Study Scheme & Syllabus of

Master of Science in Clinical Research

(M.Sc. Clinical Research)

Batch 2020 Onward

By

Board of Study Clinical Research

Main Campus

IK Gujral Punjab Technical University

IK Gujral Punjab Technical University

Vision

To be an institution of excellence in the domain of higher technical education that serves as the fountainhead for nurturing the future leaders of technology and techno-innovation responsible for the techno-economics, social, cultural and environmental prosperity of the people of the State of Punjab, the Nation and the World

Mission

To provide seamless education through the pioneering use of technology, in partnership with industry and society with a view to promote research, discovery and entrepreneurship and to prepare its students to be responsible citizens of the world and the leaders of technology and techno-innovation of the 21st Century by developing in them the desirable knowledge, skill and attitudes base for the world of work and by instilling in them a culture for seamlessness in all facets of life.

Department of Food Science and Technology

Vision

To create competent professionals those contribute towards the economic development of the nation by going in line with the policy of Government of India in the field of food processing, food safety, health and nutrition.

Mission

- Development of human resource in the field of food science and technology to serve the cause of nation
- Development of human resource in the area of clinical nutrition and research to contribute effectively in making India healthy
- Providing a strong theoretical and practical background across the food science discipline with an emphasis on developing sustainable resources to cater food and nutrition related challenges
- Create favourable environment for innovation to translate theoretical knowledge into practical applications
- Inculcating professional ethical values, innovative research capabilities and leadership abilities
- Holistic development of the youth through the process of self evaluation and continuous improvement

MSc. Clinical Research

Programme Educational Objectives

PEO1	To accomplish the demand for well qualified clinical researchers in academia and industry
PEO2	To pursue successful industrial, academic and research careers in specialized fields of clinical research and drug safety
PEO3	Solve problems through application of critical thinking and evidence-based processes
PEO4	To sensitize students about the importance of ethical practices in clinical research and practice
PEO5	Pursue self-learning to remain abreast with latest developments for continuous professional growth

Programme Outcomes

PO1	Ability to participate and contribute effectively as clinical research team member
PO2	Understand the roles and responsibilities of the different stakeholders in clinical research
PO3	Compare and summarize international regulations, clinical requirements and best practices for the clinical research process
PO4	Integrate knowledge from foundational sciences and pharmaceutical sciences for effective planning and implementation of study protocols
PO5	Apply knowledge of disease pathophysiology and current therapy in designing clinical trial protocols and analyzing data
PO6	Evaluate the suitability, accuracy, and reliability of clinical study data by analyzing experimental design, statistical tests, interpreting results, and formulating conclusions
PO7	Ability to review existing evidence in literature
PO8	Describe Good Clinical Practices in different aspects of the clinical studies
PO9	Communicate professionally both orally and in writing within the clinical research environment

Mapping of Program Outcomes with Program Educational Objectives

	PEO1	PEO2	PEO3	PEO4	PEO5
PO1	3	1	1	1	1
PO2	3	2	1	1	1
PO3	1	3	2	3	2
PO4	3	2	3	2	3
PO5	2	3	3	2	3
PO6	3	3	3	1	3
PO7	3	3	3	2	3
PO8	2	2	2	3	2
PO9	2	3	1	1	3

1: Slightly 2: Moderately 3: Substantially

Duration of course	Two Academic Years
Maximum duration for course completion & award of degree	4 Years
Eligibility	Graduation with minimum 50% marks in Life Sciences/Sciences/Medical Sciences/Pharmacy
Attendance Requirement	75%
Examination System	Semester
Marks Allocation	• Theory courses of 04 credits = 100 marks • Theory courses of 02 credits = 50marks • Practical courses of 02 credits = 50 marks
Minimum Credits for Award of Degree	• 90
Programme Structure	1. Compulsory Foundation Course 2. Core Courses 3. Elective Courses 3.1. Discipline Specific Elective Courses 3.2. Generic Elective Courses 4. Ability Enhancement Courses 5. Skill Enhancement Courses

Programme Structure

1. **Compulsory Foundation Course:** This course is a foundation course designed with the object to enhance the knowledge base of students.

2. **Core Courses:** These courses are compulsory courses studied by students as core requirement of the programme. These courses aim to impart students the basics of the MSc. Clinical Research programme.

3. **Discipline Specific Elective (DSE) Courses:** Discipline specific elective courses comprise a pool of courses offered under the main discipline/subject of study. Students will choose DSE courses from a pool of courses provided to them.

4. **Generic Elective (GE) Courses:** Generic elective comprise a pool of courses designed with a purpose to offer the students the opportunity to explore disciplines of interest beyond the choices they make in core and discipline specific elective courses. Students will choose GE courses from a pool of courses provided to them.

5. **Ability Enhancement Courses:** These courses are designed with the aim to improve the knowledge base and skills of the students to facilitate employability.

6. **Skill Enhancement Courses:** These courses are designed with the aim to improve the knowledge base and skills of the students to facilitate employability.

Internal Assessment

- The internal assessment will have two components i.e. **Continuous Mode** and **Sessional Exams**

1. For Theory Courses having Internal of 30 Marks the scheme of internal award is:
    - Sessional Exams: 20 Marks
    - Continuous Mode: 10 Marks

Sessional Exams

- The number of sessional exams and criteria for computation i.e. average marks or best of sessional exams conducted shall be according to guidelines provided by Academic Council IKG-PTU from time to time.
- Sessional exam shall be **conducted for 30 marks** for theory and shall be **computed for 20marks**.

Continuous Mode Scheme

Criteria	Maximum Marks
*Attendance (as per table given below)	4
Academic activities (Average of any 3 activities e.g. quiz, assignment, open book test, field work, group discussion and seminar)	6
Total	**10**

2. For Theory Courses having Internal of 15 Marks the scheme of internal award is:
    - Sessional Exams: 10 Marks
    - Continuous Mode: 05 Marks

Sessional Exams

- The number of sessional exams and criteria for computation i.e. average marks or best of sessional exams conducted shall be according to guidelines provided by Academic Council IKG-PTU from time to time.
- Sessional exam shall be **conducted for 20 marks** for theory and shall be **computed for 10marks**.

Continuous Mode Scheme

Criteria	Maximum Marks
*Attendance (as per table given below)	2
Academic activities (Average of any 3 activities e.g. quiz, assignment, open book test, field work, group discussion and seminar)	3
Total	**5**

Evaluation Scheme of Laboratory Courses

Internal (30 Marks)	Continuous and Comprehensive Evaluation (class performance/practical record/viva etc.) = 26
	*Attendance (as per table given below) = 04
External (20 Marks)	Synopsis = 05
	Performance = 10
	Viva = 05
Total	**50 Marks**

*Guidelines for the Allotment of Marks for Attendance

Percentage of Attendance	Theory (Attendance Maximum Marks 04)	Theory (Attendance Maximum Marks 02)	Practical (Attendance Maximum Marks 04)
More Than 93	4	2	4
87 – 92	3	1.5	3
81– 86	2	1	2
75 – 80	1	0.5	1
Less than 75	0	0	0

Evaluation Scheme Journal Club

Paper Selection and Content Delivery	10
Power Point Presentation	05
Post Presentation Discussion	10
Total	25

Note: Student will present minimum two papers in each semester

Question Paper Pattern for Theory Sessional Examinations of 30 Marks

Objective Type Questions (5x2) (Answer all the questions)	5x2=10
Short Answers (Answer 2out of 3)	2x5 =10
Long Answers (Answer 1 out of 2)	1x10=10
Total	**30 Marks**

Question Paper Pattern for Theory Sessional Examinations of 20 Marks

Objective Type Questions(5x1) (Answer all the questions)	5x1= 05
Short Answers(Answer 1out of 2)	1x5 = 05
Long Answers(Answer1out of 2)	1x10=10
Total	**20 Marks**

Question Paper Pattern for Theory External Exam of 70 Marks

Objective Type Question (10 x 2) (Answer all the questions)	10 x 2 = 20
Short Answer (Answer 4 out of 5)	4 x 5 = 20
Long Answer (Answer 3 out of 4)	3 x 10 = 30
Total	**70 Marks**

Question Paper Pattern for Theory External Exam of 35 Marks

Objective Type Question (5 x 1) (Answer all the questions)	5 x 1 = 05
Short Answer (Answer 2 out of 3)	2 x 5 = 10
Long Answer (Answer 2 out of 3)	2 x 10 = 20
Total	**35 Marks**

First Semester

Course Code	Course Type	Course Name	Load			Marks			Credits
			L	T	P	Internal	External	Total	
UC-MSCR101-19	Foundation Course	Foundation Course	3	1	-	30	70	100	4
UC-MSCR102-19	Core Theory	Fundamentals of Clinical Research	3	1	-	30	70	100	4
UC-MSCR103-19	Core Theory	General Pharmacology	3	1	-	30	70	100	4
UC-MSCR 104-19	Core Practical	Clinical Research Lab I	-	-	4	30	20	50	2
UC-MSCR 105-19	Ability Enhancement	Professional Communication	2	-	-	15	35	50	2
UC-MSCR 106-19	Skill Enhancement	Journal Club	-	-	4	50	-	50	2
UC-MSCR XXX	Discipline Specific Elective Theory	Elective –I	2	-	-	15	35	50	2
UC-MSCRYYY	Generic Elective Theory	Elective –II	2	-	-	15	35	50	2
		Total	**15**	**3**	**8**	**215**	**335**	**550**	**22**

Discipline Specific Elective Theory (Elective-I)

Subject Code	Subject Name
UC-MSCR 111-19	Intellectual Property Rights
UC-MSCR 112-19	Different Systems of Medicine

Generic Elective Theory (Elective-II)

Subject Code	Subject Name
UC-MSCR 113-19	Clinical Pharmacokinetics
UC-MSCR 114-19	Alternatives in Toxicity Testing
UC-MSCR 115-19	Fundamentals of Physiology

Second Semester

Course Code	Course Type	Course Name	Load			Marks			Credits
			L	T	P	Internal	External	Total	
UC-MSCR201-19	Core Theory	Pharmacotherapeutics - I	3	1	-	30	70	100	4
UC-MSCR202-20	Core Theory	Clinical Research Regulations & Ethics	3	1	-	30	70	100	4
UC-MSCR203-19	Core Practical	Clinical Research Lab II	-	-	4	30	20	50	2
UC-MSCR 204-19	Ability Enhancement	Professional Communication Lab	-	-	4	30	20	50	2
UC-MSCR 205-20	Skill Enhancement	Medical Writing	2	-	-	15	35	50	2
UC-MSCR 206-19	Skill Enhancement	Journal Club	-	-	4	50	-	50	2
UC-MSCR XXX	Discipline Specific Elective Theory	Elective –III	2	-	-	15	35	50	2
UC-MSCRYYY	Generic Elective Theory	Elective –IV	2	-	-	15	35	50	2
		Total	**12**	**2**	**12**	**215**	**285**	**500**	**20**

