

Study Scheme & Syllabus of

Master of Science in Clinical Research

(M.Sc. Clinical Research)

Batch 2018 onwards



By

Board of Study Clinical Research
Department of Academics

IK Gujral Punjab Technical University

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
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
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	<ul style="list-style-type: none"> • Theory courses of 04 credits = 100 marks • Theory courses of 02 credits = 50marks • Practical courses of 02 credits = 50 marks
Programme Structure	<ol style="list-style-type: none"> 1. Compulsory Foundation Course 2. Core Courses 3. Elective Courses <ol style="list-style-type: none"> 3.1. Discipline Specific Elective Courses 3.2. Generic Elective Courses 4. Ability Enhancement Courses 5. Skill Enhancement Courses

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.

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.
- ❖ Theory courses having internal assessment of 30 marks: Sessional exam shall be **conducted for 30 marks** for theory and shall be **computed for 20marks**. The remaining 10 marks for attendance, assignments, discipline, class performance, quiz etc.
- ❖ Theory courses having internal assessment of 15 marks: Sessional exam shall be **conducted for 20 marks** for theory and shall be **computed for 10marks**. The remaining 05marks for attendance, assignments, discipline, class performance, quiz etc.

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 1 out of 2)	1x5 = 05
Long Answers(Answer 1 out 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	
MSCR101-18	Foundation Course	Foundation Course	3	1	-	30	70	100	4
MSCR102-18	Core Theory	Fundamentals of Clinical Research	3	1	-	30	70	100	4
MSCR103-18	Core Theory	Pharmacology	3	1	-	30	70	100	4
MSCR 104-18	Core Practical	Clinical Research Lab	-	-	4	30	20	50	2
MSCR 105-18	Ability Enhancement	Professional Communication	2	-	-	15	35	50	2
MSCR 106-18	Skill Enhancement	Seminar/Journal Club	-	-	4	50	-	50	2
MSCR XXX	Discipline Specific Elective Theory	Elective –I	2	-	-	15	35	50	2
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
MSCR 111-18	Human Biology
MSCR 112-18	Ethics in Clinical Research
MSCR 113-18	Different Systems of Medicine

Generic Elective Theory (Elective-II)

Subject Code	Subject Name
MSCR 114-18	Pharmacokinetics
MSCR 115-18	Alternatives in Toxicity Testing

Second Semester

Course Code	Course Type	Course Name	Load			Marks			Credits
			L	T	P	Internal	External	Total	
MSCR201-18	Core Theory	Etiopathology & Pharmacotherapy-I	3	1	-	30	70	100	4
MSCR202-18	Core Theory	Clinical Research Regulations	3	1	-	30	70	100	4
MSCR203-18	Core Practical	Clinical Research Lab	-	-	4	30	20	50	2
MSCR 204-18	Ability Enhancement	Professional Communication Lab	-	-	4	30	20	50	2
MSCR 205-18	Skill Enhancement	Medical Writing	2	-	-	15	35	50	2
MSCR 206-18	Skill Enhancement	Journal Club	-	-	4	50	-	50	2
MSCR XXX	Discipline Specific Elective Theory	Elective –III	2	-	-	15	35	50	2
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
MSCR 211-18	Basic Epidemiological Principles
MSCR 212-18	Intellectual Property Rights

Generic Elective Theory (Elective-IV)

Subject Code	Subject Name
MSCR 213-18	Biostatistics in Clinical Research
MSCR 214-18	Poisoning and its Management

Third Semester

Course Code	Course Type	Course Name	Load			Marks			Credits
			L	T	P	Internal	External	Total	
MSCR301-18	Core Theory	Etiopathology & Pharmacotherapy-II	3	1	-	30	70	100	4
MSCR302-18	Core Theory	Clinical Study Design	3	1	-	30	70	100	4
MSCR303-18	Core Theory	Research Methodology	2	-	-	15	35	50	2
MSCR304-18	Core Theory	Pharmacovigilance	2	-	-	15	35	50	2
MSCR305-18	Core Practical	Clinical Research Lab	-	-	4	30	20	50	2
MSCR 306-18	Skill Enhancement	ICT Skills Lab	-	-	4	30	20	50	2
MSCR 307-18	Skill Enhancement	Journal Club	-	-	4	50	-	50	2
MSCR 308-18	Research Work	Synopsis	-	-	4	50	-	50	2
MSCR XXX	Discipline Specific Elective Theory	Elective –V	2	-	-	15	35	50	2
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
MSCR 311-18	Clinical Trial Operations
MSCR 312-18	Medical Coding

