CENTRE FOR TRANSLATIONAL AND CLINICAL RESEARCH

FACULTY OF SCIENCE

M.SC. (CLINICAL RESEARCH) SYLLABUS

CHOICE BASED CREDIT SYSTEM (CBCS)

EFFECTIVE FROM SESSION 2016-17

JAMIA HAMDARD
(Hamdard University)
New Delhi – 110062
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JAMIA HAMDARD

The History of Jamia Hamdard began with the establishment of a small Unani Clinic in the year 1906 by Hakeem Hafiz Abdul Majeed, a well known practitioner of Unani system of medicine. Hakeem Hafiz Abdul Majeed had a vision of making the practice of Unani medicine a scientific discipline so that Unani medicines could be dispensed in a more efficacious manner to patients. He gave the name “Hamdard” to his venture which means “sympathy for all and sharing pains”. His illustratious son, Hakeem Abdul Hameed, carried forward the philosophy and objectives of Hamdard in independent India.

For setting up a complex of research and educational institutions, Hakeem Abdul Hameed purchased a piece of land in Tughlaqabad area of South Delhi which was hardly inhabited in those times. The first institution in the Tughlaqabad campus was Institute of History of Medicine and Medical Research, whose foundation stone was laid on November 15, 1962 by Pandit Jawaharlal Nehru, the former Prime Minister of India.

In 1963, Indian Institute of Islamic studies was established and in the same year Hamdard Tibbi College was set up in Gali Qasim Jaan, Old Delhi. It was later shifted to Jamia Hamdard campus in 1980 to provide education in Unani Medicine.

In 1964, Hamdard National Foundation was created with a view to receive and disburse the profits earned by Hamdard Laboratories for charitable causes of education, medical relief and the advancement of knowledge.
In 1972, Hamdard College of Pharmacy was setup with the objective of providing education and training in all branches of pharmacy.

The year 1989 saw the fullfilment of the dream of Hakeem Abdul Hameed when Jamia Hamdard was given the status of Deemed to be University by Ministry of Human Resource Development, Govt. Of India on 10th May, 1989. All the above named institutions set up by Hakeem Abdul Hameed and his associates were amalgamated into Jamia Hamdard. In a brief period of only 10 years it has evolved into an institution fulfilling the objects of Hamdard National Foundation.

Jamia Hamdard was inaugurated by Late Shri Rajiv Gandhi on August 01, 1989. Since then, Jamia Hamdard has progressed towards accomplishing the dream of Hakeem sahib. Currently, Jamia Hamdard is engaged in imparting high quality teaching and research in the disciplines of Allied Health Sciences, Pharmacy, Science, Medicine, Nursing, Management, Information Technology, Islamic studies and Social Sciences.

A great milestone was achieved when in 2012 Medical Council of India (MCI) approved MBBS programme in Hamdard Institute of Medical Sciences and Research (HIMSR) with annual intake of 100.

In 2009 Jamia Hamdard has launched a full-time comprehensive study programme, M.Sc. in Clinical Research through which students are trained to meet the demands of expanding health sector in India and abroad.

FACULTY OF SCIENCE

The Faculty of Science is one of the principal Faculties which were amalgamated to create the crust of the University in 1989. Since the inauguration of University Faculty of Science has been in forefront of research and academic activities of Jamia Hamdard. All the Departments and Centres of the Faculty are research intensive. Faculty members get funding for their research from all major governmental funding agencies. Every year a large number of Ph.D. degrees are awarded from the Faculty. Faculty members and research scholars of the Faculty publish their research work in highly cited journals. Thrust areas of research in the Faculty of Science are environment and health. The research objective is to understand the etiology of diseases at molecular level and relationships between nutrients and drugs. Modern bio-medical research tools and developments in the fields of Genetic Engineering, Genomics, Proteomics and Bio-informatics are being used to understand the cellular processes associated with health and diseases. The emerging concept of role of elements in health and effect of chemicals on environment and health and ecosystem including mitigation of their toxicity and carcinogenicity are other areas of research. Scientific evaluation of the efficacy of herbal medicine is being extensively pursued. The effect of environment on growth, structure and chemistry of plants, relationship between structure and function of proteins and enzymes, development of bio-molecules by r-DNA technology, regulation of gene expression, development of new generation vaccines and diagnostic probes, enhancement of secondary metabolites in medicinal plants, metabolomics, molecular biology of infectious diseases, biotransformation of medicinal plants for better yield of medicinal compounds and transgenics of valuable crops and medicinal plants are also being studied. Pre-clinical and clinical research and bioethics are other areas of research.