Discipline Specific Elective Theory (Elective-III)

Subject Code	Subject Name
UC-MSCR 211-19	Fundamentals of Epidemiology
UC-MSCR 212-19	International Regulatory Affairs

Generic Elective Theory (Elective-IV)

Subject Code	Subject Name
UC-MSCR 213-19	Biostatistics in Clinical Research
UC-MSCR 214-19	Poisoning and Management

Third Semester

Course Code	Course Type	Course Name	Load			Marks			Credits
			L	T	P	Internal	External	Total	
UC-MSCR301-19	Core Theory	Pharmacotherapeutics -II	3	1	-	30	70	100	4
UC-MSCR302-20	Core Theory	Clinical Study Design	3	1	-	30	70	100	4
UC-MSCR303-19	Core Theory	Research Methodology	2	-	-	15	35	50	2
UC-MSCR304-19	Core Theory	Pharmacovigilance	2	-	-	15	35	50	2
UC-MSCR 305-19	Core Practical	Clinical Research Lab III	-	-	4	30	20	50	2
UC-MSCR 306-19	Skill Enhancement	ICT Skills Lab	-	-	4	30	20	50	2
UC-MSCR 307-19	Skill Enhancement	Journal Club	-	-	4	50	-	50	2
UC-MSCR 308-19	Research Work	Synopsis	-	-	4	50	-	50	2
UC-MSCR XXX	Discipline Specific Elective Theory	Elective –V	2	-	-	15	35	50	2
UC-MSCRYYY	Generic Elective Theory	Elective –VI	2	-	-	15	35	50	2
		Total	**14**	**2**	**16**	**280**	**320**	**600**	**24**

Discipline Specific Elective Theory (Elective-V)

Subject Code	Subject Name
UC-MSCR 311-20	Clinical Trial Operations
UC-MSCR 312-19	Medical Coding

Generic Elective Theory (Elective-VI)

Subject Code	Subject Name
UC-MSCR 313-19	Pharmacoeconomics & Health Technology Assessment
UC-MSCR 314-20	Quality Management in Clinical Trials

Fourth Semester

Course Code	Course Type	Course Name	Load			Marks			Credits
			L	T	P	Internal	External	Total	
UC-MSCR401-19	Seminar	Seminar	-	-	4	50	-	50	2
UC-MSCR402-19	Research Work	Dissertation	-	-	36	200	100	300	18
--	Co-curricular Activities	--	--	--	--	*Satisfactory/Unsatisfactory			--
		Total	**-**	**-**	**40**	**250**	**100**	**350**	**20**

Semester Wise Credits Distribution

Semester	Credits
I	22
II	20
III	24
IV	20
Co-curricular Activities (Attending Conference, Scientific Presentations and Other Activities)	04
Total Credit Points	**86 + 4* = 90**

- *Credits for Co-curricular Activities
- *Credits not included towards calculation of CGPA
- The award of credits for co-curricular activities will have only internal component
- The student will earn the credits for co-curricular activities anytime during the duration of MSc.
- Head of Department will award the credits based upon the submission of relevant documents pertaining to criteria as below by student.

Guidelines for Awarding Credits for Co-curricular Activities

Name of the Activity	Credit Points
Successful completion of MOOCs Courses (4 weeks)	04
Successful completion of MOOCs Courses (2 weeks)	02
Hospital Training (minimum 4weeks)	02
Participation in Seminar/ Conference/ Symposium (related to the specialization of the student)	01
Participation in Workshop/ Training Programs of duration one week (05 days) or more (related to the specialization of the student)	02
Presentation in Seminar/ Conference/ Symposium / (related to the specialization of the student)	02
Presentation in Seminar/ Conference/ Symposium / (related to the specialization of the student) and with award	03
Research / Review Publication in indexed in Scopus / Web of Science*	03
Research / Review Publication in peer reviewed journals*	02
Minimum ten days residential camp organized by NSS/ Youth Affairs	02
Inter University participation in cultural or sports activity	02
Inter University award in cultural or sports activity	03
Inter College participation in cultural or sports activity	01
Inter College award in cultural or sports activity	02

**Only those research / review publications will be considered which have been published during the tenure of M. SC. Course.*

FIRST SEMESTER

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 101-19	Foundation Course	3	1	-	30	70	1.5	3	4

Pre-requisite: None

Co- requisite: None

Course Objectives: The course is based upon the content that leads to knowledge enhancement. This course is mandatory for bringing the student of different background on a common platform.

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

CO1	Understand the basics of chemistry and analytical techniques
CO2	Develop an understanding in the basics of biochemistry and cell biology of the human body
CO3	Understand the significance of the environment related issues in the new drug discovery and development
CO4	Develop an understanding of contribution of genetic factors involved in the holistic treatment of the diseases
CO5	Apply the knowledge of biotechnology in the field of drug discovery and clinical trials

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	2	1	1	3	1	2	1	2	1
CO2	2	1	2	3	3	1	2	1	1
CO3	1	2	3	2	1	1	1	3	1
CO4	3	1	2	3	3	2	2	1	1
CO5	2	1	1	3	2	2	1	1	1

Module-I **08 Hrs**

Chemistry

Solution — Methods of expressing the concentration (molality, molarty, normality, formality etc)

Laws of mass action, reaction quotient, chemical equilibrium constant, relation of Kp & Kc, pH, buffer, buffer index, buffer capacity, arrhenius equation

Principles, classification and applications of chromatographic techniques

Basics of Spectroscopy and applications

Module-II **15 Hrs**

Biochemistry and Cell Biology

Biomolecules - carbohydrates, amino acids/proteins, lipids and nucleotides; enzymes: characteristics and nomenclature

Introductory cell biology & microbiology: prokaryotes & eukaryotes; the cell and its composition; cell organelles and subcellular fractionation; viruses, viroid's, virusoids and prions: bacterial culture and growth curve

Immunology – natural and acquired immunity; humoral and cellular immunity; vaccines and immunization; Clonal selection theory; Cells of immune system; immunoglobulins, haptens, antigens and immunogens; monoclonal & polyclonal antibodies

Clinical biochemistry: common biochemical tests; acid base disorders; liver function tests; kidney function tests

Module-III **08 Hrs**

Environmental Sciences

Biodiversity — concept, levels and conservation of biodiversity

Climate change and its consequences

Ecosystem - producers, consumers and decomposers of food chain

Environmental pollution, bioremediation

Module-IV **14 Hrs**

Genetics and Biotechnology

Genetics of inheritance - laws of inheritance, recombination and segregation of traits, segregation ratio, interaction between traits and quantitative inheritance

Molecular Biology - the genetic material, RNA as genetic material, fidelity of DNA replication, transcription, translation and transduction, mutation and mutagenesis, ames test

Genetic Engineering - essentials of gene manipulation, vectors & enzymes used in recombinant technology

Biotechnology: stem cell, its application and ethical aspects

Suggested Readings/Recommended Books (Latest Editions)

1. AI Vogel, Text Book of Quantitative Inorganic analysis, Pearson.
2. Wilson and Walker, Principles and Techniques of Biochemistry and Molecular Biology, Cambridge University.
3. Bentley and Driver's Textbook of Pharmaceutical Chemistry, Oxford University Press.
4. Anand and Chatwal, Inorganic Pharmaceutical Chemistry, Himalaya.
5. DRFerrier, Lippincott's Illustrated Reviews: Biochemistry, Wolters Kluwer India Pvt. Ltd.
6. Principles of Biochemistry by Lehninger, W H Freeman & Co.
7. Harper's Biochemistry by Robert K. Murry, Daryl K. Granner and Victor W. Rodwell, Lange.
8. Biochemistry by Stryer, WH Freeman.
9. Bharucha Erach, The Biodiversity of India, Mapin Publishing Pvt. Ltd., Ahmedabad – 380 013, India.
10. Agarwal, K.C. Environmental Biology, Nidhi Publ. Ltd. Bikaner.

11. Cunningham, W.P. Cooper, T.H. Gorhani, E and Hepworth, M.T., Environmental Encyclopedia, Jaico Publishing House, Mumbai.
12. Instrumental Methods of Chemical Analysis by B.K. Sharma, Krishna Prakashan Media (P) Ltd.
13. Quantitative Analysis of Drugs by D.C. Garrett, Springer.
14. Lodish, Molecular Cell Biology. New York :WH Freeman.
15. TA Brown, Gene Cloning and DNA Analysis: An Introduction, Wiley Blackwell.
16. GM Cooper, The Cell: A Molecular Approach, ASM Press.

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 102-19	Fundamentals of Clinical Research	3	1	-	30	70	1.5	3	4

Pre-requisite: None

Co- requisite: General Pharmacology (UC-MSCR103-19)

Course Objectives: The objective of the course is to create understanding of basic concepts of clinical research, clinical terminology and clinical trial definition. Further to give overview of the documentations in clinical research.

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

CO1	Understand the strategies and techniques involved in drug discovery process
CO2	Appreciate the impact of pharmaceutics science in new drug development and clinical use of drugs
CO3	Understand the preclinical phase of drug development
CO4	Understand different phases of clinical trials
CO5	Understand the importance of use of placebo controls and placebo response in clinical trials

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	1	3	3	2	2	3	2	1	1
CO2	1	2	1	3	1	2	3	1	1
CO3	1	1	1	3	2	2	3	1	1
CO4	2	3	3	3	3	2	1	3	1
CO5	2	3	3	2	3	2	2	2	1

Module-I **14 Hrs**

Drug Discovery Process

Approaches to drug development
Combinatorial chemistry
Lead optimization, target-centred drug design
The drug development process high throughput screening (HTS)

Module-II **09 Hrs**

Formulation Development

Introduction to different formulations, advantages and disadvantages of common formulations
Introduction to manufacturing of drugs and Good Manufacturing Practices (GMP)
Quality assurance and quality control during manufacturing a drug
Biopharmaceutical classification on drugs

Module-III **12 Hrs**

Pre-Clinical Testing

Acute, sub-acute and chronic toxicity
Mutagenicity, teratogenecity and carcinogenicity
Effect on reproductive system
Bioassays

Module-IV **10 Hrs**

Drug Evaluation and Clinical Development

Phases of developmental clinical trials: Phase 0, Phase-I, Phase-II, Phase-III, Phase-IV
Placebo response, nocebo, advantages and disadvantages of placebo

Suggested Readings/Recommended Books (Latest Edition)

1. BE Blass, Basic Principles of Drug Discovery and Development, Academic Press, Elsevier.
2. D Wang and A Bakhai, Clinical Trials A Practical Guide to Design, Analysis, and Reporting, Remedica.
3. LD Edwards, AJ Fletcher, AW Fox, Principles and practice of Pharmaceutical Medicine, Wiley-Blackwell.
4. AA Rubin, M Dekker, New Drugs: Discovery and development, Wiley-Interscience.
5. SK Gupta, Basic Principles of Clinical Research and Methodology, Jaypee Brothers, Medical Publishers Pvt. Ltd.
6. SK Gupta, Drug Discovery and Clinical Research, Jaypee Brothers, Medical Publishers Pvt. Ltd.

