MGM INSTITUTE OF HEALTH SCIENCES

(Deemed to be University u/s 3 of UGC Act, 1956)
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CHOICE BASED CREDIT SYSTEM

(CBCS)

(with effect from 2018-19 Batches)

Curriculum for

M.Sc. Clinical Research

Amended upto AC-49/2024, Dated 25/04/2024

Amended History

1. Approved as per BOM-53/2018 [Resolution No.4.5.3], Dated 19/05/2018.
2. As Amended in AC-42/2022 [Resolution No. 10.4.i], Dated 26/04/2022.
3. As Amended in AC-49/2024 [Resolution No. 3.10 ii], Dated 25/04/2024.

M.SC. (CLINICAL RESEARCH)

M.Sc. (Clinical Research) is interdisciplinary study programme with right blend of basics of clinical research, pharmacology, clinical trials, biostatistics, drug regulatory affairs and ethics. The programme focuses on imparting knowledge and thorough understanding of the basic concepts in clinical trials. It provides multidisciplinary learning with eminent scientists from reputed Pharmaceutical Industries and Academia. The teaching and learning methods used in this programme include lectures, tutorials, practical hands-on training, seminars and workshops. In order to attain learning outcomes of the programme, assessments require students to integrate theory and apply it to practical aspects of clinical research.

CHOICE BASED CREDIT SYSTEM (CBCS)

Choice Based Credit System (CBCS) is an internationally acknowledged system. The CBCS not only offers opportunities and avenues to learn core subjects but also explore additional avenues of learning beyond the core subjects for holistic development of an individual. The CBCS provides choice for students to select from the prescribed courses (core, elective or minor or soft skill courses). CBCS offers flexibility for students to study at different times and at different institutions to complete one course (ease mobility of students). Credits earned at one institution can be transferred to another institution. The CBCS facilitates benchmarking of selected courses with best international academic practices. fa

DIFFERENT COURSES UNDER CBCS

1. Compulsory Foundation Course (CFC)

There will a Compulsory Foundation Course in M.Sc. (Clinical Research) programme. The course is based upon the content that leads to Knowledge enhancement.

2. Core Courses (CC)

2.1 Discipline Core Course (DCC)

These are discipline specific papers. The course designed for papers under this category aim to cover the basics that a student is expected to imbibe in that particular discipline. DCCs should compulsorily be studied by a student as a core requirement.

1.2. Tutorials

It will be part of each course from the category of core discipline/generic specific paper.

1.3. Practicals

There will be one paper of practical/hands-on training in each semester except Semester IV.

1.4. Dissertation/Project

An elective course designed to acquire special/advanced knowledge, such as supplement study/support study to a project work, and a candidate studies such a course on his own with an advisory support by a teacher/faculty member is called dissertation/project. Project work/Dissertation is considered as a special course involving application of knowledge in solving / analyzing /exploring a real-life situation / difficult problem.

2. Elective Courses (EC)

It is generally a course which can be chosen from a pool of courses and which may be very specific or specialized or advanced or supportive to the discipline/subject of study or which provides an extended scope or which enables an exposure to some otherdiscipline/subject/domain or nurtures the candidate's proficiency/skill.

Elective courses may be of the following types.

2.1. Discipline Specific Elective Course (DSE)

Elective courses offered under the main discipline/subject of study is referred to as Discipline Specific Elective.

2.2. Generic Elective Course (GEC)

An elective course chosen from an unrelated discipline/subject, with an intention to seek exposure beyond discipline/s of choice is called a Generic Elective. The purpose of this category of papers is to offer the students the option to explore disciplines of interest beyond the choices they make in Core and Discipline Specific Elective papers.

A core course offered in a discipline/subject may be treated as an elective by other discipline/subject and vice versa and such electives may also be referred to as Generic Elective.

3 Ability Enhancement Courses (AEC)

These courses are aimed at enhancing a student's knowledge base or skills which will lead to increased employability.

3.1. Ability Enhancement Compulsory Courses (AEC)

3.2. Skill Enhancement Courses (SEC)

USEFUL GLOSSARY

Academic Year: Two consecutive (one odd + one even) semesters constitute one academic year.

Choice Based Credit System (CBCS): The CBCS provides choice for students to select from the prescribed courses (core, elective or minor or soft skill courses).

Course: Usually referred to, as 'papers' is a component of a programme. All courses need not carry the same weight. The courses should define learning objectives and learning outcomes. A course may be designed to comprise lectures/ tutorials/laboratory work/ field work/ outreach activities/ project work/ vocational training/viva/ seminars/ term papers/assignments/ presentations/ self-study etc. or a combination of some of these.

Credit Based Semester System (CBSS): Under the CBSS, the requirement for awarding a degree or diploma or certificate is prescribed in terms of number of credits to be completed by the students.

Credit Point: It is the product of grade point and number of credits for a course.

Credit: A unit by which the course work is measured. It determines the number of hours of instructionsrequired per week. One credit is equivalent to one hour of teaching (lecture or tutorial) or two hours of practical work/field work per week.

Cumulative Grade Point Average (CGPA): It is a measure of overall cumulative performance of a student over all semesters. The CGPA is the ratio of total credit points

secured by a student in various courses in all semesters and the sum of the total credits of all courses in all the semesters. It is expressed up to two decimal places.

Grade Point: It is a numerical weight allotted to each letter grade on a 10-point scale.

Letter Grade: It is an index of the performance of students in a said course. Grades are denoted by letters O, A+, A, B+, B, C, P and F.

Programme: An educational programme leading to award of a Degree, diploma or certificate.

Semester Grade Point Average (SGPA): It is a measure of performance of work done in a semester. It is ratio of total credit points secured by a student in various courses registered in a semester and the total course credits taken during that semester. It shall be expressed up to two decimal places.

Semester: Each semester will consist of 15-18 weeks of academic work equivalent to 90 actual teaching days. The odd semester may be scheduled from July to December and even semester from January to June.

Transcript or Grade Card or Certificate: Based on the grades earned, a grade certificate shall be issued to all the registered students after every semester. The grade certificate will display the course details (code, title, number of credits, grade secured) along with SGPA of that semester and CGPA earned till that semester.

M.Sc. (Clinical Research)

MATRIX OF COURSES AND CREDITS

Semester	MFC		DCC		DSE		GEC		AEC		SEC		Total credits
	No.	Credits	No.	Credits	No.	Credits	No.	Credits	No.	Credits	No.	Credits	
I	1	4	3	12	1	2	1	2	1	2	X	X	22
II	1	4	3	12	1	2	1	2	X	X	1	2	22
III	1	4	3	12	2	4	1	2	X	X	1	2	24
IV	X	X	2	20	X	X	X	X	1	4	X	X	24
												TOTAL	**92**

1. MFC = M.Sc. Foundation Course) CFC = Compulsory Foundation Course

2. DCC = Discipline Core Course

3. DSE = Discipline Specific Elective Course

4. GEC = Generic Elective Course

5. AEC = Ability Enhancement Compulsory Courses

6. SEC = Skill Enhancement Courses

M.Sc. (Clinical Research)

Syllabus – Semester I

List of courses (credits are indicated in parenthesis)

Semester – I

1. Foundation Course (MFC 101) (4)

2. Discipline Core Course (DCC) - compulsory

- MCR - DCC101: Clinical Research Methodologies (4).
- MCR - DCC102: Pharmacology- I (4).
- MCR - DCC103: Practicals (4)

3. Discipline Specific Elective Course (DSE)

Select any one course from the list provided below (2).

- MCR – DSE101: Ethics in Clinical Research
- MCR – DSE102: Different Systems of Medicine

4. Generic Elective Course (GEC)

Select any one course from the list provided below (2).

- MCR – GEC101: Pharmacokinetics (2)
- MCR – GEC102: Alternatives in Toxicity Testing (2)

5. Ability Enhancement Compulsory Courses (AEC)

- MCR – AEC101: Computer basics and biostatistics (2)

Semester – II

1. Foundation Course (MFC 201) (4)

2. Discipline Core Course (DCC) – compulsory

- MCR - DCC201: Clinical Research Guidelines I (4)
- MCR -DCC202: Pharmacology II (4)
- MCR - DCC203: Practicals and Hands-on Training (4)

3. Discipline Specific Elective Course (DSE)

Select any one course from the list provided below (2).

- MCR – DSE201: Epidemiological Principles Relevant to Clinical Research (2)
- MCR – DSE 202: Introduction to IPR and Patenting (2)

4. Generic Elective Course (GEC)

- MCR – GEC201: Introduction to database and oracle(2)

5. Skill Enhancement Courses (SEC)

Select any one course from the list provided below (2).