Faculty has the following Departments and Centre

- Centre for Translational & Clinical Research
- Department of Biochemistry
- Department of Biotechnology
- Department of Botany
- Department of Chemistry
- Department of Medical Elementology & Toxicology

CENTRE FOR TRANSLATIONAL AND CLINICAL RESEARCH

The Centre for Translational & Clinical Research was has been in existence since 2009 as a Department of Clinical Research. In 2012 it was transformed as Centre and component of 'Translational Research' was also incorporated in its activities. The Centre imparts theoretical and practical training in all aspects of clinical research. It provides opportunity to individuals desirous of pursuing a career in expanding healthcare sector in India and abroad. According to industry sources, the clinical research industry in India will require more than 35000 new professionals in the coming few years. With domestic pharma industry surging ahead in India, global pharma moving more and more clinical trials to their Indian subsidiaries, and home grown contract research organization (CROs) growing day by day, the demand for clinical research professionals is expected to grow exponentially. Moreover, personnel involved

in clinical research needs training in Good Clinical Practices (GCP) and ethics. The Centre offers a study programme of MSc in Clinical Research which takes care of all these aspects. The study programme is comprehensive based on both course work and research experience. It is broad-based multi-disciplinary study programme to prepare professionals in clinical research with training in the principles and methods of clinical research, clinical trials, epidemiology, health economics, biostatistics, bioethics, GCP and application of these principles to clinical research. The Department has established collaboration with Ranbaxy Laboratory Ltd., Max Health Care Institute Ltd., New Delhi and other leading clinical research organizations for practical training of the students. The Centre also organizes communication skills workshop for the students to train them in writing and presenting research data, clinical reports, grant applications and case study reports. Faculty includes internal faculty and faculty from industry and other academic institutions. There is a wet laboratory for behavioural and biochemical studies. Regular Seminars and Workshop on relevant and contemporary topics are organized in collaboration with industry. Students participate in these events enthusiastically. These events provide them opportunity to meet professionals from industry and get an exposure to latest development in the field of clinical research.

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.

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 other discipline/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 instructions required 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	8	3	12	1	2	1	2	1	2	X	X	26
II	X	X	3	16	1	2	1	2	X	X	1	2	22
III	X	X	3	16	2	4	1	2	X	X	1	2	24
IV	X	X	2	20	X	X	X	X	X	X	X	X	20
												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
Centre for Translational and Clinical Research

List of courses (credits are indicated in parenthesis)

Semester – I

1. **Foundation Course (MFC 001) (8)**

2. **Discipline Core Course (DCC) - compulsory**

- MCR - DCC101: Introduction to Clinical Research (4).
- MCR - DCC102: General Concepts of Pharmacology (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). May also be selected from the courses from the other Departments of Faculty or from any other Faculty of Jamia Hamdard having credit of 2.

- MCR – GEC101: Pharmacokinetics (2)

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

5. **Ability Enhancement Compulsory Courses (AEC)**

- MCR – AEC101: Professional Communication (2)

M.Sc. (Clinical Research)
Syllabus – Semester II
Centre for Translational and Clinical Research

Semester – II

1. Discipline Core Course (DCC) – compulsory

- MCR - DCC201: Etiopathology and Pharmacotherapy –I (4)
- MCR -DCC202: Regulatory Aspects of Clinical Research (4)
- MCR - DCC203: Practicals and Hands-on Training (8)

2. **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)

3. **Generic Elective Course (GEC)**

Select any one course from the list provided below (2). May also be selected from the courses from the other Departments of Faculty or from any other Faculty of Jamia Hamdard having credit of 2.

- MCR – GEC201: Biostatistical Methods in Clinical Research (2)
- MCR – GEC202: Poisoning and its Management (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)

M.Sc Clinical Research
Syllabus – Semester III
Centre for Translational and Clinical Research

List of courses/papers (credits are indicated in parenthesis)

Semester – III

1. Discipline Core Course (DCC) - compulsory

- MCR - DCC301: Etiopathology and Pharmacotherapy-II (4)
- MCR DCC-302: Concepts in Clinical Trials (4)
- MCR - DCC303: Practical's/Hands-on Training (8)

2. 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: Pharmacovigillance (2)
- MCR – DSE303: Medical Coding (2)

3. Generic Elective Course (GEC)

Select any one course from the list provided below (2). May also be selected from the courses from the other Departments of Faculty or from any other Faculty of JamiaHamdard having credit of 2.