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 103-19	General Pharmacology	3	1	-	30	70	1.5	3	4

Pre-requisite: None

Co- requisite: None

Course Objectives: To develop essential understanding of molecular basis of drug action and relationship between drug dose and pharmacological action. The students will also learn about, adverse drug reactions and therapeutic monitoring of drugs.

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

CO1	Understand the basic concepts and signal transduction mechanisms of drugs
CO2	Comprehend the relationship between dose and pharmacological action in terms of therapeutic effect and toxic effect of drugs
CO3	Understand the basic pharmacokinetic parameters and their significance in drug development process
CO4	Understand the basic concepts of neurohumoral transmission and neurotransmitters involved in drug action
CO5	Understand the different types of adverse drug reactions and significance and methods of therapeutic drug monitoring

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	1	2	1	3	1	1	3	1	1
CO2	1	3	2	3	2	2	2	1	1
CO3	1	1	1	2	3	1	1	1	1
CO4	1	1	1	2	3	1	1	1	1
CO5	1	1	3	2	3	2	3	3	2

Module-I **09 Hrs**

Basic Pharmacokinetics
Drug passage across cell membranes

Order of reaction or process
Time course of drug concentration and effect
Absorption, distribution, metabolism and elimination of drugs
Bioavailability, presystemic elimination
Routes of drug administration

Module-II **14 Hrs**

Basic Pharmacodynamics

Mechanism of drug action: full agonist, partial agonist, inverse agonist, competitive antagonist, non-competitive antagonist
Dose response relationship, potency, efficacy, ED_{50}, LD_{50}, EC_{50}, LC_{50}, therapeutic index
Receptors, transduction process, second messengers
Tachyphylaxis
Chemical interactions (additive effect, potentiation, synergism)

Module-III **06 Hrs**

Special Topics

Adverse drug reactions (ADRs)
Drug interactions
Therapeutic Drug Monitoring

Module-IV **16 Hrs**

Autonomic Nervous System

General concepts- neurohumoral transmission, neurotransmitters
Cholinergic pharmacology
Adrenergic pharmacology

Suggested Readings/Recommended Books (Latest Edition)

1. BG Katzung AJ Trevor, Basic and Clinical Pharmacology, Mc Graw-Hill.
2. HP Rang, MM Dale, JM Ritter, RJ Flower, G Henderson, Rang & Dale's Pharmacology, Elsevier.
3. PN Bennett, MJ Brown and P Sharma, Clinical Pharmacology, Churchill Livingstone Elsevier.
4. KD Tripathi, Essentials of Medical Pharmacology, Jay Pee Medical.
5. PM Conn, Animal Models for the Study of Human Disease, Academic Press Elsevier.
6. FJ Hock, Drug Discovery and Evaluation: Pharmacological Assays, Springer.
7. MJ Derelanko and MA Hollinger, Handbook of Toxicology, Taylor & Francis.

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 104-19	Clinical Research Lab I	-	-	4	30	20	3	3	2

Pre-requisite: None

Co- requisite: Fundamentals of Clinical Research (UC-MSCR102-19) & General Pharmacology (UC-MSCR103-19)

Course Objectives: To give students hands on training for preparing standard operating procedures and clinical trial protocols. To acquaint students with different routes of drug exposure and pre-clinical non-invasive techniques in drug testing.

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

CO1	Prepare standard drug solutions of various concentrations
CO2	Perform common biochemical test of clinical significance
CO3	Prepare clinical trial protocol
CO4	Perform validation and prepare standard operating procedures of laboratory equipments
CO5	Understand the different routes of drug administration and pre-clinical non-invasive techniques for drug testing

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	3	1	2	2	1	1	3	3	1
CO2	1	3	2	2	2	1	3	3	1
CO3	3	3	3	3	3	3	3	3	3
CO4	1	2	3	1	1	3	3	3	2
CO5	1	2	1	3	3	1	3	3	1

1. To prepare molar, molal and normal solutions
2. To prepare buffer solutions and determination of their pH
3. Validation of machines and analytical instruments
4. Extraction of DNA
5. Biochemical test: renal function test

6. Biochemical test: lipid profile
7. Preparation of manuals as per GLP for biochemical tests
8. Demonstration of routes of exposure/administration of drugs
9. Demonstration of some non – invasive techniques in preclinical screening of drug
10. Bioethics- do's and don'ts, confidentiality, cultural/social ethics
11. Preparation of SOPs for various equipments

Suggested Readings/Recommended Books (Latest Edition)

1. A.I. Vogel, Text Book of Quantitative Inorganic analysis, Pearson.
2. Shruti Mohanty and Aparna Verma, Practical Clinical Biochemistry, Jaypee Brothers Medical Publishers (P) Lt d.
3. Vijay Kumar and Kiran Dip Gill, Basic Concepts in Clinical Biochemistry: A Practical Guide, Springer
4. Kathleen Deska Pagana and Timothy J. Pagana, MOSBY'S Manual of Diagnostic and Laboratory Tests, Elsevier
5. D Wang and A Bakhai, Clinical Trials A Practical Guide to Design, Analysis, and Reporting, Remedica.
6. D Rosenbaum and M Dresser, Clinical Research Coordinator Handbook, CRC Press.
7. EDeRenzo, Writing Clinical Research Protocols: Ethical Considerations, Academic Press Elsevier.

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 105-19	Professional Communication	2	-	-	15	35	1	2	2

Pre-requisite: None

Co- requisite: None

Course Objectives: The objective of the course is to help the students become the independent users of English language.

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

CO1	Acquire basic proficiency in reading, comprehension and writing
CO2	Understand spoken and written English language, particularly the language of their chosen technical field
CO3	Produce on their own clear and coherent texts
CO4	Learn about the standard organization of the essay
CO5	Develop the skills to master in the writing formal e-mails and letters

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	1	1	1	2	1	2	3	1	3
CO2	3	3	1	2	1	3	3	1	3
CO3	2	1	3	1	2	2	1	1	3
CO4	1	1	2	1	1	2	2	1	3
CO5	3	1	3	1	1	1	1	1	3

Module-I **12 Hrs**

Reading

Long texts where the subject matter ranges from the descriptive and factual to the discursive and analytical (the texts taken should be from books, journals, magazines and newspapers). Reading extracts from books, magazines, newspapers, notices, advertisements, company handbooks and guidelines encounter on a daily basis in an English-speaking environment.

Module-II **14 Hrs**

Writing

Topics of general interest and suitable for candidates planning to work in Clinical Research Organisations

Describe, summarise or explain the information in own words based on a graph, table, chart or diagram. The writing would be based on the description and explanation of the given data, describe the stages of a process, flowchart of how something works or describe an object or event in a formal and academic style.

Essay writing in response to a point of view, argument or problem in a formal and academic style. Arguments should be supported by relevant examples.

Letter writing: requesting information or explaining a given situation.

Suggested Readings/Recommended Books (Latest Edition)

1. Practical English Usage. Michael Swan. OUP
2. Remedial English Grammar. F.T. Wood. Macmillan
3. On Writing Well. William Zinsser. Harper Resource Book
4. Study Writing. Liz Hamp-Lyons and Ben Heasly. Cambridge University Press
5. Communication Skills. Sanjay Kumar and Pushp Lata. Oxford University Press
6. Exercises in Spoken English. Parts. I-III. CIEFL, Hyderabad. Oxford University Press
7. DL Plung and Tracy, Professional Communication: The Corporate Insider's Approach to Business Communication, South-Western College Pub
8. M Agarwal, Professional Communication, Krishna Prakashan Media (P) Ltd
9. NR Blyler, Professional Communication: The Social Perspective, SAGE Publications

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 111-19	Intellectual Property Rights	2	-	-	15	35	1	2	2

Pre-requisite: None

Co- requisite: None

Course Objectives: The course is designed to sensitize students towards the significance of intellectual property laws in drug development process

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

CO1	Understand of the core doctrines of intellectual property law
CO2	Understand the appropriate procedures for obtaining intellectual property protection
CO3	Describe the international treaties, conventions on IPR
CO4	Appreciate importance of compulsory licensing
CO5	Understand the patent infringement related issues

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	3	1	3	3	1	1	3	2	1
CO2	3	1	3	2	1	1	3	1	2
CO3	3	2	3	1	2	1	3	1	2
CO4	2	1	1	2	1	1	3	1	2
CO5	2	1	2	1	1	1	3	1	2

Module-I **12 Hrs**

General concepts Intellectual Property Rights & International Institutions

Intellectual Property overview and its theory
Requirement for Protecting Intellectual Property- a national and international comparison
Types of Intellectual Property- Origin and Development
World Intellectual Property Organization (WIPO)
Role of WIPO and its association with World Trade Organization (WTO)

Commercialization of Intellectual Property Rights by Licensing
Financial values of IPR

Module-II **12 Hrs**

Patent Laws Introduction to Copyrights and Trademarks

Indian Patent Law
The Patents Act, 1970 and its amendments
Criteria for Patentability
Filing Patent Applications and its Granting procedure
Patent Infringement
International Laws
Paris Convention and Patent Cooperation Treaty
WTO - TRIPS agreement
Indian copyright law, types of copyright
Types of trademarks, Indian trademark law

Suggested Readings/Recommended Books (Latest Edition)

1. IP Act & Rules from ipindia.nic.in
2. CDSO publications and updates of drug and Cosmetics act and rules (Govt. of India)
3. Kanfer , L. Shargel, Generic Product Development BE issued Publisher; Informa Healthcare
4. WTO; www.wto.org

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 112-19	Different Systems of Medicine	2	-	-	15	35	1	2	2

Pre-requisite: None

Co- requisite: None

Course Objectives: To sensitize students regarding the importance of different systems of medicine that has played a crucial factor in meeting the global health care needs.

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

CO1	Understand the basic aspects about historical background, conceptual basis, different disciplines studied in the AYUSH.
CO2	Understand principles of prevention and treatment of diseases in alternative systems of medicine
CO3	Understand recent developments in the validation of different systems of medicine
CO4	Understand the use of medicinal plants and the utilization of different herbs in treatment of various ailments
CO5	Learn about drug manufacturing aspects and impact of globalization on Ayurveda

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	1	1	2	3	3	1	1	2	1
CO2	1	1	2	3	3	2	2	1	1
CO3	1	1	2	2	2	3	3	3	1
CO4	1	1	1	2	2	3	3	3	1
CO5	1	1	3	3	2	1	2	2	1

Module-I **12 Hrs**

Historical background of the different systems of medicines and different traditional practices

Principles of prevention and treatment of diseases in alternative systems of medicine

Uses of medicinal plants and the utilization of different herbs

Module-II **12 Hrs**

Medicinal plants and their different system of medicine
Recent developments in the validation of different systems of medicine
Regulations governing herbal drug development

Suggested Readings/Recommended Books (Latest Edition)

1. Marc Micozzi, Fundamentals of Complementary and Alternative Medicine, Elsevier
2. Arya Vaidya Sala, Medicinal Plants: A Compendium of 500 Species, Orient Blackswan Pvt Ltd. New Delhi
3. Mayo Clinic Book of Alternative Medicine & Home Remedies
4. www.fda.gov
5. www.ema.europa.eu
6. Ministry of AYUSH: Central Council for Research in Ayurvedic Sciences

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 113-19	Clinical Pharmacokinetics	2	-	-	15	35	1	2	2

Pre-requisite: None

Co- requisite: None

Course Objectives: To sensitize students regarding significance of pharmacokinetic principles in new drug development.