- MCR – SEC001: Medical Writing (2)
- MCR – SEC002: ICT Skills (2)
- MCR – SEC003: Pharmacoeconomics and Health Technology Assessment (2)
- MCR – SEC004: Medical Record Management (2)

Semester – III

1. Foundation Course (MFC 301) (4)

2. Discipline Core Course (DCC) - compulsory

- MCR - DCC301: Clinical Research Guidelines-II (4)
- MCR DCC-302: Pharmaceutical Jurisprudence (4)
- MCR - DCC303: Practical's/Hands-on Training (4)

3. Discipline Specific Elective Course (DSE)

Select any two courses from the list provided below (2 x 2 = 4).

- MCR – DSE301: Clinical Trial Operations (2)
- MCR – DSE302: Pharmacovigilance (2)
- MCR – DSE303: Medical Coding (2)

3. Generic Elective Course (GEC)

- MCR – GEC301: Advances to Oracle (2)

4. Skill Enhancement Courses (SEC)

Select any one course from the list provided below (2).

- MCR – SEC001: Medical Writing (2)
- MCR – SEC002: ICT Skills (2)
- MCR – SEC003: Pharmacoeconomics and Health Technology Assessment (2)
- MCR – SEC004: Medical Record Management (2)

Semester – IV

1. Discipline Core Course (DCC) - compulsory

- MCR - DCC401: Clinical Research Management (4)
- MCR - DCC402: Dissertation/Project (16)

2. Ability Enhancement Compulsory Courses (AEC)

- MCR- AEC401 Communication skills (4)

SEMESTER-WISE DISTRIBUTION OF CREDITS AND MARKS

FIRST YEAR – SEMESTER – I

Course type	No. of papers to be opted	Paper code	Credits	Contact hours/ week	Marks of internal assessment	Marks of semester examination	Total marks
Compulsory Foundation Course (CFC)	1	MFC-101	4	4	40	60	100
Discipline Core Course (DCC)	3	MCR – DCC101	4	4	40	60	100
		MCR – DCC102	4	4	40	60	100
		MCR – DCC103	4	8	50	100	150
Discipline Specific Elective Course (DSE)	1	MCR – DSE101 OR MCR –DSE 102	2	2	15	35	50
Generic Elective Course (GEC)	1	MCR – GEC101 OR MCR – GEC102	2	2	15	35	50
Ability Enhancement Compulsory Courses (AEC)	1	MCR – AEC201	2	2	40	60	100
Total	**8**		**22**		**240**	**410**	**650**

SEMESTER-WISE DISTRIBUTION OF CREDITS AND MARKS

FIRST YEAR – SEMESTER - II

Course type	No. of papers to be opted	Paper code	Credits	Contact hours/ week	Marks of internal assessment	Marks of semester examination	Total marks
Compulsory Foundation Course (CFC)	1	MFC-201	4	4	40	60	100
Discipline Core Course (DCC)	3	MCR – DCC201	4	4	40	60	100
		MCR – DCC202	4	4	40	60	100
		MCR – DCC203	4	8	50	100	150
Discipline Specific Elective Course (DSE)	1	MCR – DSE201 OR MCR –DSE 202	2	2	15	35	50
Generic Elective Course (GEC)	1	MCR – GEC201	2	2	15	35	50
Skill Enhancement Courses (SEC)	1	MCR – SEC001 OR MCR – SEC002 OR MCR – SEC003 OR MCR – SEC004	2	2	15	35	50
Total	**7**		**22**		**215**	**385**	**600**

SEMESTER-WISE DISTRIBUTION OF CREDITS AND MARKS

SECOND YEAR – SEMESTER - III

Course type	No. of papers to be opted	Paper code	Credits	Contact hours/ week	Marks of internal assessment	Marks of semester examination	Total marks
Compulsory Foundation Course (CFC)	1	MFC-301	4	4	40	60	100
Discipline Core Course (DCC)	3	MCR – DCC301	4	4	40	60	100
		MCR – DCC302	4	4	40	60	100
		MCR – DCC303	4	8	50	100	150
Discipline Specific Elective Course (DSE)	2	MCR – DSE301	2	2	15	35	50
		OR MCR –DSE 302 OR MCR –DSE 303	2	2	15	35	50
Generic Elective Course (GEC)	1	MCR – GEC301	2	2	15	35	50
Skill Enhancement Courses (SEC)	1	MCR – SEC001 OR MCR – SEC002 OR MCR – SEC003 OR MCR – SEC004	2	2	15	35	50
Total	**8**		**24**		**230**	**420**	**650**

SEMESTER-WISE DISTRIBUTION OF CREDITS AND MARKS

SECOND YEAR – SEMESTER - IV

Course type	No. of papers to be opted	Paper code	Credits	Contact hours/ week	Marks of internal assessment	Marks of semester examination	Total marks
Discipline Core Course (DCC)	2	MCR – DCC401	4	4	40	60	100
		MCR – DCC402	16	16	150	300	450
Ability Enhancement Compulsory Courses (AEC)	1	MCR – AEC201	4	4	40	60	100
Total	**3**		**24**		**230**	**420**	**650**

MFC101: Foundation course: Drug Analysis I

Course objective

This module will be compulsory for students.

Credits	Contact hours/ week	Marks – 100	
4	4	Internal assessment	Semester examination
		40	60

1. Introduction to Chemical Analysis:

- Chemical Analysis
  - Qualitative analysis
  - Quantitative analysis
- Applications of Chemical Analysis
- Sampling
- Types of Analysis
  - Proximate analysis
  - Partial analysis
  - Trace constituent analysis
  - Complete analysis
- Use of Literature
- Common Techniques
  - Volumetry
  - Atomic absorption spectroscopy
  - Emission method
  - Chromatography
- Other technique
  - X-ray method
  - Radioactivity
  - Mass spectroscopy
  - Optical method
  - Thermal method
- Factors affecting the choice of Analytical Methods
- Interference
- Data acquisition and treatment

2. Common Apparatus and Basic techniques

- Introduction
- Balances

- Analytical balance
- Electric balance
- Other balance

- Weight, References masses
- Care & use of analytical balances
- Error in weight balances
- Graduated glassware
  - Unit of volume
  - Graduate glasswares
  - Cleaning of glasswares
  - Temperature standard
  - Graduate flask
  - Pipettes
  - Burettes

- Water for laboratory use
  - Purified water
- General apparatus
  - Glassware, ceramics, plastic wares
  - Heating apparatus
  - Desiccators & dry box
  - Stirring apparatus
  - Filtration apparatus
  - Weighing bottles

- Reagents and Standard solutions
  - Reagents
  - Purification of substances

- some basic techniques
  - preparation of substance for analysis
  - weighing of sample
  - solution of the sample
- Precipitation
  - Filtration
  - Filter papers
  - Crucibles with permanent porous plates
  - Washing precipitate
  - Drying & ignition precipitate

3. Titrimetry

- Aqueous Acid - Base Titrations
  - Acid base theories
  - Law of mass action
  - Acid base equilibrium
  - Buffer solution
  - End point detection

- Neutralization curves

- Complexation Titration
  - complexation
  - detection of end point
  - metallochromic indicators

- Precipitation Titration
  - Theory of precipitation
  - Solubility of products
  - Fraction precipitation
  - Titration curves
  - End point data base
  - Mohr's method
  - Volhard method
- Oxidation - Reduction Titration
  - Oxidation – Reduction reaction
  - Redox potential
  - End point detection
  - Permanganate titration
  - Iodine titration

4. Electro-analytical methods of Analysis

- Electro-Gravimetry
  - Introduction
  - Theory
  - Apparatus
  - Application

- Conductimetry
  - Introduction
  - Apparatus & measurements
  - Conduct metric titration
  - Applications
  - High frequency measurements

- Potentiometry and potentiometric titration
  - Introduction
  - Instrumentation
  - Types
  - Variation in Potentiometry
  - Advantage Potentiometric titration

5. Photometric Techniques

- Flame Photometry and Atomic Absorption photometry
  - Introduction
  - General principle
  - Instrumentation
  - Operational procedure

- Nephelometry and Turbidimetry
  - Introduction
  - Instrumentation
  - Turbidimetric titration
  - Applications

- Fluorimetry
  - Principle
  - molecular structure and fluorescence
  - factor affecting fluorescence
  - Instrumentation
  - Applications
- Refractrometry
  - Introduction
  - Refractive index
  - Instrumentation
  - Applications
  - Optical exaltation
- Potrarirnetry
  - Introduction
  - Plane polarized light
  - Optical activity
  - Types of molecules analyzed by polarimetry
  - Polarimetry
  - Application of optical activity

Suggested Reading:

"Pharmaceutical Analysis", Kasture AV; wadodkar SG; volume I, NiraliPrakashan.