- MCR – GEC301: Quality Control, Quality Assurance and Total Quality Management in Clinical Trials (2)
- MCR – GEC302: Scientific Communication (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)

M.Sc. (Clinical Research)
Syllabus – Semester IV
Centre for Translational and Clinical Research

Semester – IV

Discipline Core Course (DCC) - compulsory

- MCR - DCC401: Research Methodology (2)
- MCR - DCC402: Dissertation/Project (18)

SEMESTER-WISE DISTRIBUTION OF CREDITS AND MARKS

FIRST YEAR – SEMESTER - I

Course type	No. of papers to be opted	Paper code	Credits	Contact hours	Marks of internal assessment	Marks of semester examination	Total marks
Compulsory Foundation Course (CFC)	1	MFC-001	8	128	50	150	200
Discipline Core Course (DCC)	3	MCR – DCC101	4	64	25	75	100
		MCR – DCC102	4	64	25	75	100
		MCR – DCC103	4	64	25	75	100
Discipline Specific Elective Course (DSE)	1	MCR – DSE101 OR MCR –DSE 102	2	32	15	35	50
Generic Elective Course (GEC)	1	MCR – GEC101 OR MCR – GEC102	2	32	15	35	50
Ability Enhancement Compulsory Courses (AEC)	1	MCR – AEC101	2	32	15	35	50
TOTAL	**7**		**26**		**170**	**480**	**650**

Paper detail

1. Compulsory Foundation Course (CFC)

- MFC 001: Foundation Course

2. Discipline Core Course (DCC) - compulsory

- MCR - DCC101: Introduction to Clinical Research
- MCR - DCC102: General Concepts of Pharmacology
- MCR - DCC103: Practicals (4)

3. Discipline Specific Elective Course (DSE)

Select any one course from the list provided below

- 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. May also be selected from the courses from the other Departments of Faculty or from any other Faculty of Jamia Hamdard having credit of 2.

- MCR – GEC101: Pharmacokinetics
- MCR – GEC102: Alternatives in Toxicity Testing

5. Ability Enhancement Compulsory Courses (AEC)

- MCR – AEC101Professional Communication

SEMESTER-WISE DISTRIBUTION OF CREDITS AND MARKS

FIRST YEAR – SEMESTER - II

Course type	No. of papers to be opted	Paper code	Credits	Contact hours	Marks of internal assessment	Marks of semester examination	Total marks
Discipline Core Course (DCC)	3	MCR – DCC201	4	64	25	75	100
		MCR – DCC202	4	64	25	75	100
		MCR – DCC203	8	256	50	150	200
Discipline Specific Elective Course (DSE)	1	MCR – DSE201 OR MCR –DSE 202	2	32	15	35	50
Generic Elective Course (GEC)	1	MCR – GEC201 OR MCR – GEC202	2	32	15	35	50
Skill Enhancement Courses (SEC)	1	MCR – SEC001 OR MCR – SEC002 OR MCR – SEC003 OR MCR – SEC004	2	32	15	35	50
TOTAL	**6**		**22**		**145**	**405**	**550**

Paper detail:

1. Discipline Core Course (DCC) – compulsory

- MCR - DCC201: Etiopathology and Pharmacotherapy –I
- MCR -DCC202: Regulatory Aspects of Clinical Research
- MCR - DCC203: Practicals and Hands-on Training

2. Discipline Specific Elective Course (DSE)

Select any one course from the list provided below.

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

3. **Generic Elective Course (GEC)**

Select any one course from the list provided below. May also be selected from the courses from the other Departments of Faculty or from any other Faculty of Jamia Hamdard having credit of 2.

- MCR – GEC201: Biostatistical Methods in Clinical Research
- MCR – GEC202: Poisoning and its Management

4. Skill Enhancement Courses (SEC)

Select any one course from the list provided below.

- MCR – SEC001: Medical Writing
- MCR – SEC002: ICT Skills
- MCR – SEC003: Pharmacoeconomics and Health Technology Assessment

- MCR – SEC004: Medical Record Management

SEMESTER-WISE DISTRIBUTION OF CREDITS AND MARKS

SECOND YEAR – SEMESTER - III

Course type	No. of papers to be opted	Paper code	Credits	Contact hours	Marks of internal assessment	Marks of semester examination	Total marks
Discipline Core Course (DCC)	3	MCR – DCC301	4	64	25	75	100
		MCR – DCC302	4	64	25	75	100
		MCR – DCC303	8	256	50	150	200
Discipline Specific Elective Course (DSE)	2	MCR – DSE301 OR MCR – DSE302 OR MCR – DSE303	2	32	15	35	50
			2	32	15	35	50
Generic Elective Course (GEC)	1	MCR – GEC301 OR MCR – GEC302	2	32	15	35	50
Skill Enhancement Courses (SEC)	1	MCR – SEC001 OR MCR – SEC002 OR MCR – SEC003 OR MCR – SEC004	2	32	15	35	50
TOTAL	**7**		**24**		**160**	**440**	**600**

