quality Management, Good clinical practice and quality assurance, Quality control vs. quality assurance
Unit-2: Audits/Inspections **9 hours**
Audits, its process and important aspects, Types of audits, Source document verification, Regulatory inspections

Unit-3: Good Manufacturing Practice (GMP)	**9 hours**
Basis of Good Manufacturing Practices, Quality Assurance and Regulation Overview of Current Good Manufacturing Practices The International GMP Regulation The Indian GMP Regulation: Drugs and cosmetic Act, CDSCO, Schedule M. Quality Assurance in Pharmaceutical Industry, Quality Control for Pharmaceutical Laboratories	
Unit-4 : GLP: GOOD LABORATORY PRACTICE	**9 hours**
GLP principles 1. Organization and Personnel, Management-Responsibilities, Sponsor-Responsibilities Study Director-Responsibilities,PrincipleInvestigator-Responsibilities, Study Personnel Responsibilities 2. Quality assurance program: Quality Assurance Personnel 3. Facilities: Test System Facilities, Facilities for Test and Reference Items 4. Equipments, reagents and Materials 5. Test systems: Physical/Chemical, Biological 6. Test & Reference items 7. Standard operating procedures 8. Performance of Study : Study Plan , Conduct of Study 9. Reporting of s 10. Storage of Records and Reports	
Unit-5: PROCESS VALIDATION AND CGMP	**9 hours**
Basic concepts of quality assurance, Requirements of CGMP/GLP, ISO 9000 series, Quality audits etc. Precision, accuracy and biases, sampling and operating characteristic curves, sampling plans, statistical inference in estimation of hypothesis testing, statistical procedure in assay development. Development of new analytical method and its validation. In-process quality control tests for various dosage forms including packaging and labeling operations. Brief introduction to general requirements of health regulatory agencies such as US FDA, , WHO etc	

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	**Project work and Dissertation**				
Course Code	**MCRT4001**				
Prerequisite					
Corequisite					
Antirequisite					
		L	**T**	**P**	**C**
		0	0	40	20

Course Objectives:
On completion of this course the students will be able to understand the clinical research industry.

Course Outcomes

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

CO1	This project work is to make the student acquainted with the industrial / business working environment. After completion of the project they will have to submit dissertation report

Course Contents

Unit-1: PROJECT WORK – LIVE PROJECT AT CRO / SITE **9 hours**
This project work or thesis presents a student's research results, describing the research with reference to relevant work done as part of the live project at a CRO or Site. It will include a description of the methods of research considered, and those actually employed, and present the student's conclusions. The thesis is the student's own work and must be written by the student. The Internal Layout of the project work or Thesis The thesis is to be submitted in the following pattern, □ Title page; □ Summary (Abstract) □ Table of contents □ List of tables □ List of figures □ Definitions or Abbreviations; □ Declarations and Statements □ Acknowledgement □ Author's declaration □ Contents page; □ Introduction □ Study Objectives □ Subject selection and withdrawal □ Study drug

- Statistical Plan
- Safety and adverse event's
- Glossary
- List of references
- Bibliography
- Index

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	00	80	100