MCR – DCC 101: Clinical Research Methodologies

Course objective: In this module students would be able to understand some basic concepts of research and its methodologies

Credits	Contact hours/ week	Marks – 100	
4	4	Internal assessment	Semester examination
		40	60

1. Research: A way of Thinking

i) Research: A way of Thinking

ii) Applications of Research

iii) Definitions of Research

iv) Characteristics of Research

v) Types ofresearch

- Applications
- Objectives
- Type of Information sought

vi) paradigms of Research

2. Research process: A quick Glance

The Research process an eight-step model:

Step I: Formulating a research problem

Step II: Conceptualizinga Research Design

Step III: constructing a instrument for data collection

Step V: Selecting a sample

Step V: Writing a research proposal

Step VI: Collecting Data

Step VII: processing Data

Step VIII: Writing A research Report

3. Reviewing the Literature

i) Reasons for Reviewing Literature

ii) Procedure for Reviewing the Literature

iii) Writing up the literature-reviewed

4. Formulating a Research problem

i) The research problem

ii) The importance of formulating a research problem

iii) Sources of Research problem

iv) Considerations in selecting a research problem

v) Steps in the formulation of a research problem

vi) The formulation of a objectives

vii) Establishing operational definitions

5. Identifying Variables

i) The definition of a variable

ii) The difference between a concept and a variable

iii) Concepts, Indicators and variables

iv) Types of Variables

- From the viewpoint of causation
- From the viewpoint of study design
- From the view point of the unit of measurement

v) Types of measurement scale

- The normal or classificatory scale
- The ordinal or ranking scale
- The Interval scale
- The ration scale

6. Constructing Hypothesis

i) The definition of a Hypothesis

ii) The function of a Hypothesis

iii) The characteristics of a hypothesis

iv) Types of Hypothesis

v) Errors in testing a hypothesis

7. The research design

i) The definition of a research design

ii) The function of a research design

8. Selecting a method of data collection

i) collecting data using primary sources

- Observation
- The interview
- The questionaire

ii) Collecting data using secondary sources

- Problems with using data from secondary sources

9. Collecting data using attitudinal scales

i) Functions of attitudinal scales

ii) Difficulties in developing an attitudinal scale

iii) Types of attitudinal scale

- The summated rating or Likert scale
- The equal-appearing-interval or Thurstone scale
- The cumulative or Guttman scale

iv) The relationship between attitudinal and measurement scales

10. Establishing the validity and reliability of a research Instrument

i) The concept of Validity

- Types of Validity

ii) The concept of Reliability

- Factors affecting the reliability of a research instrument
- Methods of determining the reliability of an instrument

11. Sampling

i) The concept of sampling

ii) Sampling Technology

iii) Principles of sampling

iv) Factors affecting the inference drawn from the a sample

v) Aims in selecting a sample

vi) Types of sampling

vii) The calculation of sample size

12. Writing a research proposal

i) The research proposal

ii) The preamble introduction

iii) The problem

iv) The objectives of thestudy

v) The hypothesis to be tested

vi) The study design

vii) The setting

viii) Measurement procedures

ix) Sampling

x) Analysis of Data

xi) Structure of Report

xii) Problems and limitations

xiii) Work Schedule

xiv) Appendix

13. Considering ethical issues in data collection

i) Ethics

ii) Stakeholders in research

iii) Ethical considerations concerning research participants

- Collecting information
- Seeking consent
- Providing incentives
- Seeking sensitive information
- The possibility of causing harm to participants
- Maintaining confidentiality

iv) Ethical issues relating to the researcher

- Avoiding bias
    - Types of Bias
- Provision of deprivation of a treatment
- Using appropriate research methodology
- Correct reporting
- Using information

v) Ethical considerations regarding the sponsoring organization

- Restrictions imposed by the sponsoring organization
- The use of information

14. Processing data

i) Editing data

ii) Coding data

iii) Developing a frame of analysis

iv) Analysing data

v) The role of computers in Research

vi) The role of statistics in Research

15. Displaying data

i) Tables

- Structure
- Types of Tables
- Types of percentages

ii) Graphs

- The histogram
- The bar chart
- The stacked bar chart
- The 100 percent bar chart
- The frequency polygon
- The cumulative frequency polygon
- The stem and leaf display
- The line diagram or trend curve
- The area chart
- The scattergram

16. Writing a research Report

i) Research writing in general

ii) Referencing

iii) Writingabibliography

iv) Developing an outline

v) Writing about a variable

17. Types of clinical trials

i) Treatment trials

ii) Prevention trials

iii) Diagnostic trials

iv) Screening trials

v) Quality of life trials

vi) Experimental trial

- Randomized controlled trial
- Double-blind trial
- Single blind trial
- Non-blind trial
- Non-randomized controlled trial
- Randomized database study
- Placebo controlled trial

vii. Non-Experimental trial

- Cross-sectional study
- Longitudinal study
- Cohort study
  - Prospective cohort
  - Retrospective cohort
  - Time trend study
- Case cohort study
  - Case-control study
  - Nested case-control study

viii) Descriptive trial

18. Clinical Trial Designs

i) Parallel Study Design

ii) Crossover Study Design

iii) Parallel-Crossover Study Design

iv) Sequential Study Design

19. Standard Operating Procedures (SOP's), Quality policy

i) What are SOP's?

ii) Why SOP's are needed?

iii) How to write a SOP?

iv) Implementation of SOP's

Suggested Reading:

1. Guide to Clinical Trials. Author: Bert Spilker; Raven press, New york, 1991. 11gl pages.
2. Becoming a Successful Clinical Research Investigator. Authors: Dr. David Ginsberg and Karen E. Woodin. Thomson Centerwatch publication.
3. A Guide to Patient Recruitment and Retention. Author: Diana L. Anderson. Thomson Centerwatch Publication.
4. Protecting Study Volunteers in Research. Authors: Cynthia McGuire Dunn & Gary Chadwick. Thomson Centerwatch publication.
5. The CRC's Guide to Coordinating Clinical Research Author: Karen E. Woodin. Thomson Centerwatch Publication.
6. The CRA's Guide to Monitoring Clinical Research. Author: Karen E. Woodin and John C. Schneider. Thomson Centerwatch publication.

MCR – DCC 102: Pharmacology-I

Course objective: In this module students would be able to understand concept of pharmacology

Credits	Contact hours/ week	Marks – 100	
4	4	Internal assessment	Semester examination
		40	60

1. General Pharmacology

- History of Pharmacology
- Drug Sources
  - Drug and Active Principle
  - Drug Development
- Drug Administration
  - Various routes of drug administration
- Pharmacokinetics
- Pharmacodynamics
- ADRs

2.Drug Acting on the Autonomic Nervous System

- General Considerations
- Cholinergic system and cholinergic drugs
- Anticholinergic drugs and Drugs acting on Autonomic Ganglia
- Adrenergic system and drugs
- Antiadrenergic drugs

3.Drugs Acting on the Peripheral (somatic) Nervous System

- Skeletal Muscle relaxants
- Local anaesthetics

4. Drugs Acting on the Central Nervous System

- General Anaesthetics
- Sedatives and Hypnotics
- Antiepileptic drugs
- Antiparkinsonian drugs
- Opioid Analgesics and antagonists
- Nonopioids and NSAIDS
- CNS stimulants

5.Autacoids

- Histamines, 5-HT and their Antagonists
- Plasma kinins, Angiotensin and ACE inhibitors
- PGs, Leukotrienes and Platelet activating factors.

6. Drugs Acting on Respiratory System

- Drugs for cough and Bronchial Asthma

7. Cardiovascular Drugs

- Cardiac Glycosides and drugs for CCF
- Antiarrhythmic Drugs
- Antianginal drugs
- Antihypertensive drugs

Suggested Readings:

1.Satoskar and Bhandarkar

2.KD Tripathi

MCR – DCC 103: Practical

Course objective:
In this module a basic orientation to various instruments as well as common laboratory tests will be included. The practical exercises of the first semester will include hands on training on blood and tissue sample collection, biological sample handling, transport, storage and archiving. Working and handling of simple laboratory equipment. It will also involve training on use of spectrophotometer and other instruments used in a clinical biochemistry laboratory. Students will also be exposed to some pharmacological and biochemical laboratory exercises relevant to clinical research

Credits	Contact hours/ week	Marks – 150	
4	8	Internal assessment	Semester examination
		50	100

UNIT I

- Visits to hospital: Patient's history and demographics
- Medical record keeping
- Bioethics- do's and don'ts, confidentiality, cultural/social ethics

UNIT-II

- Basic learning of operation of common laboratory equipment

UNIT III

- Demonstration of routes of exposure/administration of drugs.
- Demonstration of some non – invasive techniques in preclinical screening of drug