Paper detail:

1. Discipline Core Course (DCC) - compulsory

- MCR - DCC301: Etiopathology and Pharmacotherapy-II
- MCR DCC-302: Concepts in Clinical Trials
- MCR - DCC303: Practicals/Hands-on Training

2. Discipline Specific Elective Course (DSE)

Select any two courses from the list provided below.

- MCR – DSE301: Clinical Trial Operations
- MCR – DSE302: Pharmacovigillance
- MCR – DSE303: Medical Coding

3. Generic Elective Course (GEC)

Select any one course from the list provided below. May also be selected from the courses from the other Departments of Faculty or from any other Faculty of Jamia Hamdard having credit of 2.

- MCR – GEC301: Quality Control, Quality Assurance and Total Quality Management in Clinical Trials
- MCR – GEC302: Scientific Communication

4. Skill Enhancement Courses (SEC)

Select any one course from the list provided below.

- MCR – SEC001: Medical Writing
- MCR – SEC002: ICT Skills

- MCR – SEC003: Pharmacoeconomics and Health Technology Assessment
- MCR – SEC004: Medical Record Management

SEMESTER-WISE DISTRIBUTION OF CREDITS AND MARKS

SECOND YEAR – SEMESTER - IV

Course type	No. of papers to be opted	Paper code	Credits	Contact hours	Marks of internal assessment	Marks of semester examination	Total marks
Discipline Core Course (DCC)	2	MCR – DCC401	2	32	15	35	50
		MCR – DCC402	18	576	150	300	450
TOTAL	**2**		**20**		**165**	**335**	**500**

Paper detail:

1. Discipline Core Course (DCC) - compulsory

- MCR - DCC401: Research Methodology
- MCR - DCC402: Dissertation/Project

MFC001:Foundation course

Course objective

This module will be compulsory for students from disciplines.

Credits	Contact hours	Marks – 200	
8	120-128	Internal assessment	Semester examination
		50	150

UNIT I: Chemistry	
1	Solution — Methods of expressing the concentration (Molality, Moarlity. Normality etc).
2	Laws of mass action, Reaction Quotient, Chemical equilibrium constant, Relation of Kp & Kc, pH, buffer, buffer index, buffer capacity, Arrhenius equation.
3	Colligative properties: Molecular mass determination using colligative properties.
4	Rate of reaction, order of reaction
5	Different types of chemical bonds
6	Principles, classification and applications of chromatographic techniques
7	Basics of Spectroscopy and applications.
8	Basic applications of Nanotechnology.
UNIT II: Biochemistry and Cell Biology (Biochemistry)	
1	Biomolecules: Carbohydrates, amino acids/proteins, lipids and nucleotides; Enzymes: Characteristics and nomenclature.
2	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.
3	Bioenergetics and Intermediary Metabolism: ATP as energy currency: Intermediary metabolism
4	Immunology - Active, passive, Humoral and Cellular immunity; Clonal selection theory; Cells of immune system; Immunoglobulins, Haptens, Antigens and Immunogens; Monoclonal & Polyclonal antibodies.
5	Clinical Biochemistry: Common biochemical tests; Acid base disorders; Liver function test; Kidney function tests.
Unit 3: Environmental Sciences (Botany)	
1	Biodiversity — Concept, levels and Conservation of biodiversity

2	Climate change and its consequences
3	Ecosystem - Producers, consumers and decomposers of food chain.
4	Plants with medicinal values.
5	Environmental pollution, bioremediation
UNIT IV: Biotechnology	
1	Genetics of Inheritance - Laws of inheritance, recombination and segregation of traits, segregation ratio, interaction between traits and quantitative inheritance.
2	Molecular Biology - The genetic material. RNA as genetic material, fidelity of DNA replication, transcription, translation. Mutation and mutagenesis. Ames test.
3	Genetic Engineering - Essentials of gene manipulation, vectors & enzymes used in recombinant technology.
4	Biotechnology: Applications and Ethical aspects: Stem cell and its application, Concept of GM Crops and their relevance to society
UNIT V: Toxicology	
1	Introduction to Toxicology.
2	Various types of toxicities (Acute, subacute, sub chronic and chronic).
3	Chemical interactions (Additive effect, potentiation, synergism and antagonism). Dose response relationship (ED50, LD50 EC50, LC50.)
4	Routes of exposure, biotransformation of toxicants. In vitro and in vivo models in toxicological studies
5	Xenobiotics: Common toxicants of air, water & food and their adverse effect on health.
UNIT VI: Drug Development Process (Clinical Research)	
1	Process of Drug development
2	Phases of clinical trials
3	Drug regulatory affairs
4	Principles of GLP, GMP & GCP
5	Basic concepts of Intellectual Property rights