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

CO1	Apply pharmacokinetic information in clinical drug development
CO2	Contribute at planning, design and analysis of clinical studies, from pharmacokinetics perspective
CO3	Describe various types of variables that are used to measure and model drug effects
CO4	To use relevant clinical pharmacokinetic data to demonstrate the ability to determine doses of drugs in special patient populations
CO5	Understand significance of pharmacogenomics in clinical pharmacokinetics

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	2	1	1	3	3	1	2	1	1
CO2	3	1	1	3	3	1	1	2	1
CO3	3	1	1	1	1	1	1	1	1
CO4	3	1	1	2	3	1	2	1	1
CO5	2	1	1	3	2	1	1	1	1

Module-I **13 Hrs**

Basic Concepts

Clinical pharmacokinetic and pharmacodynamic concepts
Clinical pharmacokinetic equations and calculations
Pharmacogenomics in pharmacokinetics
Rational use of drug concentration measurements

Module-II **13 Hrs**

Drug Dosing in Special Populations

Renal and Hepatic Disease
Dialysis
Heart Failure
Obesity
Paediatric Patients
Therapeutic drug monitoring in geriatric patient

Suggested Readings/Recommended Books (Latest Edition)

1. Larry A. Bauer, Applied Clinical Pharmacokinetics, McGraw-Hill Companies, Inc.
2. John E. Murphy, Clinical Pharmacokinetics, American Society of Health-System Pharmacists.
3. Robin L. Southwood, Virginia H. Fleming, Gary Huckaby, Concepts in Clinical Pharmacokinetics, American Society of Health-System Pharmacists.
4. PN Bennett, MJ Brown and P Sharma, Clinical Pharmacology, Churchill Livingstone Elsevier.

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 114-19	Alternatives in Toxicity Testing	2	-	-	15	35	1	2	2

Pre-requisite: None

Co- requisite: None

Course Objectives: To provide the clear understanding of various regulations involving animal use and the various models of toxicity testing

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

CO1	Relate the toxicological findings in clinical safety
CO2	Support in selecting species
CO3	Sensitize students in selecting treatment regimen and designing subsequent non clinical toxicity studies
CO4	Animal ethics and regulatory requirements, CPCSEA guidelines
CO5	Concept of 4Rs (reduce, refine, replacement and rehabilitation)

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	1	1	2	2	2	1	1	1	1
CO2	1	1	2	2	2	2	1	1	1
CO3	1	1	2	2	2	2	1	1	1
CO4	1	2	2	1	1	1	1	2	1
CO5	1	1	1	1	1	1	1	1	1

Module-I **12 Hrs**

Animal ethics and regulatory requirements, CPCSEA guidelines
Concept of 4Rs (reduce, refine, replacement and rehabilitation)
Alternative models in toxicity testing (non-mammalian and non-animal models)

Module-II **12 Hrs**

ARRIVE guidelines: reporting of animal trials
QT interval screening in drug development

Examples of successful replacement: Draize test
Examples of successful replacement: Zebra fish
Examples of successful replacement: Drosophilae
Examples of successful replacement: *C. elegans*

Suggested Readings/Recommended Books (Latest Edition)

1. Frank A Barile, Principles of Toxicology Testing, CRC Press
2. Pal Grave, Animals and Alternatives in Toxicity Testing: Present Status and Future Prospects, Palgrave Macmillan

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 115-19	Fundamentals of Physiology	2	-	-	15	35	1	2	2

Pre-requisite: None

Co- requisite: None

Course Objectives: To make students understand the basic physiology of human body. To improve the foundation of students for better understanding and comprehension of subject matters related to drug discovery, pre-clinical and clinical testing of drugs.

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

CO1	Understand the anatomy and physiology of the systems of the human body
CO2	Appreciate the changes in normal physiology occurring in diseased states
CO3	Better understand the pharmacological principles involved in clinical testing of drug
CO4	Apply the understanding of functions of different parts of gastrointestinal tract in drug absorption and development of new drugs
CO5	Apply the knowledge of physiology of different organs in toxicity testing of drugs

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	1	1	1	3	3	1	2	1	1
CO2	1	1	2	3	2	2	2	2	1
CO3	1	1	2	3	3	3	2	3	3
CO4	1	1	2	3	2	2	2	1	1
CO5	1	1	2	3	2	3	2	2	1

Module-I

Smooth Muscles **02 Hrs**

Morphology, electrical and mechanical activity, molecular basis of contraction, relation of length to tension and plasticity.

Gastrointestinal System **05 Hrs**

Gross anatomy of the gastro-intestinal tract, functions of its different parts including those of liver, pancreas and gall bladder, various gastrointestinal secretions and their role in the absorption and digestion of food

Haemopoietic System **03 Hrs**

Composition and functions of blood and its elements, their disorders, blood groups and their significance, mechanism of coagulation, disorders of platelets and coagulation.

Module-II

Cardiovascular System **05 Hrs**

Morphology, electrical properties of cardiac muscle, pacemaker tissue, basic anatomy of the heart, physiology of heart, blood vessels and circulation, cardiac cycle, heart sounds, cardiac cycle, blood pressure and its regulation

Central Nervous System **05 Hrs**

Basic anatomy and physiology of brain, spinal cord

Endocrine System **06 Hrs**

Basic anatomy and physiology of pituitary, thyroid, parathyroid, adrenals, pancreas, testes and ovary, their hormones and functions

Suggested Readings/Recommended Books (Latest Edition)

1. A Waugh and A Grant, Ross and Wilson Anatomy and Physiology in Health and Illnes, Churchill Livingstone Elsevier
2. K E Barrett, SM Barman, S Boitano, H Brooks, Ganong's Review of Medical Physiology, Lange
3. AC Guyton, JE. Hall, Guyton and Hall Textbook of Physiology, Saunders-Elsevier

Course Code	Course Title	Teaching Load			Marks		Exam	Credits
		L	T	P	Int.	Ext.	Internal	
UC-MSCR 106-19 UC-MSCR 206-19 UC-MSCR 307-19	Journal Club	-	-	4	50	-	Continuous Mode	2

Pre-requisite: None

Co- requisite: Professional Communication (UC-MSCR 105-19), Professional Communication Lab (UC-MSCR 204-19), ICT Skills Lab (UC-MSCR 305-19)

Course Objectives: The course is designed to instil an analytical temperament in the students for critical review of the existing literature and better understanding of clinical research.

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

CO1	Critically review the literature
CO2	Develop an approach to analyse the various types of articles
CO3	Become familiar with sources of bias and types of study designs
CO4	Comprehend how results of study are clinically significant
CO5	Demonstrate skill in scientific communication both orally and in writing

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	2	1	3	3	2	2	3	2	1
CO2	2	1	3	3	3	3	3	2	1
CO3	2	1	1	2	2	3	3	2	1
CO4	2	1	2	2	3	3	3	2	1
CO5	1	1	1	1	1	1	1	1	3

Instructions

1. Students are to work with assigned mentor to chose and analyze an appropriate article followed by a power point presentation.
2. Power-point presentations should be organized as follows: 10 minutes background, 10 minutes article 15 minutes analysis 5 minutes discussion
3. Students are encouraged to critically appraise the literature, and develop their own independent criticisms

SECOND SEMESTER

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 201-19	Pharmacotherapeutics-1	3	1	-	30	70	1.5	3	4

Pre-requisite: General Pharmacology (UC-MSCR 103-19)

Co- requisite: None

Course Objectives: The course is designed to introduce to the learners about the common diseases and effect of target drugs on human body system. The aim would be to introduce the pharmacological basis of treatment.

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

CO1	Develop an understanding of the basic concepts of common diseases prevalent in the society
CO2	Apply their knowledge and understanding of the pathophysiology and management (pharmacological and non-pharmacological) of diseases
CO3	Choose and justify appropriate drug and treatment duration to a given patient with regard to current recommendations and patient-related factors such as other diseases, age, organ functions and other drug treatment
CO4	Integrate pharmacology, pathophysiology, pharmacodynamic, pharmacokinetics and other biomedical and pharmaceutical sciences as they pertain to clinical therapeutics of certain disorders
CO5	Identify the need for further knowledge and formulate relevant learning outcomes

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	1	3	3	2	3	3	2	1	1
CO2	1	2	1	3	1	2	3	1	1
CO3	1	1	3	1	1	1	3	1	1
CO4	2	3	3	3	3	2	1	3	1
CO5	2	3	3	2	3	2	2	2	3

Module-I **12 Hrs**

Basic Concepts

Quality of Life and Pharmacotherapy

Measuring Quality of Life
Pharmacogenetics
Paediatrics- ADME, factors affecting paediatric drug therapy, issues in paediatric drug therapy
Geriatrics- Epidemiology of Aging, Human Aging and Changes in Drug Pharmacokinetics and Pharmacodynamics, Altered Pharmacokinetics, Clinical Geriatrics, Provision of Comprehensive Geriatric Assessment
Pharmacoepidemiology- limits of knowledge at the time of new drug approval, role of the FDA and pharmacoepidemiology
Clinical Toxicology

Module-II **12 Hrs**

Neurologic and Psychiatric Disorders

Etiology, Pathophysiology and Pharmacotherapy of Neurologic Illness – Depression; Epilepsy; Mania; Pain; Schizophrenia; Alzheimer's disease; and Parkinson's disease

Module-III **12 Hrs**

Gastrointestinal Disorders

Etiology, Pathophysiology and Pharmacotherapy of Gastrointestinal illness- Gastroesophageal Reflux Disease; Inflammatory Bowel Disease; Drug-Induced Liver Disease; Pancreatitis

Module-IV **12 Hrs**

Cardiovascular Disorders

Etiology, Pathophysiology and Pharmacotherapy of cardiovascular illness - Hypertension, Ischemic Heart Disease, Congestive Heart Failure, Venous Thromboembolism, Hyperlipidaemia