UNIT IV

- Visit to research institute/CRO/SMO

MCR – DSE 101:Ethics in Clinical Research

Course objective:
In this module, students will explore ethical issues important to sound clinical research, review the foundations of regulations for clinical investigations, and come to better understand the operational imperatives of Good Clinical Practices (GCP). Students will learn through case discussions how to identify and resolve common ethical dilemmas that arise in clinical research, how research on human subjects is regulated, and what constitutes research misconduct. Various case-based topics focusing on specific ethical policies, federal regulations, and the legal practices of quality clinical research will be analyzed with particular attention paid to the institutional review board, the informed consent process, and common mechanisms in place to ensure the adequate protection of the human research participant. The following broad topics will be covered

Credits	Contact hours/ week	Marks – 50	
2	2	Internal assessment	Semester examination
		15	35

UNIT I:

- Evolution of ethics in clinical research
- Tuskegee experiment, Nuremberg Code, Declaration of Helsinki, Belmont report
- Establishment of CIOMS, NIH and ICMR guidelines
- Legal Liability in Clinical research, negligence, strict liability, criminal liability.
- Legal obligations of the investigator
- Compensation to subjects/patients for clinical trial related injuries

UNIT-II Overview of IRB/IEC/ERB

- Independent Ethics Committees.
- Ethics review procedure
- Importance of Inform Consent Document; Patient Information Sheet & Inform

Consent Form

- Fraud and misconduct, detection of fraud in clinical research
- Ethics in academia.
- Violations of ethics in research

Suggested Readings:

1. Basic Principles of Clinical Research and Methodology by S.K Gupta;Jaypee Brothers and Medical Publishers; First Edition
2. Oxford Text Book of Clinical Research Ethics by Ezekiel J. Emanuel, Christine C. Grady, Robert A. Crouch; OUP USA; 2008 Edition

MCR – DSE 102: Different systems of Medicine

Course objective:
This module is designed to instruct the students on the importance of different systems of medicine that have played a crucial factor in meeting the global health care needs. India has a unique distinction of having six different systems of medicine. They are Ayurveda, Siddha, Unani and Yoga, Naturopathy and Homoeopathy. The aspects covered include information about historical background, conceptual basis, different disciplines studied in the systems, Research and Development aspects, Drug manufacturing aspects and impact of globalization on Ayurveda. In addition, basic information on Siddha and Unani systems will be covered.

Credits	Contact hours/ week	Marks – 50	
2	2	Internal assessment	Semester examination
		15	35

UNIT I:

- Historical background of the different systems of medicines
- Different traditional practices
- Principles of prevention and treatment of diseases in alternative systems of medicine

UNIT-II

- Recent developments in the validation of different systems of medicine
- Uses of medicinal plants and the utilization of different herbs
- Medicinal plants and their different system of medicine
- Recent advances: US botanical drug development

Suggested Readings

1. Ayurvedic perspectives of certain communicable diseases by K.V Dilip Kumar

2. Indian systems of Medicine by B Ravishankar & V J Shukla- Pub med Central
3. Ancient Indian Medicine by P.Kutumbiah

MCR – GEC 101: Pharmacokinetics

Course objective:
This module provides the understanding the basics concepts of pharmacokinetics describe and understand how changes in physiology effect drug pharmacokinetics in the different age groups.

Credits	Contact hours/ week	Marks – 50	
2	2	Internal assessment	Semester examination
		15	35

UNIT I: Concepts of Pharmacokinetics

- Absorption, Factors affecting absorption, Distribution: barriers, aVd etc.
- Metabolism, biotransformation: phase I & II reactions, cytochrome p450
- Elimination, Zero order and first order kinetics, Michales mentis equation

UNIT II: 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
- Interpretation of results and use of softwares

Suggested Readings

1. Design and analysis of bioavailability and bioequivalence studies by SC Chow, J P Liu

2. Handbook of Bioequivalence Testing Sarfaraz K Niazi
3. Guidelines USFDA,Drugs and Cosmetics Act, EMEA, ANVISA

MCR – GEC 102: Alternatives in Toxicity Testing

Course objective:
The purpose of this module is to provide the clear understanding of various regulations involving animal use and the various models of toxicity testing.

Credits	Contact hours/ week	Marks – 50	
2	2	Internal assessment	Semester examination
		15	35

UNIT I:

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

UNIT II:

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

Suggested Readings

1. Principles of toxicological testing by Franke A Barley; CRC press; Second edition
2. Animals and Alternatives in Toxicity Testing: Present Status and Future Prospects by Pal Grave McMillan; Second Edition
3. Principles of toxicological testing by Franke A Barley; CRC press; Second edition

MCR – AEC101: Computer basics and biostatistics

Course objective:
The purpose of this module is to provide the clear understanding of fundamentals and principles of computers and biostatistics.It covers the basic tools for the collection, analysis, and presentation of data in all areas of public health

Credits	Contact hours/ week	Marks – 100	
2	2	Internal assessment	Semester examination
		40	60

1. Introduction to Biostatistics:

- Basic Definitions and Applications.
- Sampling
  - Representative sample
  - Sample size
  - Sampling bias
  - Sampling technique
- Data Collection and presentation
  - Types of data
  - Methods of collection of primary and secondary data
  - Methods of data presentation
  - Graphical representation

Histogram

Polygon

Ogive curves

Pie diagram

2. Measures of Central Tendency

- Measures of Central Tendency
  - Mean
  - Median
  - Mode
- Measures of Variability
  - standard deviation
  - standard error
  - range
  - mean deviation
  - coefficient of variation
- Correlation and Regression
  - Positive and negative Correlation
  - Calculation of karl-pearson's co-efficient of correlation
  - Linear regression and regression equation
  - Multiple linear regression
  - ANOVA: Definition and Classification.

3. Tests of significance

- Tests of significance
- Small Sample Test (Chi-Square test, t-test, F-test)
- Large Sample Test (Z-test)
- Standard Error
- Introduction to Probability Theory
- Distributions
  - Binomial
  - Poison
  - Normal
- Computer Oriented Statistical Techniques
  - Frequency table of:

    Single Discrete Variable

    Bubble Spot

    Computation of Mean

    Variance and Standard Deviations

    T-test

Correlation Coefficient

4.Introduction to Computers and Computer Applications

- Introduction to Computers
- Generation of Computers
- Computers application
- Types of Computers
- Concept of hardware and software
- Overview of Computers viruses
- Operating system
- File,folder,direction and commonly used commands
- Flow charts and programming techniques
- Introduction to C
- Introduction of Ms Office

5. Networking Concepts

- Networking fundamentals
- Client and server
- Types of Networking (LAN,WAN,MAN)
- Network topologies gadget & protocols
- Data communication and communication links
- telNET, internet and NICNET
- WWW,html,E mail
- Introduction to MEDLINE,CCOD and PUBMED (for accessing biological information)
- Introduction ot bioinorganic software-biojava,bioXML,bioORACLE

Suggested readings:

1. Statistics in biology, vol. 1 by Bliss, C.I.K. (1967) Mc Graw Hill, Newyork.
2. Practical Statistics for experimental biologist by wardlaw, A.C. (19g5).
3. Programming in C by E. Ballaguruswamy
4. How Computers work - 2000. By Ron Whire. Tech. Media
5. How the Internet work 2000 by Preston Gralla Tech. Media.
6. Statistical Methods in Biology - 2000 by Bailey, N.T. J. English univ. press.

7. Biostatistics - 7th Edition by Daniel
8. Fundamental of Biostatistics by Khan
9. Biostatistician Methods by Lachin
10. Statistics for Biologist by Campbell R.C. (1974) Cambridge University press, UK.
11. INTERNET - CDC publication, India

MFC201: Foundation course: Drug Analysis II

Course objective

This module will be compulsory for students.

Credits	Contact hours/ week	Marks – 100	
4	4	Internal assessment	Semester examination
		40	60

1. Spectro-Analytical Methods

- IR Absorption Spectroscopy
  - Introduction
  - The Range of Infrared Radiation
  - Nomenclature of Infra spectra
  - Theory of Infrared Absorption Spectroscopy or Requirement for Infrared Radiation Absorption
  - Mathematical Theory of IR Absorption Spectroscopy
  - Linear Molecules
  - Symmetric Top Molecules
  - Asymmetric Top Molecules
  - Instrumentation
  - Single Beam and Double Beam Spectrometers
  - Mode of Vibrations of Atoms in Polyatomic Molecules
  - Factors Influencing Vibrational Frequencies
  - Selection Rules
  - Position and Intensity of Bands Intensity of Absorption Bands
  - Units of Measurements
  - Application of IR Spectroscopy to Organic Compounds
  - Application of IR Spectroscopy to In-organic Complexes
  - Miscellaneous Examples
  - Attenuated Total Reflectance
  - Non-dispersive IR
  - Polythermal Beam Deflection Spectroscopy
  - Application of IR Spectroscopy to Quantitative Analysis