MCR – DCC 101:Introduction to Clinical Research

Course objective

This module covers the basics of Clinical Research, medical terminology, clinical trial definition, the parties involved, and processes and documents used in clinical trials. Learners would also expose to scope of clinical research, career prospects, and overview of documentations. The following broad topics will be covered.

Credits	Contact hours	Marks – 100	
4	64	Internal assessment	Semester examination
		25	75

UNIT I – Drug development process and Drug discovery

1	• The drug development process; high throughput screening (HTS) • Combinatorial chemistry • Lead optimization, target-centered drug design • Problems in extrapolating data from animals to humans

UNIT-II –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

UNIT III – Non Clinical Testing

	• Introduction to toxicology • Acute, sub acute and chronic toxicity • Organ specific toxicity • Mutagenicity, teratogenecity and carcinogenicity • Effect on reproductive system • Bioassays • Animal models of certain diseases

UNIT IV – 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

1	Principles and practice of Pharmaceutical Medicine edited by Lionel D. Edwards, Andrew J Fletcher, Anthony W Fox; Wiley ;Edition second
2	New Drugs: Discovery and development, edited by Alan A. Rubin; Marcel Dekker

MCR – DCC 102:General Concepts of Pharmacology			
Course objective			
This module covers the basics of Clinical Research, medical terminology, clinical trial definition, the parties involved, and processes and documents used in clinical trials. Learners would also expose to scope of clinical research, career prospects, and overview of documentations. The following broad topics will be covered.			
Credits	Contact hours	Marks – 100	
4	64	Internal assessment	Semester examination
		25	75
UNIT I :Pharmacokinetics			
1	• Absorption, Distribution, Metabolism and Excretion (ADME) of drugs • Biotransformation • PK-PD correlations		
UNIT-II –Pharmacodynamics			
	• Mechanism of drug action • Receptors • Transduction process • Second messengers • Dose response relationship		
UNIT III – Special Topics			
	• Adverse drug reactions (ADRs) • Drug interactions • Therapeutic Drug Monitoring		
UNIT IV-Autonomic Nervous System			
	• General concepts- neurohumoral transmission, neurotransmitters • Cholinergic pharmacology • Adrenergic pharmacology		
Suggested Readings			
1	Basic and Clinical Pharmacology by Bertram G. Katzung and Anthony J. Trevor Mc Graw-Hill;12th Edition		
2	Essentials of Medical Pharmacology by K.D. Tripathi Jay Pee Medical; Seventh edition		
3	Principles of Pharmacology by HL Sharma and KK Sharma: Paras Medical Publishers, New Delhi;6th edition		

MCR – DCC 103:Practicals

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 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	Marks – 100	
4	64	Internal assessment	Semester examination
		25	75

UNIT I	
1	• 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/National Medical Library

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	Marks – 50	
2	32	Internal assessment	Semester examination
		15	35

UNIT I :

1	• 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	Marks – 50	
2	32	Internal assessment	Semester examination
		15	35

UNIT I :

1	• 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 – AEC 101:Professional Communication

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	Marks – 50	
2	32	Internal assessment	Semester examination
		15	35

UNIT I :Professional Communication

1	• Communication: Meaning and definition, language as a tool of communication, the process of communication, levels of communication, barriers of communication, modern tools of communication: Fax, email, telephone, voice mails etc. • Functional Grammar: parts of speech, tense, correct usage, synonyms and antonyms homophones • Development of expression through paragraph writing, proposal writing, report writing, application of job, resume, letter writing: Formal and informal

UNIT II- PERSONALITY DEVELOPMENT COURSE

	• Soft skills: the Bedrock of career growth, need of soft skills, components of soft skills • Personality Development • Types of personality, concept of emotional quotient, importance of positive thinking, interpersonal and intra-personal relationships, stress management