Suggested Readings/ Books

1. Pharmacotherapy: A Pathophysiologic Approach. Di Piro JT (Eds) New York, NY, The Mc-Graw Hill Co., Inc
2. L.Y. Young MAK-K, et.al., (Eds). Applied Therapeutics: Clinical Use of Drugs. Vancouver: Applied Therapeutics, Inc
3. Textbook of Therapeutics: Drug and Disease Management, Eighth Edition edited by Richard A. Helms
4. Pharmacotherapy Principles and Practice. Chishlom-Burns (Eds). NewYork, The Mc Graw-Hill Co., Inc
5. Clinical Pharmacy and Therapeutics. Roger Walker and Cate Whittlesea (Eds). Churchill Livingstone Elsevier
6. Virginia Poole Arcangelo, Andrew M. Peterson, Veronica Wilbur, Jennifer A. Reinhold, Pharmacotherapeutics for Advanced Practice: A Practical Approach, Wolters Kluwer Health

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 202-20	Clinical Research Regulations & Ethics	3	1	-	30	70	1.5	3	4

Pre-requisite: Fundamentals of Clinical Research (UC-MSCR102-19)

Co- requisite: Clinical Research Lab II (UC-MSCR203-19)

Course Objectives: To educate the students about drug regulatory affairs and significance of regulatory guidelines in drug development and marketing

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

CO1	Comprehend clinical trial regulations and appreciate their importance
CO2	Understand the practical use and evolution of these regulations
CO3	Be familiar with the documents required to be compiled for an ethical & regulatory clinical trial application
CO4	Appreciate the importance of quality system and SOPS
CO5	Make comparison between the regulatory guidelines applicable in different regions

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	2	2	3	1	1	1	2	3	1
CO2	2	1	3	1	1	1	2	3	1
CO3	3	3	3	1	1	2	2	3	1
CO4	3	3	2	2	1	2	1	3	1
CO5	1	1	3	1	1	2	3	3	1

Module-I **09 Hrs**

Evolution of Regulatory Control

European Medicines Agency (EMA)

Vaccine Act, Biological Control Act, Pure food drugs act, Food and Drug Administration (FDA), Kefauver Harris amendments act, Waxman Hatch act, Code of federal regulations, Prescription Drug User Fee Amendments (PDUFA)

International Council for Harmonisation (ICH)

Drugs and cosmetic act 1945

Module-II **13 Hrs**

Regulatory Aspects of Different Regions

Investigational New Drug (IND), New Drug Application (NDA), Abbreviated New Drug Application (ANDA), Paper NDA
Market authorization holders (MAH), its procedures
Regulation of medical devices
Regulation of vaccines
Safety Report filing
Regulation of Complementary Medicine
Regulation of non-prescription drugs

Module-III **14 Hrs**

Regulatory Guidelines

International Conference on Harmonization (ICH) GCP guidelines
Overviews of good laboratory practice (GLP)
Schedule Y of Indian Drugs and Cosmetic Act, New Drugs and Clinical Trials Rules (2019)
Basic regulation of bioavailability/ bioequivalence (BA/BE) studies

Module-IV **09 Hrs**

Ethics in Clinical Research

Evolution of ethics in clinical research: Thalidomide disaster, Tuskegee experiment, Nuremberg Code, Declaration of Helsinki, Belmont report
Establishment of Council for International Organizations of Medical Sciences (CIOMS), National Institutes of Health (NIH) and Indian Council of Medical Research (ICMR) guidelines
Compensation to subjects/patients for clinical trial related injuries

Suggested Readings/Recommended Books (Latest Edition)

1. John. P. Griffin, Textbook of Pharmaceutical Medicine, Wiley Blackwell
2. John I, Gallin, Principles and Practice of Clinical research, Academic Press
3. Ira R. Berry, Robert P. Martin, The Pharmaceutical Regulatory Process, Publisher; Informa Healthcare
4. Guidelines: Drugs and Cosmetics Act, EMA
5. www.ich.org
6. www.fda.gov
7. Central Drugs Standard Control Organization: www.cdsco.gov.in
8. SK Gupta, Drug Discovery and Clinical Research, Jaypee Brothers, Medical Publishers Pvt. Ltd.

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 203-19	Clinical Research Lab II	-	-	4	30	20	1.5	3	4

Pre-requisite: Fundamentals of Clinical Research (UC-MSCR102-19)

Co- requisite: Clinical Research Regulations (UC-MSCR 202-20)

Course Objectives: The course is designed to impart practical knowledge to students about the various aspects of clinical research in accordance to GCP, GLP and clinical trial regulations

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

CO1	Understand the practical application of clinical trial regulations for conduct of clinical trials
CO2	Trained about the sample collection and analysis and interpretation of lab data in compliance with GLP
CO3	Develop SOPs and various documents required for conduct of quality clinical studies
CO4	Apply GCP in collection of clinical data
CO5	Appreciate the significance of statistical analysis in clinical research

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	3	2	3	2	2	1	1	2	1
CO2	2	1	2	2	3	3	1	1	2
CO3	3	2	2	3	2	2	3	2	1
CO4	2	2	2	3	3	3	2	3	1
CO5	3	1	1	3	2	2	3	2	2

1. Measurement of pulse rate and body temperature
2. Effect of exercise on blood pressure
3. Biochemical tests: protein estimation by Lowry's method
4. Biochemical tests: liver function test
5. Biochemical tests: blood glucose

6. Demography: assessment of age, sex, height, weight, waist, BMI, smoking, educational attainment, area-based measure (eg. index of deprivation or disadvantage, rurality distance from health centres etc)
7. Application of simple statistical test to the results obtained in above experiments
8. Haematology tests: haemoglobin, total leukocyte count, differential leukocyte count, erythrocyte sedimentation rate
9. Interpreting Electrocardiography (ECG)
10. Case studies solutions
11. Summary of Product Characteristics (SmPC) development

Suggested Readings/Recommended Books (Latest Edition)

1. Shruti Mohanty and Aparna Verma, Practical Clinical Biochemistry, Jaypee Brothers Medical Publishers (P) Lt d.
2. Vijay Kumar and Kiran Dip Gill, Basic Concepts in Clinical Biochemistry: A Practical Guide, Springer
3. Kathleen Deska Pagana and Timothy J. Pagana, MOSBY'S Manual of Diagnostic and Laboratory Tests, Elsevier
4. John G. Brock-Utne, Clinical Research: Case Studies of Successes and Failures, Publisher; Springer.
5. Duolao Wang and Ameet Bakhai, Clinical Trials: A Practical Guide to Design, Analysis, and Reporting, Remedica
6. Guidelines: ICH, USFDA, Drugs and Cosmetics Act, EMA
7. Electronic Medicines Compendium (eMC): https://www.medicines.org.uk/emc/

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 204-19	Professional Communication Lab	-	-	4	30	20	3	3	2

Pre-requisite: Professional Communication Theory Course

Co- requisite: None

Course Objective: The objective of the course is to help the students become the independent users of English language.

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

CO1	Acquire basic proficiency in listening and speaking English language
CO2	Understand spoken and written English language, particularly the language of their chosen technical field
CO3	Produce on their own clear and coherent texts
CO4	Develop the skills to communicate in English language with clients at work place
CO5	Identify the need for further knowledge and formulate relevant learning outcomes

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	1	3	3	2	3	3	2	1	1
CO2	1	2	1	3	1	2	3	1	1
CO3	1	1	3	1	1	1	3	1	3
CO4	2	3	3	3	3	2	1	3	1
CO5	2	3	3	2	3	2	2	2	1

Module-I **12 Hrs**

Listening English

A conversation between two people set in an everyday social context, e.g. a conversation in an accommodation agency

A monologue set in an everyday social context, e.g. a speech about local facilities
A conversation between up to four people set in an educational or training context, e.g. a tutor and a student discussing an assignment
A monologue on an academic subject, e.g. a classroom lecture

Module-II **12 Hrs**

Speaking English

Candidates will be asked to answer general questions about themselves and a range of familiar topics, such as their home, family, work, studies and interests. This activity lasts between 4 and 5 minutes
Candidates will be given a minute to prepare their thoughts on an assigned topic, before being invited to speak for up to two minutes. The examiner will then ask one or two questions on the same topic to finish this part of the test
Candidates will be asked further questions connected to the topic in Part 2. These questions will provide an opportunity to discuss more abstract issues and ideas. This part lasts between four and five minutes

Suggested Books/ Manuals

1. Listen Here! Intermediate Listening Activities; Clare West; Georgian Press and Cambridge University Press
2. Skillful Foundation Level Listening & Speaking Digital Student's Book Pack; Macmillan Education

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 205-20	Medical Writing	2	-	-	15	35	1	2	2

Pre-requisite: None

Co- requisite: None

Course Objective: The course is designed to explore the basic skills of medical writing. Medical writing is an essential part of clinical research and drug development programme. The goal of this module is to provide overview in both medical science and writing fundamentals.

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

CO1	Improve medical writing skills and better understanding the biomedical publication process
CO2	Demonstrate writing, reading, editing, and reviewing skills
CO3	Become ready to be absorbed Professionals
CO4	Understand about clinical research and the latest techniques and trends in the industry
CO5	Understand career prospects in the medical writing

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	1	3	3	2	2	2	3	1	1
CO2	1	2	1	2	1	2	2	1	3
CO3	3	2	3	1	1	1	3	1	3
CO4	2	3	3	3	3	2	1	3	1
CO5	2	3	3	2	2	2	2	2	2

Module-I **12 Hrs**

Introduction to Medical writing and Healthcare Communication
The Writing Process: prewriting strategies and steps in writing process
Online search techniques
Rules of writing: basic structure of write up; plagiarism and copyrights

Module-II **12 Hrs**

Scientific Writing: writing case reports, drug monograph and abstract writing
Regulatory writing: medical writing in clinical research, study design, observational studies, experimental studies
ICH-E3: structure and content of clinical study reports
Common Technical Document: Format of dossier, eCTD

Suggested Readings/ Books

1. Medical Writing: A Guide for Clinicians, Educators, and Researchers, Springer
2. The Complete Guide to Medical Writing by Mark C. Stuart, Mark Stuart Pharmaceutical Press
3. Guidelines for Reporting Health Research by David Moher Doughlas Altman BMJ books
4. Medical writing a good practice guide by Justina-Orleans; Wiley-Blackwell
5. Successful scientific writing: a step-by-step guide for the biological and medical sciences, Cambridge University Press.
6. ICH: https://www.ich.org

Suggested Software

1. MS Office especially the subscription-based Office 365.
2. Google Docs
3. Scrivener
4. ReadCube
5. Endnote
6. RefMan
7. PerfectIt3 (and PerfectIt Pro)
8. Medical spellcheckers: (Spellex and Stedman's)
9. Dragon Naturally Speaking
10. Statistical analysis: R, SAS, MS SQL Server
11. Adobe Creative Cloud (Acrobat, Photoshop, Audition, etc)

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 211-19	Fundamentals of Epidemiology	2	-	-	15	35	1	2	2

Pre-requisite: None

Co- requisite: None

Course Objectives: To cover concepts of molecular epidemiology and its applications in effective clinical outcome

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

CO1	Understand measures of disease occurrence and disease association, mortality indicators and morbidity indicators
CO2	Understand different mechanisms of bias in clinical research
CO3	Implicate evidence-based clinical medicine, including the specifications of diagnostic tests, screening tests, and prognostic tests
CO4	Interpret and assess the genetic measures in research
CO5	Understand the significance of pharmacogenomics in clinical research