Generic Elective Theory (Elective-VI)

Subject Code	Subject Name
MSCR 313-18	Pharmacoeconomics and Health Technology Assessment
MSCR 314-18	Quality Management in Clinical Trials
MSCR 315-18	Health Research Fundamentals (SWAYAM/MOOCs)
MSCR 316-18	Organic Chemistry in Biology and Drug Development (SWAYAM/MOOCs)
MSCR 317-18	Ultrafast Optics and Spectroscopy (SWAYAM/MOOCs)
MSCR 318-18	Research Ethics (SWAYAM/MOOCs)

Fourth Semester

Course Code	Course Type	Course Name	Load			Marks			Credits
			L	T	P	Internal	External	Total	
MSCR401-18	Seminar	Seminar	-	-	4	50	-	50	2
MSCR402-18	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.
- 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
Participation in Seminar/ Conference/ Workshop/ Symposium/ Training Programs (related to the specialization of the student)	01
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 participation 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.	
MSCR 101-18	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, Molarity, Normality, Formality etc)

Laws of mass action, Reaction Quotient, Chemical equilibrium constant, Relation of K_p & K_c , 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: Applications and Ethical aspects: Stem cell and its application

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.	
MSCR 102-18	Fundamentals of Clinical Research	3	1	-	30	70	1.5	3	4
Pre-requisite: None									
Co- requisite: Pharmacology (MSCR 103-18)									
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 pharmaceuticals science in new drug development and clinical use of drugs								
CO3	Identify with the issues related to patents and intellectual property rights of drugs								
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	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

14 Hrs

Drug Development Process and Drug Discovery

The drug development process; high throughput screening (HTS)
Combinatorial chemistry
Lead optimization, target-centered drug design

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

10 Hrs

Drug regulatory affairs

Drug regulatory affairs

Basic concepts of Intellectual Property rights, Copyrights, Patents Registration and Infringements, Trade Marks, TRIPS

Module-IV

12 Hrs

Drug Evaluation and Clinical Development

Phases of developmental clinical trials

Phase 0, Phase-I, Phase-II, Phase-III, Phase-IV

Placebo response, 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.	
MSCR 103-18	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 toxicity testing of drugs, 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	Design the protocols for toxicity testing of drugs and describe the specific organ toxicity testing of drugs
CO4	Describe the animal models of diseases for drug screening and evaluation
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	3	2	3	3	3	2	3
CO4	1	1	3	2	3	3	3	3	1
CO5	1	1	3	2	3	2	3	3	2

Module-I

10 Hrs

Pharmacodynamics

Mechanism of drug action
Receptors
Transduction process
Second messengers
Dose response relationship

Chemical interactions (Additive effect, potentiation, synergism and antagonism), Dose response relationship (ED50, LD50 EC50, LC50.)

Module-II

12 Hrs

Non Clinical Testing-I

Introduction to toxicology; Routes of exposure, biotransformation of toxicants.
Acute, sub acute and chronic toxicity
Organ specific toxicity
Mutagenicity, teratogenicity and carcinogenicity
Effect on reproductive system
Bioassays

Module-III

12 Hrs

Non Clinical Testing-II

Animal models of certain diseases: diabetes, hypertension, Alzheimer's, depression
Problems in extrapolating data from animals to humans

Module-IV

11 Hrs

Special Topics

Adverse drug reactions (ADRs)
Drug interactions
Therapeutic Drug Monitoring
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.	
MSCR 104-18	Clinical Research Lab	-	-	4	30	20	3	3	2
Pre-requisite: None									
Co- requisite: Fundamentals of Clinical Research (MSCR102-18)&Pharmacology (MSCR103-18)									
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. Protein estimation by Lowry's method
4. Validation of machines & analytical instruments
5. Extraction of DNA
6. Preparation of SOPs for various equipments
7. To perform liver function test and renal function test
8. Preparation of a Clinical trial protocol for submission to regulatory agency