Suggested Readings

1	Professional Communication: The Corporate Insider's Approach to Business Communication by Daniel L.Plung and Tracy
2	Professional communication by Malti Agarwal
3	Professional Communication: The Social Perspective by Nancy Roundy Blyler

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	Marks – 50	
2	32	Internal assessment	Semester examination
		15	35

UNIT I: Concepts of Pharmacokinetics

1	• Absorption, Factors affecting absorption, Distribution: barriers, aVd etc. • Metabolism, biotransformation: phase I & II reactions, cytocrhome 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	Marks – 50	
2	32	Internal assessment	Semester examination
		15	35

UNIT I:

1	• 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 – DCC 201:Etiopathology and Pharmacotherapy-I

Course objective

This module is designed to introduce to the learners to some common diseases of body systems which may be target of drugs under investigation. The aim would be to introduce the pharmacological basis of treatment. The following broad topics will be covered.

Credits	Contact hours	Marks – 100	
4	64	Internal assessment	Semester examination
		25	75

UNIT I

1	• Central Nervous System (CNS) Disorders: Alzheimer's disease, multiple sclerosis, pain, epilepsy, Parkinson's Disease

UNIT-II

	• Cardiovascular, Hematopoietic & Renal System Disorders: Hypertension, heart failure, Ischemic heart diseases, thromboembolic disorders, dyslipidemia

UNIT III

	• Respiratory System Disorders: Bronchial asthma, **chronic obstructive pulmonary disease (**COPD), pulmonary hypertension, tuberculosis

UNIT IV

	• Gastrointestinal (GI) System Disorder: Acid peptic disease, irritable bowel syndrome

Suggested Readings

1	Essentials of Medical Pharmacology by K.D. Tripathi; Jaypee Brothers; 6th Edition.
2	Basic and Clinical Pharmacology by Bertram G. Katzung and Anthony J. Trevor;Mc Graw Hill;12th Edition
3	Goodman and Gilman Manual of Pharmacology and Therapeutics,(Goodman and Gilman's Manual of Pharmacology)

MCR – DCC 202:Regulatory Aspects of Clinical Research

Course objective

This module is designed to instruct the students on drug regulatory affairs and various conventions in this regard. The following broad topics will be covered.

Credits	Contact hours	Marks – 100	
4	64	Internal assessment	Semester examination
		25	75

UNIT I- Introduction of Evolution of regulatory control	
1	• Evolution of Regulatory controls: An international comparison • Pure food drugs act, Drugs and cosmetic act 1945, Thalidomide disaster, Kefauvers Harris amendments act, Waxman Hatch act, Nuremberg's code, Declaration of Helsinki • ICH • NICE
UNIT II – 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 • Regulatory system in Japan, Australia and Brazil
UNIT III Regulatory Guidelines	
	• **International Conference on Harmonization** (ICH) GCP guidelines • Overviews of GLP • Schedule Y of Indian Drugs and Cosmetic Act. • Basic regulation of BA/BE studies • Introduction to EMEA,OECD,ANVISA,TGA • Regulation of Traditional and Herbal Remedies
UNIT IV- Common Technical documents: Format of dossier	
Suggested Readings	
1	Textbook of Pharmaceutical Medicine. Edited by John. P. Griffin;Wiley Blackwell;10th Edition
2	Principles and Practice of Clinical researxch by John I, Gallin;Academic Press Inc;3rd Edition
3	Regulatory guidelines ICH, USFDA, Indian GCP, EMEA etc

MCR – DCC 203:Practicals 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 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 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	Marks – 200	
8	256	Internal assessment	Semester examination
		50	150

UNIT I-

1	• 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 at Industry

Exposure to various components of planning, co-ordination and conduct of clinical trials viz., screening and enrollment 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 and
  - 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	Marks – 50	
2	32	Internal assessment	Semester examination
		15	35

UNIT I	
1	• 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
3	Methods by Brian MacMahon and Thomas F. Pugh;Lippinkot William and Wilkins;2nd 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	Marks – 50	
2	32	Internal assessment	Semester examination
		15	35

UNIT I General concepts Intellectual Property Rights & International Institutions

1	• Intellectual Property overview and its theory o Requirement for Protecting Intellectual Property- a national and international comparison o 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 Trademarks

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

Suggested Reading

1	IP Act & Rules from ipindia.nic.in

MCR-GEC201:Biostatistical Methods in Clinical Research

Course objective

The aim of this module offers introduction to major biostatistical methods used in clinical research. Problem/Practical based learning will be followed throughout the module. The following broad topics will be covered.