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	2	2	1	1	2	2	2	1	1
CO2	1	1	1	2	2	2	2	1	2
CO3	1	2	1	1	1	2	1	1	1
CO4	1	2	1	1	2	1	1	2	1
CO5	1	2	1	1	1	1	2	1	1

Module-I **13 Hrs**

Measures of disease occurrence and disease association

Mortality indicators and morbidity indicators

The different mechanisms of bias in clinical research (study, response, information, interviewer, site selection, measurement, and confounding); and a conceptual approach to multivariable analysis

Instruction in the research implications of evidence-based clinical medicine, including the specifications of diagnostic tests, screening tests, and prognostic tests
Pharmacoepidemiological studies
Calculation of relative risk and odds ratio

Module-II **13 Hrs**

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, genome-wide association study (GWAS)

Suggested Readings/Recommended Books (Latest Edition)

1. David Duncan Collier, Epidemiology: Basis for Disease Prevention and Health Promotion, Macmillan Publishers.
2. Robert H. Fletcher and Suzanne W. Fletcher, Clinical Epidemiology: The Essentials, WHO Press
3. Brian MacMahon and Thomas F Pugh, Epidemiology Principles and methods, Lippincot William and Wilkins
4. Japhet Killewo, Epidemiology and Demography in Public Health, Elsevier

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 212-19	International Regulatory Affairs	2	-	-	15	35	1	2	2

Pre-requisite: None

Co- requisite: None

Course Objectives: The course is designed to impart advanced knowledge and skills required to learn the concept of various regulatory filings in different countries, different phases of clinical trials and submitting regulatory documents

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

CO1	Understand the regulatory guidance's and guidelines for filing and approval process applicable in different regions
CO2	Participate as an effective member in pharmaceutical regulatory affairs team
CO3	Understand preparation of dossiers and their submission to regulatory agencies in different countries
CO4	Understand clinical trials requirements for approvals for conducting clinical trials
CO5	Make comparison between the regulatory guidelines applicable in different regions

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	2	1	3	1	1	1	2	1	2
CO2	3	1	1	1	1	2	2	1	1
CO3	3	1	3	2	1	1	2	2	2
CO4	3	1	3	2	2	1	2	3	1
CO5	1	1	3	1	1	2	3	3	1

Module-I **12 Hrs**

Introduction to regulatory bodies

Organisation for Economic Co-operation and Development (OECD)
Brazilian Health Surveillance Agency (ANVISA)
Therapeutic Goods Administration (TGA)

Pharmaceuticals and Medical Devices Agency (PMDA)

Module-II **12 Hrs**

Introduction to regulatory bodies

Gulf Co-Operation Council: Central Drug Registration
New Zealand Medicines and Medical Devices Safety Authority (Medsafe)
Health Canada
South African Health Products Regulatory Authority (SAHPRA)
Ministry of Health of the Russian Federation

Suggested Readings/Recommended Books (Latest Edition)

1. Ira R. Berry and Robert P. Martin, The Pharmaceutical Regulatory process, Drugs and the Pharmaceutical Sciences, Informa Health Care
2. Richard A Guarino, New Drug Approval Process: Accelerating Global Registrations Drugs and the Pharmaceutical Sciences
3. Sandy Weinberg, Guidebook for drug regulatory submissions, John Wiley & Sons.lnc.
4. https://www.sahpra.org.za/
5. https://www.tga.gov.au/
6. https://www.pmda.go.jp/
7. https://www.canada.ca/en/services/health/drug-health-products.html
8. http://portal.anvisa.gov.br/english
9. http://ghc.sa/en-us/pages/centraldrugregistration.aspx
10. https://www.medsafe.govt.nz/
11. https://www.oecd.org/chemicalsafety/

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 213-19	Biostatistics in Clinical Research	2	-	-	15	35	1	2	2

Pre-requisite: None

Co- requisite: None

Course Objectives: The course is designed to impart ability to think critically about data, make valid inferences, and understand how statisticians are an essential element of clinical investigations

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

CO1	Apply an appropriate statistical test
CO2	Demonstrate skills in the analysis of clinical research data
CO3	Demonstrate skills in interpreting and communicating the results of statistical analysis, orally and in writing
CO4	Acquire practical understanding of parametric and nonparametric assumptions and tests
CO5	Understand and apply statistical considerations when preparing a protocol

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	2	1	1	2	3	3	2	1	1
CO2	3	1	1	2	3	3	3	2	1
CO3	3	1	1	2	3	3	3	1	3
CO4	2	1	1	2	3	3	1	1	1
CO5	3	1	1	3	2	2	3	2	1

Module-I **12 Hrs**

Types of data and its analysis (categorical *vs* quantitative)
Organization of data, distribution of data and calculation of central tendencies
Confidence interval, SD, SE, regression and correlation
Comparison of data between different groups: using null hypothesis and test of significance (paired t-test, unpaired t-test, Analysis of variance (ANOVA), Analysis of covariance (ANCOVA)

Module-II **12 Hrs**

Comparison of data between different groups: Coefficient of Variation, chi-square test, Fischer exact, Mann-Whitney, Wilcoxon, McNemar test, Kruskal Wallis
Intention-to-treat (ITT) and Per-protocol (PP) and Treatment-received (TR) analyses of results in clinical research, sample size calculation
Introduction to common statistical software packages used in clinical research (e.g. SAS, SPSS)

Suggested Readings/Recommended Books (Latest Edition)

1. Geoffrey R. Norman, David L. Streiner, Biostatistics: The Bare Essentials, Publisher; PMPH USA
2. Beth Dawson, Robert G. Trapp, Basic & Clinical Biostatistics, Publisher; McGraw-Hill
3. Marcello Pagano, Kimberlee Gauvreau, Principles of Biostatistics, Publisher; CRC Press
4. Antonella Bacchieri, Giovanni Della Cioppa, Fundamentals of Clinical Research, Publisher; Springer
5. Katsumi Kobayashi, K. Sadasivan Pillai, A Handbook of Applied Statistics in Pharmacology, Publisher; CRC Press

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 214-19	Poisoning and Management	2	-	-	15	35	1	2	2

Pre-requisite: None

Co- requisite: None

Course Objectives: The course is designed to provides the understanding on the general concepts and the various types of drug poisoning and its management

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

CO1	Understand the general concepts of poisoning
CO2	Identify various types of poisoning
CO3	Understand toxicology of heavy metals
CO4	Learn about treatment and management of poisoning
CO5	Understand the science of chelating agents

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	1	1	1	2	2	1	1	1	1
CO2	1	2	2	1	1	1	1	1	1
CO3	1	2	2	1	1	1	1	1	1
CO4	1	2	2	1	1	1	1	1	1
CO5	1	1	1	1	1	1	1	1	1

Module-I **12 Hrs**

General concepts and some common types of drug poisoning

Introduction to science of poisons, pollutants, industrial solvents etc.

Poisoning and its types

Some common poisoning: atropine poisoning, paracetamol, aspirin, organophosphorous compounds, barbiturates, cyanides, benzodiazepines, methyl alcohol, digoxin, opioids

Management of poisoning: general measures and treatment of poisoning poison control/information centre's

Module-II **12 Hrs**

Heavy metal poisoning and its management

Toxicology of heavy metals: mercury, lead, arsenic, iron

Chelating agents: dimercaprol, succimer, unithol, edentate calcium disodium (EDTA), d-penicillamine

Suggested Readings/Recommended Books (Latest Edition)

1. Andrew L. Reeves, Toxicology: Principles And Practice, Wiley Blackwell
2. Raymond Niesink and Mannfred A. Hollinger, Toxicology: Principles and Applications, American Chemical Society
3. Frank A. Barile, Barile's Clinical Toxicology: Principles and Mechanisms, CRC Press
4. Bev-Lorraine True, Dreisbach's Handbook of Poisoning: Prevention, Diagnosis and Treatment, CRC Press

Course Code	Course Title	Teaching Load			Marks		Exam	Credits
		L	T	P	Int.	Ext.	Internal	
UC-MSCR 106-19 UC-MSCR 206-19 UC-MSCR 307-19	Journal Club	-	-	4	50	-	Continuous Mode	2

Pre-requisite: None

Co- requisite: Professional Communication (UC-MSCR 105-19), Professional Communication Lab (UC-MSCR 204-19), ICT Skills Lab (UC-MSCR 305-19)

Course Objectives: The course is designed to instil an analytical temperament in the students for critical review of the existing literature and better understanding of clinical research.

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

CO1	Critically review the literature
CO2	Develop an approach to analyse the various types of articles
CO3	Become familiar with sources of bias and types of study designs
CO4	Comprehend how results of study are clinically significant
CO5	Demonstrate skill in scientific communication both orally and in writing

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	2	1	3	3	2	2	3	2	1
CO2	2	1	3	3	3	3	3	2	1
CO3	2	1	1	2	2	3	3	2	1
CO4	2	1	2	2	3	3	3	2	1
CO5	1	1	1	1	1	1	1	1	3

Instructions

1. Students are to work with assigned mentor to chose and analyze an appropriate article followed by a power point presentation.
2. Power-point presentations should be organized as follows: 10 minutes background, 10 minutes article 15 minutes analysis 5 minutes discussion
3. Students are encouraged to critically appraise the literature, and develop their own independent criticisms

THIRD SEMESTER

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 301-19	Pharmacotherapeutics-II	3	1	-	30	70	1.5	3	4

Pre-requisite: Pharmacotherapeutics-I (UC-MSCR 201-19)

Co- requisite: None

Course Objectives: The course is designed to introduce to the learners about the common diseases and effect of target drugs on human body system. The aim would be to introduce the pharmacological basis of treatment.