- Limitations of IR Spectroscopy

- Visible Spectroscopy Colorimetry
  - Introduction
  - Theory of spectrophotometer and Colorimetry Deviations from Beer's law
  - Instrumentation
  - Obtaining and Interpreting Data
  - Applications of Colorimetry and Spectrophotometry
  - Molar Compositions of Complexes
  - Spectrophotometry Titrations

- UV Spectroscopy
  - Introduction
  - Origin and Theory of UV Spectra
  - Types of Transitions of In-organic Molecules
  - Types of Transitions of Organic Molecules
  - The Shape of UV Absorption Curves
  - Transition Probability
  - Chromospheres and Related Terms
  - Effect of Conjugation
  - Solvent Effects
  - Woodward-Feiser Rules for Calculating Absorption Maximum
  - Instrumentation
  - Application of Spectroscopy to Organic Compounds
  - General Application of UV Absorption Spectroscopy

- NMR Spectroscopy
  - Introduction
  - Quantum Description of NMR
  - Rules Predicting Spin Numbers of Nuclei and Calculation of Spin Numbers of Elements Responding to NMR
  - Width of Absorption Lines in NMR
  - Number of Signals: Equivalent and Non-equivalent Protons
  - Chemical Shift
  - Chemical Shift of Different Types of Protons & Positions of PMR Signals
  - Spin-Spin Coupling: Splitting of Signals
  - Coupling Constants
  - Instrumentations
  - Relationship between Area of Peaks & Molecular Formula
  - Solvents Used in NMR
  - Interpretations of NMR Spectra
  - Application of NMR Spectroscopy
  - Limitations of NMR Spectroscopy
  - F1uorine-9 NMR
  - Phosphorus-31 NMR
  - Carbon-13 NMR

- Mass Spectroscopy
    - Introduction
    - Theory
    - Components of Mass Spectrometer
    - Recordings of Mass Spectrogram
    - Resolution of Mass Spectrometer
    - Types of the Ions Produced in Mass Spectrometer
    - General Rule for the Interpretations of Mass Spectra
    - Typical Example of Interpretation of Molecular Mass Spectra
    - Some Examples of Mass Spectra
    - Quantitative Analysis
    - Applications of Mass Spectroscopy

2.Chromatography

- Introduction
    - Definition
    - Types of Chromatography
    - Theoretical Principles Underlying Chromatographic Techniques
    - Theories of Chromatography
    - Development of Chromatogram
    - Qualitative and Quantitative Analysis by Chromatography

- Paper Chromatography
    - Introduction
    - Principle
    - Migration Parameter
    - Types of Paper chromatography
    - Experimental Details for Qualitative Analysis
    - Experimental Details for Quantitative Analysis
    - Application

- Thin Layer Chromatography
    - Introduction
    - Superiority of TLC Over otherChromatographic Techniques
    - Experimental Techniques
    - Applications of TLC
    - Applications of Some Other Forms of TLC
    - Limitations Scope
    - High Performance Thin Layer Chromatography

- Liquid-Liquid Partition Chromatography
    - Introduction
    - Theory
    - Solid Supports
    - Selection of Mobile and Stationary Phases
    - Solvent Systems

- Reversed Phase Chromatography
- Choice of Adsorption or Partition
- Applications of Partition Chromatography

- HPLC
  - Introduction
  - Principle
  - Instrumentation
  - Apparatus & Materials
  - Column Efficiency and Selectivity
  - Comparison of HPLC & GLC
  - Applications
  - HPLC Adsorption Chromatography
  - HPLC Partition Chromatography

- Column Chromatography
  - Introduction
  - Principle
  - Experimental Details
  - Theory of Development
  - Column Efficiency
  - Applications of Column Chromatography

- Gel Chromatography
  - Introduction
  - Principle
  - Materials
  - Gel Preparation, Column Packing and Detectors
  - Applications
  - Advantage of Gel Chromatography

- Ion Exchange Chromatography
  - Introduction
  - Definition
  - Principle
  - Cation Exchangers
  - Anion Exchangers
  - Regeneration
  - Ion Exchange Column Used in Chromatographic Separations Selection of Suitable Systems
  - Ion Exchange Capacity
  - Ion Exchange Techniques
  - Applications of Ion Exchangers

- Gas Chromatography

- Introduction
- Principle of Gas Chromatographic Separations
- Gas-Liquid Chromatography
- Instrumentation
- Evaluation
- Retention volume
- Resolution
- Branches of Gas Chromatography
- Applications
- Gas-Solid Chromatography
- Gas Chromatography-Mass Spectrometry (GC-MS)

Suggested Reading:

1. "Pharmaceutical Analysis", Kasture AV, Wadodkar SG, Volume II, NiraliPrakashan.

MCR – DCC 201: Clinical Research Guidelines I

Course objective: In this module students would be able to understand various guidelines related to clinical research.

Credits	Contact hours/ week	Marks – 100	
4	4	Internal assessment	Semester examination
		40	60

1. CDSCO Guideline Published by Ministry of Health and Family Welfare, Guideline for Bioavailability & Bioequivalence Studies.

2. World Medical Association Declaration of Helsinki: Ethical principles for Medical Research Involving Human Subjects.

3. Drugs and Cosmetics Act, Schedule Y.

4. Guidelines for Good Clinical practice E6 (R1).

5. EMEA Guideline: BA BE studies for veterinary Medicines.

6. ASEAN Guidelines for The Conduct of Bioavailability and Bioequivalence Studies

7. E2A: Clinical Safety Data Management: Definitions and Standards for Expedited Reporting
8. E2B (M): Maintenance of The ICH Guideline on Clinical Safety Data Management, Data Elements for Transmission of individual Case Safety Reports.

9. E2B (R3): Revision of The ICH Guideline on Clinical Safety Data Management Data Elements for Transmission of Individual Case safety Reports.

10. E2C (R1): Clinical Safety Data Management, Periodic Safety Update Reports for Marketed Drugs.

11. E7: studies In Support of special Populations, Geriatrics.

12. E9: Statistical principles For Clinical Trials.

13. FDA Comment for highly variable drugs

14. FDA Guideline for, Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid oral Dosage Forms Based on a Biopharmaceutics Classification System.

15. EU Guidelines For, Evaluation of Bioequivalence of Highty variable Drugs And Drug Products.

16. FDA Guideline for The Monitoring of Clinical Investigations.

MCR – DCC 202: Pharmacology-II

Course objective: In this module students would be able to understand concepts of pharmacology.

Credits	Contact hours/ week	Marks – 100	
4	4	Internal assessment	Semester examination
		40	60

1. Drugs acting on Kidneys

- Diuretics
- Antidiuretics

2. Drugs acting on GIT

- Drugs used for Peptic ulcers
- Emetics, Antiemetics
- Drugs for constipation and diarrhoea

3. Antimicrobial drugs

- Beta lactum antibiotics
- Tetracyclines and Chloramphenicol
- Aminoglycosides
- Anti TB
- Drugs used for UTI
- Antileprotic drugs
- Antifungal drugs
- Antiviral drugs
- Antimalerial drugs

- Antiamoebic and antiprotozoal drugs
- Anthelmintics

4. Hormones and related drugs

- Anterior Pituitary Hormones
- Thyroid hormones and thyroid inhibitors
- Insulin, oral hypoglycaemics and glucagon
- Corticosteroids
- Oxytocin and drugs acting on Uterus

Suggested Readings:

1. Satoskar and Bhandarkar
2. KD Tripathi

MCR – DCC 203: Practical and Hands on Training

Course objective: In this module a basic orientation to various instruments as well as common laboratory tests will be included. The practicals of the semester will include hands on training on blood and tissue sample collection, biological sample handling, transport, storage and archiving. Working and handling of simple laboratory equipments. It will also involve training on use of spectrophotometer and other instruments used in a clinical biochemistry laboratory. Students will also be exposed to some pharmacological and biochemical laboratory exercises relevant to clinical research.

Credits	Contact hours/ week	Marks – 150	
4	8	Internal assessment	Semester examination
		50	100

UNIT I-

- Measurement of Pulse rate, BP, Temperature
- Assessment of Height, weight, demography, waist
- ECG recoding
- Application of Simple statistical test to the results obtained in above tests

UNIT II –Training

- Exposure to various components of planning, co-ordination and conduct of clinical trials viz., screening and enrolment of subjects, obtaining informed consent, monitoring of drug administration, adverse events, vital functions, collection and processing of blood samples, SOPs, protocol design, adverse event reporting. Some practical exercise will comprise use of statistical packages in clinical research
- Basic orientation to common analytical instruments used in clinical research: LC-MS and related instruments
- Validation and calibration of biomedical instruments

- Students will be exposed to ongoing clinical research activities viz.,
  - Different Phases of CTs,
  - Bioavailability (BA) and bioequivalence (BE) studies,
  - Pharmacokinetics & pharmacodynamics
  - Monitoring and auditing of CTs, data management
  - Statistical software used in clinical research
  - Drug regulatory activities.