Credits	Contact hours	Marks – 50	
2	32	Internal assessment	Semester examination
		15	35

UNIT I	
1	• Types of data and its analysis (categorical *vs* quantitative), paired and unpaired test • 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 (t-test, paired t-test, Analysis of variance (ANOVA), Analysis of covariance (ANCOVA), Coefficient of Variation, chi-square test, Fischer exact, Mann-Whitney, Wilcoxin, McNeman test, Kruskal Wallis.
UNIT II	
	• Use of software in Statistical analysis • Intention-to-treat (ITT) and Per-protocol (PP) and Treatment-received (TR) analyses of results in clinical research, Sample size calculation, • Advanced topics in biostatistics related to design and analysis of randomized clinical trials • Introduction to common software packages used in clinical research (e.g. Statistical Analysis System, SAS or Oracle software)
Suggested Reading	
1	Biostatistics for Medical, Nursing and Pharmacy Students. by A. Indrayan and L. Satyanarayana; Prentice-hall Of India Pvt Ltd ;2009 Edition
2	Biostatistics: The Bare Essentials by Geoffrey R. Norman and David L. Streiner; McGraw Hill; 3RD Edition
3	Methods in Biostatistics for Medical Students & Research workers by B.K Mahajan;Jaypee;7th Edition

MCR-GEC202:Poisoning and its Management

Course objective
This module provides the understanding on the general concepts and the various types of drug poisoning and its management. The following broad topics will be covered.

Credits	Contact hours	Marks – 50	
2	32	Internal assessment	Semester examination
		15	35

Unit I: General concepts and some common types of drug poisoning

1	• Introduction to science of poisons, poisons, pollutants, industrial solvents etc. • Poisoning and its types. Some common poisoning: atropine poisoning, paracetamol, aspirin, organophosphorous compounds, barbiturates, cyanides, benzodiazepines, methyl alcohol, digoxin, opioids etc. • Management of poisoning: general measures and treatment of poisoning poison control/information centre's

Unit II: Heavy metal poisoning and its management

	• Toxicology of heavy metals: mercury, lead, arsenic, iron • Chelating agents: dimercaprol, succimer, unithol, edentate calcium disodium (EDTA), d-penicillamine etc.

Suggested Reading

1	Toxicology: Principles And Practice by Reeves; Wiley Blackwell
2	Toxicology: Principles and Applications by Raymond Niesink and Mannfred A. Hollinger; Praeger
3	Driesbaches handbook of Poisoning; Prevention Diagnosis and treatment;Informa Thirteenth Edition

MCR- SEC001:Medical Writing

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,The following broad topics will be covered in this module

Credits	Contact hours	Marks – 50	
2	32	Internal assessment	Semester examination
		15	35

Unit I:

1	• 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- SEC002: ICT Skills

Course objective:

The objective of this module is to improve the student learning through the technology and improve there concepts. The following broad topics will be covered

Credits	Contact hours	Marks – 50	
2	32	Internal assessment	Semester examination
		15	35

Unit I:

1	• ICT: meaning, advantages, disadvantages and uses • General abbreviations and terminology of ICT • Basics of internet and emailing • Use of internet in research works • Literature survey of the previous works and searches for articles online and in the library • Cyber laws

Unit II: Internet Basic Features and Tools

	• Data Base, concepts, components and uses • Information retrieval system • IT based library and information system • New developments in Information communication technology

Suggested Reading

1	Communication research techniques, methods and applications by Arnaudet, ML and Barrett, 7TH Edition;Wadsworth California
2	Distinctive qualities in communication and research by Donal Carburg; Taylor and Francis

MCR-SEC003:Pharmacoeconomics and Health Technology Assessment			
Credits	Contact hours	Marks – 50	
2	32	Internal assessment	Semester examination
		15	35
Unit I: Introduction to pharmacoeconomics			
1	• 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: Health Technology Assessment			
	• 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

The course work is designed abreast the students with medical record management in a hospital set-up. The following broad topics will be covered

Credits	Contact hours	Marks – 50	
2	32	Internal assessment	Semester examination
		15	35

UNIT 1: The Medical Records definition and contents	
1	• 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 Health Records (EHR) – Definition	
	• 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

MCR – DCC 301:Etiopathology and Pharmacotherapy-II

Course objective

This module is designed to introduce to the learners to some common diseases of body systems which may be target of drugs under investigation. The aim would be to introduce the pharmacological basis of treatment. The following broad topics will be covered**.**