9. Demonstration of routes of exposure/administration of drugs
10. Demonstration of some non – invasive techniques in preclinical screening of drug
11. Bioethics- do's and don'ts, confidentiality, cultural/social ethics

Suggested Readings/Recommended Books (Latest Edition)

1. A.I. Vogel, Text Book of Quantitative Inorganic analysis, Pearson.
2. D Wang and A Bakhai, Clinical Trials A Practical Guide to Design, Analysis, and Reporting, Remedica.
3. D Rosenbaum and M Dresser, Clinical Research Coordinator Handbook, CRC Press.
4. 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.	
MSCR 105-18	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 are authentic and are taken 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 are of general interest and suitable for candidates planning to work in Clinical Research Organisations. Based on a graph, table, chart or diagram candidates are asked to describe, summarise or explain the information in own words. 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.

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

Write a letter requesting information or explaining a given situation. The letter may be personal, semi-formal or formal in style. Test takers will be asked to write an essay in response to a point of view, argument or problem. Opinions should be supported by relevant examples.

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 Heasley. 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.	
MSCR 111-18	Human Biology	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 (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
MSCR 112-18	Ethics in Clinical Research	2	-	-	15	35	1	2	2
Pre-requisite: None									
Co- requisite: Fundamentals of Clinical Research (MSCR102-18)									
Course Objectives: To sensitize students that ethics is an integral part of good clinical research for generating meaningful and useful data.									
Course Outcomes: At the end of the course, the student will be able to									
CO1	Understand significance of ethics in clinical research								
CO2	Identify and resolve common ethical dilemmas in clinical research								
CO3	Understand regulations and policies governing clinical research in human subjects								
CO4	Learn about the elements which comprise misconduct in clinical research								
CO5	Understand the importance of Institutional Review Boards, Informed Consent and other mechanism to ensure safety of human subjects in research								
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	3	1
CO2	2	1	3	1	2	1	2	3	1
CO3	2	1	3	1	2	1	3	3	1
CO4	2	1	2	1	2	2	2	3	1
CO5	2	1	1	1	2	1	1	3	1

Module-I

13 Hrs

Evolution of ethics in clinical research: 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

Legal liability in clinical research: negligence, strict liability, criminal liability

Legal obligations of the investigator

Compensation to subjects/patients for clinical trial related injuries

Module-II

13 Hrs

Independent Ethics Committees: Institutional Review Board IRB/IEC

Ethics review procedure

Inform consent form and patient information sheet

Fraud and misconduct, detection of fraud in clinical research

Suggested Readings/Recommended Books (Latest Edition)

1. Ezekiel J. Emanuel, Christine C. Grady, Robert A. Crouch, Oxford Text Book of Clinical Research Ethics, OUP USA.
2. John I. Gallin and Frederick P. Ognibene, Principles and Practice of Clinical Research, Academic Press.
3. Richard Chin and Bruce Y. Lee, Principles and Practice of Clinical Trial Medicine, Academic Press.
4. Lionel D. Edwards, Andrew J. Fletcher, Anthony W. Fox and Peter D. Stonier, Principles and Practice of Pharmaceutical Medicine, JohnWiley & Sons Ltd.
5. John P. Griffin, John Posner and Geoffrey R. Barker, The Textbook of Pharmaceutical Medicine, John Wiley & Sons, Ltd.
6. www.ich.org
7. www.fda.gov
8. Guidelines: ICMR

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
MSCR 113-18	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.	
MSCR 114-18	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	Understand the basic pharmacokinetic parameters that describe drug absorption and disposition								
CO2	Understand various terms related to bioavailability and bioequivalence								
CO3	Judge the bioequivalence of two drug products								
CO4	Understand the statistical test applied in bioequivalence studies								
CO5	Identify the different study designs applied in the bioequivalence studies								
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

13 Hrs

Concepts of Pharmacokinetics

Absorption, Factors affecting absorption, Distribution: barriers, apparent volume of distribution etc.