MCR – DSE 201: Epidemiological Principles Relevant to Clinical Research

Course objective: This module would cover brief introduction to epidemiological principles and instruction in clinical research study design. It would also cover concepts of molecular epidemiology and its applications. The following broad topics will be covered.

Credits	Contact hours/ week	Marks – 50	
2	2	Internal assessment	Semester examination
		15	35

UNIT I-

- Measures of disease occurrence and disease association
- Mortality indicators
- 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

UNIT II

- 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, GWAS

Suggested Reading

1. Epidemiology: Basis for Disease Prevention and Health Promotion by David Duncan Collier Macmillan publishers 5th edition
2. Clinical Epidemiology: The Essentials by Robert H. Fletcher and Suzanne W. Fletcher; WHO Press;5TH Edition

MCR – DSE 202: Introduction to IPR and Patenting

Course objective: This module will cover basic and general concept of Intellectual property; patent laws copy right and trademarks. Following broad topics will be covered

Credits	Contact hours/ week	Marks – 50	
2	2	Internal assessment	Semester examination
		15	35

UNIT I- 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- An Overview.
- World Intellectual Property Organization (WIPO)
- Role of WIPO and its association with WTO
- Commercialization of Intellectual Property Rights by Licensing
- Financial values of IPR

UNIT II-Patent Laws Introduction to Copyrights and Trademark

- 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, CBD
- Indian copyright law, types of copyright etc.

- Types of trademarks, Indian trademark law etc

Suggested Reading

IP Act & Rules from ipindia.nic.in

MCR – GEC201: Introduction to database and oracle

Course objective:This module will cover basic and general concepts of database and oracle.

Credits	Contact hours/ week	Marks – 50	
2	2	Internal assessment	Semester examination
		15	35

1. **Database Architecture:**
   - DBMS Architecture
   - Data Abstraction
   - Instances & Schemas.
2. **Data model**:
   - E-R Model
   - Network Data Model
   - Hierarchical Data Model
   - Relational Data model
3. **Database Storage Structure:**
   - Indexing
   - Hashing
   - ISAM
   - B+ Tree indexed files & B Tree indexed files
   - Static Hash functions and Dynamic Hash functions 4: ORACLE Objects:
   - Tables
   - Views
   - Indexes

- Sequences
- Synonyms
- Snapshots

5. Oracle Architecture:

- Database

  Table space S

  Data files

  Blocks

  Extents

  Segments

- Oracle Background Processes:

  PMON

  SMON

  LGWR

  CKPT

- Oracle Instance Startup, Shutdown/Init.ora. Control files;

6. Oracle Memory Management —

- SGA
- Rollback Segments
- Redo logs/Archival
- Transaction Control & Locking / Dead Lock
- Security
- Grants
- Roles
- Privileges

7. Oracle Utilities

- Oracle Server Manager
- Export-Import/SQL Monitor Backup & Recovery (Archiving)
- Physical Storage & Logical Storage

8. Oracle Reports

- Reports Features
- Full Integration with Forms and Graphics
- Data Model and layout editors

9. Layout Objects

- Frames & Repeating Frames
- Fields and Anchor
- Interface Components
- Report Formats
- Single Query and Multi Query
- User Defined Columns
- PL/SQL Interface/ Triggers
- Packaged Procedure
- Calling Report from a Form

10. Menus

- Default Menus, Custom Menus
- Menu Objects, Menu Module
- Main Menu, Individual Menus, Sub Menus
- Menu Items;

  Menu Editor

  PL/SQL in Menu Modules

  Menu Security

11. SQL (Structured Query Language)

- Data Definition Statements
- Data Manipulation Statements
- Data Control Statements
- Other Database Objects
- Transaction control statements.
- Joins
- Unions
- Views
- Sequences
- Synonyms

Suggested Readings:

1) Database System Concepts; HaneryKorth and Abraham Silberschatz; Tata Mac-Graw Hill Publications
2) Parallel and Distributed Databases; Wilteach et.a1.

3) Simplified approach to DBMS; Parteek Bhatia and Guruvinder Singh
4) Introduction to Database Systems; C.I.Date
5) Database system organization; J.M. Martin; Princeton-Hall.
6) Introduction to Database systems; J.M. Martin; Princeton-Hall

MCR- SEC001: Medical Writing

Course objective: In this module students will 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 generally to provide overview in both medical science and writing fundamentals. Medical writing is the fast developing and exciting discipline that involves writing topics helpful for medical fraternity. In the end of this course the students will be able to write reports, narratives etc.

Credits	Contact hours/ week	Marks – 50	
2	2	Internal assessment	Semester examination
		15	35

Unit I

- Basic introduction to medical terminology and fundamentals of medical writing.
- Literature survey-Use of books and journals and internet.
- Designing and development of clinical research documents i.e. protocol, ICF, CRF, SOP on various functional clinical trial procedures.
- Research report and paper writing
- Plagiarism

Unit II

- Patient narrative preparation.
- Abstracts & manuscript.
- Writing of Clinical Study reports.
- Educational materials for subjects in clinical research
- Softwares relevant to medical writing

Suggested Reading

1. Guidelines for Reporting Health Research by David Moher Doughlas Altman BMJ books; August 2014
2. Medical Writing: A Guide for Clinicians, Educators, and Researchers Second Edition; Springer 2011
3. Medical writing a good practice guide by Justina-Orleans;WileyBlackwell 2012

MCR-SEC003: Pharmacoeconomics and Health Technology Assessment

Course objective: In this module students will explore the concept of pharmacoeconomics and Health technology Assessment.

Credits	Contact hours/ week	Marks – 50	
2	2	Internal assessment	Semester examination
		15	35

Unit I

- 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
- Measuring benefits

Unit II

- INHATA
- HTA system: practice and process
- Models of HTA agencies
- Structure of the HTA report: principles, practice and process

Suggested Reading

1.Health Economics. Fundamentals and Flow of Founds. Thomas E. Getzen;Wiley;4th Edition
2. Methods for the Economic Evaluation of Health Care Programmes Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg; Oxford University Press 2005
3. Decision Modeling for Health Economic Evaluation Andrew Briggs, Karl Claxton,

Mark Sculpher, Published by the Oxford University Press 2006

MCR – SEC004: Medical Records Management

Course objective: The course work is designed abreast the students with medical record management in a hospital set-up.

Credits	Contact hours/ week	Marks – 50	
2	2	Internal assessment	Semester examination
		15	35

Unit I

- Definition & contents, Objectives
- Problem oriented medical record (POMR)
- Basic hospital records in detail, Obstetrics records, New born records
- Uses and values of medical records
- Functions of medical records department (MRD)
- Medical record professional duties and Responsibilities
- Medical Record Administrator and Medical Record Technician
- Medical Record Committee
- Medical staff and their responsibility for the Medical Record
- Discharge Analysis- Computerized and Manual
- Medical Audit

Unit II

- Electronic Medical Records (EMR) Issues, Interoperability, Privacy, Social and organization Barriers, Technology limitation, Preservation of EMR, Benefits, obstacles to adoption, pictorial material, free text, structured text – the potions, optical mark reader (OMR), advantage of EHR over Paper Health records,
- Voice recognized system (VRS), picture archive and communication system (PACS), Selection of Hardware and Software for health, Cost, customization, Integration and Interfacing

Suggested Reading

1.Health information and Management by Margaret A.Skuka by John Wiley & Sons 14TH March 2012
2 Medical Records organization and management by GD Mogli;First Edition

MFC301: Foundation course: Drug Analysis III

Course objective

This module will be compulsory for students.