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

CO1	Develop an understanding of the basic concepts of common diseases prevalent in the society
CO2	Apply their knowledge and understanding of the pathophysiology and management (pharmacological and non-pharmacological) of diseases
CO3	Choose and justify appropriate drug and treatment duration to a given patient with regard to current recommendations and patient-related factors such as other diseases, age, organ functions and other drug treatment
CO4	Integrate pharmacology, pathophysiology, pharmacodynamic, pharmacokinetics and other biomedical and pharmaceutical sciences as they pertain to clinical therapeutics of certain disorders
CO5	Identify the need for further knowledge and formulate relevant learning outcomes

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	1	3	3	2	3	3	2	1	1
CO2	1	2	1	3	1	2	3	1	1
CO3	1	1	3	1	1	1	3	1	1
CO4	2	3	3	3	3	2	1	3	1
CO5	2	3	3	2	3	2	2	2	3

Module-I **12 Hrs**

Endocrine System Disorders

Etiology, Pathophysiology and Pharmacotherapy: diabetes mellitus, thyroid disorders,

obesity
Infertility and antifertility drugs

Module-II **12 Hrs**

Therapeutics in Infectious Diseases
Gastro-intestinal infections, urinary tract infections
Fungal infections
Protozoal and viral infections (HCV, H1N1, rotavirus)
HIV and its management

Module-III **12 Hrs**

Respiratory System Disorders
Etiology, Pathophysiology and Pharmacotherapy: bronchial asthma, chronic obstructive pulmonary disease (COPD), pulmonary hypertension, tuberculosis

Module-IV **12 Hrs**

Cancer therapeutics: chemotherapy
Arthritis: osteoarthritis, rheumatoid arthritis
Drugs avoided during pregnancy and lactation

Suggested Readings/ Books (Latest Edition)

1. Pharmacotherapy: A Pathophysiologic Approach. Di Piro JT (Eds) New York, NY, The Mc-Graw Hill Co., Inc
2. L.Y. Young MAK-K, et.al., (Eds). Applied Therapeutics: Clinical Use of Drugs. Vancouver: Applied Therapeutics, Inc
3. Textbook of Therapeutics: Drug and Disease Management, Eighth Edition edited by Richard A. Helms
4. Pharmacotherapy Principles and Practice. Chishlom-Burns (Eds). NewYork, The Mc Graw-Hill Co., Inc
5. Clinical Pharmacy and Therapeutics. Roger Walker and Cate Whittlesea (Eds). Churchill Livingstone Elsevier
6. Virginia Poole Arcangelo, Andrew M. Peterson, Veronica Wilbur, Jennifer A. Reinhold, Pharmacotherapeutics for Advanced Practice: A Practical Approach, Wolters Kluwer Health

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 302-20	Clinical Study Design	3	1	-	30	70	1.5	3	4

Pre-requisite: Fundamentals of Clinical Research (UC-MSCR102-19)

Co- requisite: None

Course Objectives: The course is designed to provide opportunity to students to learn about regulatory and scientific rationale of designing, conducting, and successfully completing a clinical trial.

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

CO1	Develop an understanding of the basic concepts of different types of clinical study designs
CO2	Apply their knowledge and understanding in choosing the appropriate study design
CO3	Understand the key study design elements for preventing bias
CO4	Understand what are the essential documents required to conduct a clinical trial
CO5	Learn about the trial design for special population

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	3	1	1	2	2	3	1	3	1
CO2	3	1	1	2	2	3	2	3	1
CO3	3	1	1	1	1	3	2	3	1
CO4	3	1	3	1	1	1	1	2	1
CO5	3	1	2	2	3	1	2	3	1

Module-I **12 Hrs**

Inclusion and exclusion criteria
Screening and recruitment of subjects
Methods of randomization, blinding
Placebo
Endpoints: primary, secondary, composite, surrogate

Module-II **12 Hrs**

Type of Studies

Observational studies: case report, case series, cross-sectional studies, case control study, cohort study, relative risk and odds ratio

Experimental studies: randomized trial, open label study, cross over, equivalence trials, superiority trials and non-inferiority trials

Module-III **12 Hrs**

Phases of clinical trials

Designing phase I, II, III and IV trials: design types (dose ranging, safety studies, proof of concept studies, cluster randomized, factorial design, sequential design), their characteristics, and parameter to measure

Module-IV **12 Hrs**

Trial designs of common diseases like CVS (anti-hypertensive drugs), CNS (neurodegenerative diseases), cancer and metabolic disorders

BA-BE study designs

Trials for special population: paediatric, geriatric, pregnant women and lactating women

Suggested Readings/ Books (Latest Edition)

1. Stephen B. Hulley, Steven R. Cummings, Warren S. Browner, Deborah G. Grady and Thomas B. Newman, Designing Clinical Research, Lippincott Williams and Wilkins
2. Duolao Wang and Ameet Bakhai, Clinical Trials: A Practical Guide to Design, Analysis, and Reporting, Remedica
3. Shein-Chung Chow, Design and Analysis of Bioavailability and Bioequivalence Studies, CRC Press
4. Stephen P. Glasser, Essentials of Clinical Research, Springer
5. Beth Dawson, Robert G. Trapp, Basic and Clinical Biostatistics, Publisher; McGraw-Hill
6. Richard Chin and Bruce Y. Lee, Principles and Practice of Clinical Trial Medicine, Academic Press
7. John I. Gallin, Frederick P. Ognibene, Laura Lee Johnson, Principles and Practice of Clinical Research, Academic Press.

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 303-19	Research Methodology	2	-	-	15	35	1	2	2

Pre-requisite: None

Co- requisite: Clinical Study Design (UC-MSCR 302-20)

Course Objectives: The course is designed to provide opportunity to students to learn about some basic concepts of research and its methodologies.

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

CO1	Develop an understanding of the basic concepts of research methodologies
CO2	Apply their knowledge and understanding in defining specific research problems
CO3	Develop an understanding about different research designs
CO4	Differentiate between primary and secondary data and significance of each type of data
CO5	Understand the basics of writing and presenting scientific data

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	2	1	1	2	1	3	2	1	1
CO2	2	1	1	1	3	1	2	2	1
CO3	2	1	1	1	1	2	2	2	1
CO4	2	1	1	1	1	1	3	1	1
CO5	3	1	1	1	1	2	3	3	3

Module-I **12 Hrs**

Definition, general and specific characteristics of research, classification, types and objective of research, research process, criteria of good research, basic concept of experiments and research, significance of research

Planning and designing a research study: choosing a research topic, literature review, research problem formulation articulating hypothesis, selection of variables, research participants

Module-II **12 Hrs**

Meaning, nature and types of data: primary and secondary; observational; experimental
Data Collection: types of sampling design
Experimental designs, quasi-experimental designs, non-experimental or qualitative designs
Art of scientific writing: Steps to better writing, flow method, organization of material and style, drawing figures, graphs, tables, footnotes, references etc. in a research paper
Levels of Evidence for Clinical Studies
Meta-analysis

Suggested Readings/ Books (Latest Edition)

1. Geoffrey Marczyk, David DeMatteo, David Festinger;.Essential of Research Design and Methodology. John Wiley & Sons
2. Kothari, C.R; Research Methodology: Methods and Techniques.. New Age International Publishers, New Delhi
3. Beth Dawson, Robert G. Trapp, Basic and Clinical Biostatistics, Publisher; McGraw-Hill

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 304-19	Pharmacovigilance	2	-	-	15	35	1	2	2

Pre-requisite: None

Co- requisite: None

Course Objectives: This course focuses on importance of drug safety issues that have potential to affect public health.

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

CO1	Develop an understanding of early detection of new adverse reactions and to introduce measures to manage those risks
CO2	Define and classify ADRs, detection, reporting and causality assessment
CO3	Demonstrate basic tools used in pharmacovigilance safety studies
CO4	Develop practical understanding of signal detection and communication of safety signals with stakeholders
CO5	Understand drug monitoring, risk management studies and apply statistical considerations when preparing a protocol

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	2	1	2	2	3	1	1	1	2
CO2	3	1	1	2	2	1	1	1	2
CO3	3	1	1	2	2	1	1	1	3
CO4	2	2	2	2	1	1	1	1	1
CO5	3	1	1	1	2	1	1	2	1

Module-I **12 Hrs**

Introduction to Pharmacovigilance
Definition and classification of ADRs, Detection, reporting and causality assessment
Pharmacovigilance in India and global perspective
Pharmacovigilance methods, passive surveillance-spontaneous reports and case series, Active surveillance-drug event monitoring and registries

Basic tools used in pharmacovigilance, Safety studies, Importance of pharmacovigilance

Module-II **12 Hrs**

Pharmaceutical preparations (Adverse effects), product surveillance and post marketing
Signal detection and follow-up
Communicating safety signals with stakeholders, Erice Declaration, Risk management studies
Introduction to translational medicine, drug monitoring, pharmacovigilance in drug regulation
Overview of various software used in pharmacovigilance
Introduction to artificial intelligence in pharmacovigilance
Introduction to herbavigilance
Introduction to materiovigilance

Suggested Reading/ Recommended Books (Latest Edition)

1. Brian L. Storm and Stephen K. Kimmel, Textbook of Pharmacoepidemiology, Wiley Blackwell
2. Ronald D. Mann, Elizabeth Andrews, Pharmacovigilance, Wiley Blackwell
3. Andrew Bate, Evidence-Based Pharmacovigilance, Human Press
4. Patrick Waller, Mira Harrison-Woolrych, An Introduction to Pharmacovigilance, Wiley-Blackwell
5. Uppsala Monitoring Centre: https://www.who-umc.org/

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 305-19	Clinical Research Lab III	-	-	4	30	20	1.5	3	2

Pre-requisite: Fundamentals of Clinical Research (UC-MSCR102-19) and Clinical Research Regulations & Ethics (UC-MSCR 202-20)

Co- requisite: Clinical Study Design (UC-MSCR302-19)

Course Objectives: The course is designed to impart practical knowledge to students about the various aspects of clinical research in accordance to GCP, GLP and clinical trial regulations

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

CO1	Understand the practical application of clinical trial regulations for conduct of clinical trials
CO2	Develop SOPs and various documents required for conduct of quality clinical studies
CO3	Develop various documents essential in clinical research
CO4	Develop clinical study protocols
CO5	Comprehend the significance of documentation in clinical research

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	3	2	3	2	2	1	1	2	1
CO2	3	2	2	3	2	2	3	2	1
CO3	3	1	2	2	2	2	2	3	2
CO4	3	1	1	3	2	2	2	3	2
CO5	3	1	1	1	1	1	2	3	1

1. Development of clinical research documents: SOPs development
2. Development of clinical research documents: investigator brochure
3. Development of clinical research documents: informed consent forms
4. Development of clinical research documents: case record form
5. Development of clinical research documents: preparation of dummy problem-based protocol clinical research protocol

6. Development of clinical research documents: preparation of dummy bioequivalence protocols
7. Preparation of a clinical trial protocol for submission to regulatory agency
8. How to take case history
9. Mock Case report – Causality assessment
10. Use of software used in clinical research

Suggested Readings/Recommended Books (Latest Edition)

1. John G. Brock-Utne, Clinical Research: Case Studies of Successes and Failures, Publisher; Springer
2. Duolao Wang and Ameet Bakhai, Clinical Trials: A Practical Guide to Design, Analysis, and Reporting, Publisher; Remedica
3. Stephen P. Glasser, Essentials of Clinical Research, Publisher; Springer
4. Deborah Rosenbaum and Michelle Dresser, Clinical Research Coordinator Handbook, Publisher; Interpharm/CRC
5. Evan DeRenzo and Joel Moss, Writing Clinical Research Protocols: Ethical Considerations, Publisher; Elsevier
6. Guidelines: ICH, USFDA, Drugs and Cosmetics Act, EMA

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 306-19	ICT Skills Lab	-	-	4	30	20	1	2	2

Pre-requisite: None

Co- requisite: None

Course Objectives: The course is designed to improve the student learning through the technology

