# 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 | • Theory courses of 04 credits = 100 marks<br>• Theory courses of 02 credits = 50marks<br>• Practical courses of 02 credits = 50 marks |
| Programme Structure | 1. Compulsory Foundation Course<br>2. Core Courses<br>3. Elective Courses<br>3.1.Discipline Specific Elective Courses<br>3.2.Generic Elective Courses<br>4. Ability Enhancement Courses<br>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 for10marks**.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)<br>(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)<br>(Answer all the questions) | 5x1= 05 |
| Short Answers(Answer 1outof 2) | 1x5 = 05 |
| Long Answers(Answer1outof2) | 1x10=10 |
| **Total** | **20 Marks** |

## Question Paper Pattern for Theory External Exam of 70 Marks

| | |
|---|---|
| Objective Type Question (10 x 2)<br>(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)<br>(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 |
| 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. | |
| 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, 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 imunity; 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 pharmaceutics 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, teratogenecity 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 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. | |
| 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, cytocrhome 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<br>MSCR 206-18<br>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** **12 Hrs**

**Basic Concepts: Introduction of Pharmacoeconomics**

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.cdsco.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 Doughlas 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** **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. | |
| 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<br>MSCR 206-18<br>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; Ist 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 Founds, 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<br>MSCR 206-18<br>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