Credits	Contact hours/ week	Marks – 100	
4	4	Internal assessment	Semester examination
		40	60

1. Modern Pharmaceutical Analysis: An Overview

- Identity and Purity Requirements
- Bioavailability/Dissolution Requirements
- RegulatoryConsiderations
- RegulatoryCompliance
- International Conference on Harmonization
- Global CMC NDA
- Highlights of Modern Pharmaceutical Analysis

2**. Combinatorial Chemistry and High-Throughput Screening in Drug Discovery and Development**

- Introduction
- CombinatorialMethods
- Methods for Structural Assignment o Diversity
- Drug likeness
- Designing Combinatorial Libraries with optimal ADME properties
- Existing Computational Methods for ADME properties
- OptimizationPhilosophy
- Applying Existing ADME Models to combinatorial Library Design o The Future of ADME Modeling
- High-Throughput Screening and Combinatorial Chemistry
- Assay Plate Formats: Move to Miniaturization
- Non-separation or Homogeneous Assays o Identification of Receptor Antagonists for Chemokine Receptor and Bradykinin-lby Screening a 150,000-Member Combinatorial
- Library
- Structure-based Design of Somatostatin Agonists

3. Preformulation Studies

- Introduction
- PreformulationStudies
- Analytical Techniques and Instruments for Preformulation Studies
- Regulatory Requirements for Preformulation

4. Solid Dosage-Form Analysis

- Introduction
- Physicochemical Characterization Techniques
- Near-Infrared Analysis
- Automation
- Future Directions

5. Parenteral Dosage Forms

- Characteristics of Parenteral Dosage Forms
- Pharmaceutical Analysis During Formulation and Process Development
- Analytical Testing for Finished Parenteral Products
- Packaging Components Testing
- Process Development Support
- In-Process Testing
- Release Testing
- Raw Material Testing
- Validation of Analytical Procedure
- Stability-Indicating Methods
- Method Transfer
- Cleaning Method Validation
- Admixture Studies
- Microbiological Testing of Parenteral Formulations
- Sterility Testing

6. New Drug Delivery Systems

- Introduction
- Oral Drug Delivery
- Direct Drug Delivery
- Dermatological Delivery System
- Tumor-Targeted Drug Delivery Systems
- Biodegradable Drug Delivery System
- Protein Drug Delivery System
- Devices

7.Validation of Pharmaceutical Test Methods

- Background and Chapter Overview
- Validation Terminology and Definitions
- Method Development and Its Influence on Method Validation
- Validation Requirements of The Method
- Validation Documentation
- Validation Experimentation

- Method Transfer
- Revalidation
- Reference Standards

8. Stability Studies

- Introduction
- Operational Issues
- Excipients
- Drug Substance
- Drug Product

9. Pharmaceutical Analysis Documentation

- Scope
- Introduction
- Pharmaceutical Analysis During Product Life Cycle
- Regulatory Documents
- Compliance Documents
- Research Documents

Suggested Reading:

1. 'HANDBOOK OF MODERN PHARMACEUTICAL ANALYSN, satinder Ahuja Ahuja Consulting, Calabash, North Carolina; Stephen Scypinski, RW Johnson Pharmaceutical Research Institute, Raritan, New Jersey.

MCR - DCC301: Clinical Research Guidelines-II

Course objective: In this module students would be able to understand various guidelines related to clinical research.

Credits	Contact hours/ week	Marks – 100	
4	4	Internal assessment	Semester examination
		40	60

1.E1: The Extent of Population Exposure to Assess Clinical Safety for Drugs Intended for Long-Term Treatment of Non-Life-Threatening Conditions

2. E2B: Implementation working Group questions & Answers (R5)

3. E2D: Post-Approval Safety Data Management Definitions and Standards for Expedited Reporting

4. E2E: Pharmacovigilance Planning

5. E3: Structure and Content of Clinical Study Reports

6. E4: Dose-Response Information to Support Drug Registration

7. E5 (R1): Ethnic Factors in the Acceptability of Foreign clinical Data

8. E5: Implementation Working Group, questions & Answers

9. E8: General Considerations for Clinical Trials

10. E10: choice of Control Group and Related Issues In clinical trials

11. E11: Clinical investigation of Medicinal Products in the pediatric population

12.E12A: Principles for clinical Evaluation of New Antihypertensive Drugs

13. E14: The Clinical Evaluation of QTC Interval Prolongation and proarrhythmic Potential for Non-Antiarrhythmic Drugs

14. Guidance for Industry pharmacogenomic Data Submissions

15. Attachment to Guidance on Pharmacogenomic Data Submissions Examples of Voluntary Submissions or Submissions Required under 21 CFR 312,314, or 601

16. Guidance for Clinical Trial Sponsors Establishment and Operation of Clinical Trial

Data Monitoring Committees

17. RatioPharm, Highly variable Drugs and Drug products (HVD/HVDp) overview
18. Guidance for Industry. part 11
    - Electronic Records
    - Electronic Signatures - Scope and Application

MCR DCC-302: Pharmaceutical Jurisprudence

Credits	Contact hours/ week	Marks – 100	
4	4	Internal assessment	Semester examination
		40	60

1: Man, and His Laws

- Religion
- Ethic
- Law

2: Pharmaceutical Legislations

- Advent of Allopathic System
- The l9th and early 20th Centuries
- Drugs enquiry committee and aftermath
- The drugs act
- Pharmacy act and other legislations

3: The Pharmacy Act

- Introduction
- Objectives of the act
- The Pharmacy council of India
- State Pharmacy Councils
- Preparation of the First Registers by State Governments
- Offences and penalties
- Miscellaneous

4. Narcotic and Psychotropic substances Act and Rules

- Introduction
- Narcotic drugs and psychotropic substances
- Controlled operations
- Offences and penalties
- Procedures o Miscellaneous
- Cultivation, production, Sales etc of Opium o Manufacture of Manufactured Drugs and psychotropic Substances

- Import, Export, Trans shipment of Narcotic Drugs and Psychotropic Substances

5: Drugs and cosmetic Act

- Introduction
- Import of Drugs
- Manufacture of Drugs
- Sales of Drugs o Labeling and Fackaging of Drugs
- Administration of the act
- Provisions applicable to Ayurvedic, Siddha and Unani Drugs
- Provisions applicable to Homeopathic Drugs
- Provisions applicable to cosmetics
- Miscellaneous

6: Poison Act

- Introduction
- Import of Poisons
- Possession and sales of poisons
- Penalties for Offences under the act
- Issue of warrants
- Rules

7: Medical Termination of pregnancy Cat,1971

- Introduction
- Termination of Pregnancies
- Offences and Penalties
- Rules and Regulations

8: Drugs and Magic Remedies (Objectionable Advertisements) Act and Rule

- introduction
- Definitions
- Prohibited Advertisements
- Prohibition of Import and Export of Advertisements
- Penalties
- Miscellaneous

9: Prevention of Cruelty to Animals Act

- Introduction
- Experimentation on Animals
- Penalties

Suggested Reading:

'Pharmaceutical Jurisprudence' by BM Mittal, BITS Pilani.

MCR – DCC303: Practical and Hands on Training

Course objective: This module will cover some of the basic exercises in the field of clinical research. The following topics will be covered

Credits	Contact hours/ week	Marks – 150	
4	8	Internal assessment	Semester examination
		50	100

UNIT I

- Preparation of problem-based protocol
- Preparation of CRF and ICD
- Safety Reports
- Mock Case report – Causality assessment
- Aggregate Safety reports
- How to take case history

UNIT II: Training

- Exposure to various components of planning, co-ordination and conduct of clinical trials viz., screening and enrolment of subjects, obtaining informed consent, monitoring of drug administration, adverse events, vital functions, collection and processing of blood samples, SOPs, protocol design, adverse event reporting.
- Students will also be exposed to ongoing clinical research activities viz., different Phases of CTs, bioavailability (BE) and bioequivalence (BE) studies, pharmacokinetics, pharmacodynamics, monitoring and audit of CTs, data management, drug regulatory activities and statistical software used in clinical research

MCR-DSE301:Clinical Trial Operations

Course objective: This module would cover the following issues of real-time planning and coordination of clinical trials.

Credits	Contact hours/ week	Marks – 50	
2	**2**	Internal assessment	Semester examination
		15	35

UNIT I: Site initiation

- 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

UNIT II: Site conduct

- Recruitment, IP/IMP/Pharmacy file receipt and storage, CT site master file, Databases, SOPs
- Roles and responsibilities of Monitors and Auditors/Inspectors, Monitoring visits, audits and inspections
- independent data monitoring activities.
- Contingency planning to prepare for unexpected situations.

UNIT III: 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.

MCR-DSE302: Pharmacovigilance

Course objective: This module focuses on importance of Drug safety issues that have potential to affect publichealth. Pharmacovigilance is an important and integral part of clinical research and its growing field. Pharmacovigilance helps us in early detection of new adverse reactions and to introduce measures to manage those risks.

Credits	Contact hours/ week	Marks – 50	
2	**2**	Internal assessment	Semester examination
		15	35

Unit I:

- 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

Unit II:

- Pharmaceutical preparations (Adverse effects)
- Product surveillance and post marketing
- Signal detection and follow-up
- Communicating safety signals with stakeholders

- Risk management studies
- Introduction to translational medicine
- Drug monitoring
- Pharmacovigilance in drug regulation
- Overview of various software used in pharmacovigilance

Suggested Reading

1. Textbook of Pharmacoepidemiology, Edited by Brian L. Storm and Stephen K. Kimmel;Wiley Blackwell;5TH Edition
2. Pharmacovigilance by Ronald D. Mann, Elizabeth Andrews; Wiley Blackwell;3RD Edition

MCR-DSE303:Medical Coding

Course objective: This module is designed to instruct the students on the importance of the data generated in clinical trials. Medical coding is performed to categorize the medical terms appropriately so that they can be analysed and reported appropriately in the standardized format. The module covers the various medical dictionaries used worldwide for the representation of the data. This module also gives an exposure on the International Classification of Diseases (ICD) which is the standard diagnostic tool for epidemiology and health management for getting the mortality and morbidity statistics by World Health Organization (WHO).