Metabolism, biotransformation: phase I & II reactions, cytochrome p450

Elimination, Zero order and first order kinetics, Michales Menton's equation

Module-II

13 Hrs

Bioavailability and bioequivalence testing

Bioavailability and its types, Factors modifying bioavailability, bioavailability of new

drugs, absolute and relative bioavailability
Regulatory Guidelines for in vivo bioavailability
Criteria for waiver of in vivo bioavailability
Methods to assess bioavailability

Suggested Readings/Recommended Books (Latest Edition)

1. SC Chow and JP Liu, Design and Analysis of Bioavailability and Bioequivalence Studies, CRC Press
2. SK Niazi, Handbook of Bioequivalence Testing, CRC Press
3. Guidelines: USFDA, Drugs and Cosmetics Act, EMEA, ANVISA

Course Code	Course Title	Teaching Load			Marks		Exam	Credits
		L	T	P	Int.	Ext.	Internal	
MSCR 106-18 MSCR 206-18 MSCR 307-18	Journal Club	-	-	4	50	-	Continuous Mode	2

Pre-requisite: None

Co- requisite: Professional Communication (MSCR 105-18), Professional Communication Lab (MSCR 204-18), ICT Skills Lab (MSCR 305-18)

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.	
MSCR 201-18	Etiopathology & Pharmacotherapy-I	3	1	-	30	70	1.5	3	4
Pre-requisite: Pharmacology (MSCR 103-18)									
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
Basic Concepts: Introduction of Pharmacoeconomics

12 Hrs

Principles, Methods, and Applications

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

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
MSCR 202-18	Clinical Research Regulations	3	1	-	30	70	1.5	3	4
Pre-requisite: Fundamentals of Clinical Research (MSCR102-18)									
Co- requisite: Clinical Research Lab (MSCR203-18)									
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

Evolution of Regulatory controls: An international comparison
 Pure food drugs act, Food and Drug Administration (FDA), Drugs and cosmetic act 1945,
 Thalidomide disaster, Kefauver Harris amendments act, Waxman Hatch act, Nuremberg's
 code, Declaration of Helsinki
 International Council for Harmonisation (ICH)

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
Post-marketing Surveillance (PMS)
Regulation of medical devices
Regulation of vaccines
Safety Report filing
Regulation of prescription drugs and 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
Basic regulation of bioavailability/ bioequivalence (BA/BE) studies
Introduction to European Medicines Agency (EMA), Organisation for Economic Co-operation and Development (OECD), Brazilian Health Surveillance Agency (ANVISA), Therapeutic Goods Administration (TGA)
Regulation of Traditional and Herbal Remedies

Module-IV

09 Hrs

Common Technical Document

Format of dossier

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, ANVISA
5. www.tga.gov.au/tga-basics
6. www.ich.org
7. www.fda.gov
8. Central Drugs Standard Control Organization: www.cdsc.gov.in

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
MSCR 203-18	Clinical Research Lab	-	-	4	30	20	1.5	3	2
Pre-requisite: Fundamentals of Clinical Research (MSCR102-18)									
Co- requisite: Clinical Research Regulations (MSCR 202-18)									
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, blood pressure, temperature
2. 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)
3. Application of simple statistical test to the results obtained in above experiments
4. Biochemical tests: total proteins, lipid profile, blood glucose

5. Haematology tests: haemoglobin, total leukocyte count, differential leukocyte count, erythrocyte sedimentation rate
6. Electrocardiography (ECG) recoding
7. Case studies solutions
8. Development of clinical research documents: SOPs development, investigator brochure, informed consent forms, case record form
9. Dummy clinical research and bioequivalence protocols

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.	
MSCR 204-18	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

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

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.	
MSCR 205-18	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 terminology and fundamentals of medical writing
Literature survey using books, research journals and other online sources
Designing and development of clinical research documents i.e. Protocol, Informed Consent Form (ICF), Case Report Form (CRF), Standard Operating Procedure (SOP) on various functional clinical trial procedures