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

CO1	Understand the basics of ICT and the terminologies used in ICT
CO2	Appreciate the potential of technologies in modern society
CO3	Learn about and using different kinds of IT tools suitably and safely
CO4	Search information on the internet in digital encyclopedias, repositories, etc., or using search engines, in a systematic and coherent fashion
CO5	Understand basic functions of a search engine and implement search criteria definition strategies for filtering the results obtained

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	2	1	1	1	1	1	2	1	2
CO2	1	1	1	1	1	1	1	1	2
CO3	3	1	1	1	1	1	1	1	1
CO4	3	1	1	1	1	3	3	1	2
CO5	3	1	1	1	1	3	3	1	2

1. ICT: meaning, advantages, disadvantages and uses
2. General abbreviations and terminology of ICT
3. Basics of internet and emailing
4. Use of internet in research works
5. Literature survey of the previous works and searches for articles online and in the library
6. Cyber laws
7. Database, concepts, components and uses

8. Information retrieval system
9. IT based library and information system
10. New developments in Information communication technology

Suggested Readings/ Books (Latest Edition)

1. Arnaudet, ML and Barrett, Communication Research Techniques: Methods and Applications, Wadsworth California
2. Donal Carburg, Distinctive Qualities in Communication and Research, Taylor and Francis
3. Chrisanthi Avgerou, Robin Mansell, Danny Quah, and Roger Silverstone, The Oxford Handbook of Information and Communication Technologies, Oxford University Press

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 311-20	Clinical Trial Operations	2	-	-	15	35	1	2	2

Pre-requisite: None

Co- requisite: None

Course Objectives: To sensitize students regarding significance of real time planning and coordination of clinical trials

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

CO1	Understand the criteria for selection of clinical trial site and clinical investigators
CO2	Understand roles and responsibilities of various stakeholders in clinical trial
CO3	Conduct activities at the site related to maintenance of clinical trial documents
CO4	Understand the roles and responsibilities of monitors and auditors
CO5	Conduct activities related to trial site closure and submission of site close out report

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	2	1	1	3	3	1	3	1	2
CO2	2	1	3	1	1	2	3	2	3
CO3	1	1	3	3	1	3	3	3	1
CO4	1	1	1	2	2	3	3	3	1
CO5	1	1	1	1	3	3	3	2	2

Module-I **12 Hrs**

Selection of clinical trial sites, site-initiation visits, clinical investigators and making budget and outsourcing clinical trial related work and selection of vendor

The roles and responsibilities of the following in CT: sponsor, institution, clinical trial coordinator, clinical investigator

Documents required at site, site initiation and conduct activities, protocol, CRF, ICD, investigator brochure, clinical trial agreement, ethics committee and regulatory approval, site-initiation visits

Recruitment, IP/IMP/pharmacy file receipt and storage, clinical trial site master file,

databases, SOPs
Roles and responsibilities of monitors and auditors/inspectors, monitoring visits, audits and inspections, independent data monitoring activities

Module-II **12 Hrs**

Contingency planning to prepare for unexpected situations
Site close-out activities, suspending and premature termination of a trial
Handling missing data, query and resolution, database lock
Site close-out report, clinical study report, submission to ethics committee and regulatory agency, publication of results

Suggested Reading (Latest Edition)

1. Principles and practice of Clinical Research by John. I Gallin.; Academic Press
2. Principles and practice of clinical trial medicine by Richard Cin and Bruce Y. Lee; Academic Press
3. Guidelines like GCP, USFDA, EMEA, Indian GCP etc.
4. SK Gupta, Drug Discovery and Clinical Research, Jaypee Brothers, Medical Publishers Pvt. Ltd.
5. JoAnn Pfeiffer, Cris Wells, A Practical Guide to Managing Clinical Trials, CRC Press.
6. Lionel D. Edwards, Anthony W. Fox, Peter D. Stonier, Principles and Practice of Pharmaceutical Medicine, Blackwell Publishing Ltd.
7. Graham D. Ogg, A Practical Guide to Quality Management in Clinical Trial Research, CRC Press.
8. Delva Shamley, Brenda Wright, A Comprehensive and Practical Guide to Clinical Trials, Academic Press.

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 312-19	Medical Coding	2	-	-	15	35	1	2	2

Pre-requisite: None

Co- requisite: None

Course Objectives: This course is designed to instruct the students about various medical dictionaries used worldwide for the representation of the data

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

CO1	Categorize the medical terms appropriately
CO2	Analyze medical clinical narratives and correctly assign medical codes
CO3	Assign and understand diagnostic and procedure codes using ICD coding systems
CO4	Develop an understanding of medical coding as a data collection tool
CO5	Demonstrate entry level skills in coding

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	3	1	1	1	3	1	3	3	1
CO2	3	1	1	1	3	1	3	3	1
CO3	3	1	1	1	3	1	1	1	1
CO4	3	1	1	1	1	3	1	3	1
CO5	3	1	1	1	1	1	1	3	1

Module-I **12 Hrs**

MedDRA- Medical dictionary for regulatory activities
WHO-DDE-World Health Organization Drug dictionary
WHO-ART-World Health Organization Adverse reaction terminology

Module-II **12 Hrs**

International Classification of Diseases

Suggested Reading

1. ICH: M1 guidelines
2. https://www.who.int/classifications/icd/en/
3. https://www.cdc.gov/nchs/icd/

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 313-19	Pharmacoeconomics & Health Technology Assessment	2	-	-	15	35	1	2	2

Pre-requisite: None

Co- requisite: None

Course Objectives: To make students understand the basics concept and significance of pharmacoeconomics in clinical research

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

CO1	Outline the steps for conducting a pharmacoeconomic analysis
CO2	Identify strengths and issues associated with current pharmacoeconomic methods
CO3	Critique current pharmacoeconomic literature
CO4	Describe the rationale of pharmacoeconomic analysis
CO5	Understand impact of pharmacoeconomics of pharmaceutical care services on the health and health care of a community

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	3	1	2	2	2	1	1	1	1
CO2	3	1	3	1	1	1	1	1	1
CO3	3	1	1	3	3	1	3	1	1
CO4	3	1	2	3	3	1	3	1	1
CO5	1	1	1	3	3	1	2	1	1

Module-I **12 Hrs**

Introduction to pharmacoeconomics

Definitions, costs and consequences in pharmacoeconomic studies, perspectives, difference between pharmacoeconomics and outcomes research

Types of pharmacoeconomic analysis: cost-effective analysis, cost-minimization analysis, cost- benefit analysis, cost-utility analysis, cost-offset analysis

Health related quality of life, health utilities index

Module-II **12 Hrs**

Health Technology Assessment

International Network of Agencies for Health Technology Assessment (INHATA)
Health Technology Assessment (HTA) system: practice and process
Models of Health Technology Assessment agencies
Structure of the Health Technology Assessment report: principles, practice and process

Suggested Readings/Recommended Books (Latest Edition)

1. Thomas E. Getzen, Health Economics: Fundamentals and Flow of Funds, Wiley
2. Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg, Methods for the Economic Evaluation of Health Care Programmes, Oxford University Press
3. Andrew Briggs, Karl Claxton, Mark Sculpher, Decision Modeling for Health Economic Evaluation, Oxford University Press
4. http://www.inahta.org/

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
UC-MSCR 314-20	Quality Management in Clinical Trials	2	-	-	15	35	1	2	2

Pre-requisite: None

Co- requisite: None

Course Objectives: The course is designed to sensitize students regarding significance of quality control, and quality management in clinical trials

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

CO1	Contribute effectively in conduct of clinical studies taking into consideration the aspects of quality control and management.
CO2	Understand importance of clinical quality assurance department in industry
CO3	Conduct activities at the site related to maintenance source documents
CO4	Understand the roles and responsibilities of monitors and auditors/ inspectors in monitoring visits/ audits and inspections
CO5	To manage the clinical study appropriately for audits and regulatory inspections

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	3	3	2	1	1	2	1	3	2
CO2	3	1	3	1	1	2	1	3	2
CO3	3	1	2	1	1	2	1	3	1
CO4	1	3	2	1	1	2	1	2	2
CO5	2	1	2	1	1	3	1	2	2

Module-I **12 Hrs**

Quality Control, Quality Assurance and Total Quality Management
Overview of QA and QC in clinical trials and their comparison
Total quality management
Good clinical practice guidelines for quality assurance
Corrective and Preventive Action (CAPA) program, Root Cause Analysis (RCA)

Module-II **12 Hrs**

Audits/Inspections
Audits, its process and important aspects, types of audits
Clinical Quality Assurance Audit
Regulatory inspections
Source document verification
Risk based quality management & monitoring

Suggested Readings/Recommended Books (Latest Edition)

1. Graham D, Ogg, A practical guide to quality management in clinical trial research, CRC Press.
2. VM Madzarevic, Clinical Trial Audit preparation: A guide for Good clinical practice inspections, Wiley.
3. Regulatory guidelines: ICH, USFDA, Indian GCP.
4. JoAnn Pfeiffer, Cris Wells, A Practical Guide to Managing Clinical Trials, CRC Press.
5. Lionel D. Edwards, Anthony W. Fox, Peter D. Stonier, Principles and Practice of Pharmaceutical Medicine, Blackwell Publishing Ltd.
6. Graham D. Ogg, A Practical Guide to Quality Management in Clinical Trial Research, CRC Press.
7. Delva Shamley, Brenda Wright, A Comprehensive and Practical Guide to Clinical Trials, Academic Press.

Course Code	Course Title	Teaching Load			Marks		Exam	Credits
		L	T	P	Int.	Ext.	Internal	
UC-MSCR 106-19 UC-MSCR 206-19 UC-MSCR 306-19	Journal Club	-	-	4	50	-	Continuous Mode	2

Pre-requisite: None

Co- requisite: Professional Communication (UC-MSCR 105-19), Professional Communication Lab (UC-MSCR 204-19), ICT Skills Lab (UC-MSCR 305-19)

Course Objectives: The course is designed to instil an analytical temperament in the students for critical review of the existing literature and better understanding of clinical research.

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

CO1	Critically review the literature
CO2	Develop an approach to analyse the various types of articles
CO3	Become familiar with sources of bias and types of study designs
CO4	Comprehend how results of study are clinically significant
CO5	Demonstrate skill in scientific communication both orally and in writing

Mapping of course outcomes with the programme outcomes

	PO1	PO2	PO3	PO4	PO5	PO6	PO7	PO8	PO9
CO1	2	1	3	3	2	2	3	2	1
CO2	2	1	3	3	3	3	3	2	1
CO3	2	1	1	2	2	3	3	2	1
CO4	2	1	2	2	3	3	3	2	1
CO5	1	1	1	1	1	1	1	1	3

Instructions

1. Students are to work with assigned mentor to chose and analyze an appropriate article followed by a power point presentation.
2. Power-point presentations should be organized as follows: 10 minutes background, 10 minutes article 15 minutes analysis 5 minutes discussion

3. Students are encouraged to critically appraise the literature, and develop their own independent criticisms
4. Minimum two presentations in a semester by each student