Credits	Contact hours/ week	Marks – 50	
2	**2**	Internal assessment	Semester examination
		15	35

Unit I:

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

Unit II:

- ICD9-International Classification of Diseases 9 Revision.
- ICD10-International Classification of Diseases10 Revision

Suggested Reading

1.Guidelines on ICD9 and ICD10

MCR – GEC301: Advances to Oracle

Course objective: This module is designed to provide knowledge regarding advances to Oracle

Credits	Contact hours/ week	Marks – 50	
2	**2**	Internal assessment	Semester examination
		15	35

Unit 1: Basic Concepts

- Introduction to Database
- Database System Concept Architecture
- Entity Relationship Model

Unit 2: Relational Databases

- Relational Model
- Relational Algebra & Calculus
- Relational languages SQLand QBE
- RDBMS System SQL server & MS Access

Unit 3: Object-Oriented Database Systems

- Object-Oriented Concepts
- Object-Oriented Databases
- Object- Database Languages
- Object- Database Design
- Object-Relational and Extended Relational Database Systems

Unit 4: Database Design

- Functional Dependencies
- Normalization

Unit 5: System Implementation Techniques

- Query Processing Optimization
- Transaction Processing
- Concurrency Control
- Recovery
- Security Authorization

Unit 6: Advances in Database Environment

- Distributed Database
- Data Fragmentation Replication and Allocation
- Distributed Query Processing
- Distributed Concurrency Control
- Client Server Architecture
- Programme Evaluation
- Multimedia Database
- Data Warehousing
- Data Mining
- OLAP

Unit 7: PL/SQL

- Procedural Statements
- Database Triggers
- Built in and User Defined Function
- Package to organize PL/SQL code
- Expressions with Operators
- Cursors in PL/SQL blocks , Types of Cursors : Implicit and Explicit Cursors

Suggested Readings:

1. Database Management and Design by G.W. Hansen and J. V. Hansen, Prentice-Hall ofIndia, Eastern Economy Edition, Latest Edition.
2. Database System Concepts by A. Silberschatz, H.F. Korth and S. Sudarshan, 3rd edition,McGraw-Hill, Latest International Edition.
3. Database Systems: The Complete Book by Garcia-Molina, J. D. Ullman, and J. Widom. ,Prentice Hall, Latest Edition.
4. Fundamentals of Database Systems by RamezElmasri and Shamkant B. Navathe,Addison- Wesley. Latest Edition
5. Database Management Systems by R. Ramakrishnan and J. Gehrke., McGraw-Hill.
6. Database Systems by T. Connolly and C. Begg. , Addison-wesley, Latest Edition.

MCR - DCC401: Clinical Research Management

Course objective: Following topics related to management of clinical trials will be covered through this module.

Credits	Contact hours/ week	Marks – 100	
4	**4**	Internal assessment	Semester examination
		40	60

1. The Food and Drug Administration Past and Present

- The Establishment of the Food and Drug Administration;
- The History of the Legislation and Regulations, which Govern the clinical Research Process;
- The History of the Legislation and Regulations, which Protect the Rights, Safety, and Well-Being of Human Subjects'

2. Overview of Medicinal Product Research and Development

- Drug Discovery and Pre-Clinical Research;
- The Clinical Research and New Drug Application Approval Process;
- The Biologics Research, Development, and Licensing Process;
- Medical Device Research, Development, and Marketing.

3. Good Clinical Practice (GCP)

- Investigational New Drug Application 21 CFR 312: Sponsor's obligations;
- Investigational New Drug Application 21 CFR 312: Investigator's Obligations;
- Institutional Review Boards 21 CFR 56;
- Protection of Human Subjects 21 CFR 50;
- Financial Disclosure 21 CFR 54.

4. International Conference of Harmonization

- The History of the International Conference of Harmonization;
- The ICH Good Clinical Practice Consolidated Guideline (E6);
- The ICH Clinical safety Data Guideline (E2)

5. Clinical Trial Development

- Protocol Design and Development;
    - Bioavailability and Bioequivalence study
    - Clinical Trials
- Case Report Form Design and Development;
    - Bioavailability and Bioequivalence study
    - Clinical Trials
- Principles of Data Management and the Query Resolution Process;
- The Study Types Providing Expanded Access to Investigational Products.

6. Clinical Trial Management

Investigator Site Perspective: Coordinating a Clinical Trial at the Site

- Essentials of Source Documentation;
- Maintaining and Managing Essential Documents;
- Recording and Reporting Non-Serious and Serious Adverse Events.

Sponsor's Perspective: Managing a Clinical Trial

- Selecting Investigators and Monitors;
- Maintaining and Managing Essential Documents (e.g. FDA Form 1572);
- Case Report Form Data Transmission and Generation of the Clinical Study Report;
- Reviewing and Reporting of Serious Unexpected Adverse Drug Experiences;
- Implementing a Monitoring Plan and Performing Quality Control.

7. Monitoring Obligations and Methods

- Monitoring Role and Responsibilities According to the FDA Guideline;
- Monitoring Role and Responsibilities According to ICH Good Clinical Practice Consolidated Guideline (E6);
- Monitoring Responsibilities: Type of Monitoring Visits, Monitoring Activities Pre-Visit, On-Site, and Post Visit;
- Monitoring Method: Implementing a Systematic Monitoring Approach to EffectivelyMonitor a Multi-Center Trial;
- Problem Solving and Trouble Shooting GCP / ICH Issues;

- Writing Strategic Monitoring Reports and Follow-Up Visit Letters.

8. Project Management

- Timelines
- Gantt Chart (Microsoft Project)
- Budgeting

Suggested Reading:

1. Conducting GCP-Compliant Clinical Research' W. Bohaychuk and G. Ball

2. ICH GCP E6 Guidelines by US FDA

<table>
<tr><th colspan="4">MCR-DCC402:Dissertation/Project</th></tr>
<tr><td colspan="4">Course objective: The module will help the candidate in developing a research proposal and will give the understanding of the fundamentals involved in designing a research study.</td></tr>
<tr><td>Credits</td><td>Contact hours/ week</td><td colspan="2">Marks – 450</td></tr>
<tr><td>16</td><td>16</td><td>Internal assessment</td><td>Semester examination</td></tr>
<tr><td></td><td></td><td>150</td><td>300</td></tr>
<tr><td colspan="4">A project will be prescribed in the course structure in the 4th semester. Under this assignment a candidate shall be required to write a Dissertationon a topic allotted to him/her. Topics will be allotted in the 3rd Semester. The evaluation of dissertation shall be done at the final Examination by the Examiners as part of Viva-voce examination. For project work, the Head of the Department shall call a meeting of the teachers of the Department and assign appropriate number of students to each teacher to act as aGuide for project work. The student in consultation with the Guide shall select a topic for the project work and inform the Head to the Department.</td></tr>
</table>

MCR- AEC401 Communication skills

Course objective: This module will help the students in exploring the relationship between good communication and professionalism used in various aspects of research.

Credits	Contact hours/ week	Marks – 100	
4	**4**	Internal assessment	Semester examination
		40	60

1. Language and Communication
2.Non-Verbal Communication
3. Communication in Organization
4. Dyadic Communication
5. Meetings
6. Seminars and Conferences
7. Group Discussions
8. Audio-visual Aids
9. Formal Reports
10. Style
11. Technical Proposals
L2. Business correspondences
13. Notices, Agenda and Meetings
14. Handbooks and Manuals
1.5. Research Papers and Articles
16. Advertising and Job Descriptions
17. Graphic Aids
18. Copy Editing

19. Punctuation and Capitalization

20. Words commonly misspelt

21. Abbreviations and Numerical.

Suggested reading:

1. "Developing Communication Skills"; by Krishna Mohan and Meera Banerji; BITS Pilani, Rajasthan.

Resolution No. 10.4 of Academic Council (AC-42/2022):

i) "Resolved to accept "50% eligibility in internal assessment" pattern for all the CBCS programs (UG & PG) running under the constituent units of MGMIHS.(MGM School of Biomedical Sciences, MGM School of Physiotherapy, MGM Medical College (M.Sc. Medical 3 year courses).

This will be applicable to all existing batches (for remaining regular examinations) and forthcoming batches from June 2022 onwards"

Resolution No. 3.10 of Academic Council (AC-49/2024):

Resolved and approved to collect the Dissertations/Projects 60 days before the University examination for all 2-year M.Sc. programs under MGM School of Biomedical Sciences to fulfil the credit allotted for project work, to be effective from batch 2023-24 onwards.

MGM INSTITUTE OF HEALTH SCIENCES

(Deemed to be University u/s 3 of UGC Act, 1956)

Grade 'A' Accredited by NAAC

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