Module-II

12 Hrs

Patient narrative preparation, abstracts and manuscript
Writing of clinical study reports
Educational materials for subjects in clinical research
Research report and paper writing and plagiarism
Software relevant to medical writing

Suggested Readings/ Books

1. Medical Writing: A Guide for Clinicians, Educators, and Researchers Second Edition; Springer 2011,
2. The Complete Guide to Medical Writing by Mark C. Stuart, Mark StuartPharmaceutical Press, 2007,
3. Guidelines for Reporting Health Research by David Moher Douglas Altman BMJ books; August 2014
4. Medical writing a good practice guide by Justina-Orleans;WileyBlackwell 2012

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.	
MSCR 211-18	Basic Epidemiological Principles	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.	
MSCR 212-18	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

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.	
MSCR 213-18	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, Wilcoxin, 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	Credits	
		L	T	P	Int.	Ext.	Internal		
MSCR 106-18 MSCR 206-18 MSCR 307-18	Journal Club	-	-	4	50	-	Continuous Mode	2	
Pre-requisite: None									
Co- requisite: Professional Communication (MSCR 105-18), Professional Communication Lab (MSCR 204-18), ICT Skills Lab (MSCR 305-18)									
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.	
MSCR 301-18	Etiopathology & Pharmacotherapy-II	3	1	-	30	70	1.5	3	4
Pre-requisite: Etiopathology & Pharmacotherapy-I (MSCR 201-18)									
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 anti-fertility 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.	
MSCR 302-18	Clinical Study Design	3	1	-	30	70	1.5	3	4
Pre-requisite: Fundamentals of Clinical Research (MSCR102-18)									
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

Methods of randomization, blinding
Screening and recruitment of subjects
Placebo
Biomarker

Module-II

12 Hrs

Type of Studies

Randomized trial, open label study, double blind, single blind, matched pair study, cross over trial, case control study, cohort study, equivalence trials, superiority trials and non-inferiority

trials

Module-III

12 Hrs

Trial designs of common diseases like CVS, CNS, cancer and metabolic disorders
BA-BE study designs

Module-IV

12 Hrs

Phases of clinical trials
Designing phase I, II, III and IV trials: Design types, their characteristics, and parameter to measure, endpoints, inclusion and exclusion criteria
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

Course Code	Course Title	Teaching Load			Marks		Exam (hrs)		Credits
		L	T	P	Int.	Ext.	Int.	Ext.	
MSCR 303-18	Research Methodology	2	-	-	15	35	1	2	2
Pre-requisite: None									
Co- requisite: Clinical Study Design (MSCR 302-18)									
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.	
MSCR 304-18	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.	
MSCR 305-18	Clinical Research Lab	-	-	4	30	20	1.5	3	2
Pre-requisite: Fundamentals of Clinical Research (MSCR102-18) and Clinical Research Regulations (MSCR 202-18)									
Co- requisite: Clinical Study Design (MSCR302-18)									
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.	
MSCR 306-18	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.	
MSCR 311-18	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, clinical investigators and making budget and vendor selection

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

1. Principles and practice of Clinical Research by John. I Gallin.;Academic Press;3rd Edition
2. Principles and practice of clinical trial medicine by Richard Cin and Bruce Y. Lee; Academic Press; 1st Edition
3. Guidelines like GCP, USFDA, EMEA, Indian GCP etc.
4. 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.	
MSCR 312-18	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.	
MSCR 313-18	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.	
MSCR 314-18	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 : relevance of QA and QC in clinical trials and their comparison

Importance of clinical quality assurance department in industry

Total quality management, good clinical practice and quality assurance

Quality control vs. quality assurance

Module-II

12 Hrs

Audits/Inspections

Audits, its process and important aspects, types of audits
Source document verification
Regulatory inspections

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

Course Code	Course Title	Teaching Load			Marks		Exam	Credits	
		L	T	P	Int.	Ext.	Internal		
MSCR 106-18 MSCR 206-18 MSCR 307-18	Journal Club	-	-	4	50	-	Continuous Mode	2	
Pre-requisite: None									
Co- requisite: Professional Communication (MSCR 105-18), Professional Communication Lab (MSCR 204-18), ICT Skills Lab (MSCR 305-18)									
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