Credits	Contact hours	Marks – 100	
4	64	Internal assessment	Semester examination
		25	75

UNIT I	
1	• Endocrine System Disorders: Diabetes mellitus, thyroid disorders, obesity • Infertility and antifertility drugs
UNIT II	
	• Therapeutics in infectious diseases: Bacterial, systemic fungal functions, protozoal and viral infections(HCV, H1N1, rotavirus) • HIV and its management
UNIT III	
	• Cancer therapeutics- chemotherapy, radiotherapy • Arthritis
UNIT IV	
	Special topic • Drugs avoided during pregnancy and lactation • Drugs avoided in pediatrics and geriatric population • Vaccines
Suggested Reading	
1	Principles of Pharmacology by HL Sharma and KK Sharma;Paras Medical Publishers;2nd Edition
2	Goodman and Gilman Manual of Pharmacology and Therapeutics, Second Edition (Goodman and Gilman's Manual of Pharmacology) by Laurence Brunton
3	Essentials of Medical Pharmacology by K.D. Tripathi

MCR – DCC 302:Concepts in Clinical Trials

Course objective

This module will provide the students with an opportunity to learn and understand the regulatory and scientific rationale of designing, conducting, and successfully completing a clinical trial. Also, the essential documents required to conduct a clinical trial will be introduced along with critical issues to be considered when designing a protocol for a clinical study. Broadly, this module will cover the following topics

Credits	Contact hours	Marks – 100	
4	64	Internal assessment	Semester examination
		25	75

UNIT I	
1	• Methods of randomization, blinding, • Screening and recruitment of subjects • Placebo • Biomarker
UNIT II	
	• 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.
UNIT III	
	Trial designs of common diseases like CVS, CNS, Cancer and metabolic disorders BA-BE study designs
UNIT IV	
	• 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 etc
Suggested Reading	
1	Methods for the Economic Evaluation of Health Care Programmes Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien and Greg; Oxford University Press 2005
2	Health Economics. Fundamentals and Flow of Founds. Thomas E. Getzen;Wiley;4th Edition
3	Decision Modeling for Health Economic Evaluation by Andrew Briggs, KarlClaxton, Mark Sculpher, Published by the Oxford University Press 2006

MCR – DCC 303:Practicals 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	Marks – 200	
8	256	Internal assessment	Semester examination
		50	150

UNIT I

1	• 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 :Industrial 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. The following broad topics will be covered.

Credits	Contact hours	Marks – 50	
2	32	Internal assessment	Semester examination
		15	35

Unit I: Site initiation	
1	• 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 IIa: 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 IIb: 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

This module focuses on importance of Drug safety issues that have potential to affect public

health. 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. Following broad topics will be covered in this module.

Credits	Contact hours	Marks – 50	
2	32	Internal assessment	Semester examination
		15	35

Unit I:

1	• 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 • Erice Declaration • 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 analyzed 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).The following basic topics will be covered throughout this module

Credits	Contact hours	Marks – 50	
2	32	Internal assessment	Semester examination
		15	35

Unit I:	
1	• 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:Quality control, Quality Assurance and Total Quality Management in Clinical Trials

Credits	Contact hours	Marks – 50	
2	32	Internal assessment	Semester examination
		15	35

Unit I: QC, QA and TQM overview

1	• Relevance of QA and QC in clinical trials and their comparison • Importance of Clinical Quality Assurance department in industry • Total quality Management • Good clinical practice and quality assurance • Quality control vs. quality assurance

Unit II: Audits/Inspections

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

Suggested Reading

1	A practical guide to quality management in clinical trial research by Graham D, Ogg;CRC Press ;2ND Edition
2	Clinical Trial Audit preparation: A guide for Good clinical practice by VM Madzarevic;ABC of Complementary medicine;2nd edition
3	Regulatory guidelines like ICH, USFDA, Indian GCP etc

MCR-GEC302:Scientific Communication

Course objective: This module will focus on the need for scientific communication in research and the various sources of scientific information. The students will get the understanding of the below mentioned topics

Credits	Contact hours	Marks – 50	
2	32	Internal assessment	Semester examination
		15	35

Unit I: General Concepts	
1	• Need for scientific communication • Relevance and use of science communication - Public Understanding of Science (PUS) • Sources of scientific information – books, scientific reports, scientific journals, magazines, leaflets, speeches, seminars, press releases, databases, encyclopedias on science etc
Unit II: Scientific writing	
	• Writing journal article, proposal writing, usage of graphics and formatting • Grammatical error • Hypothesis testing Proposal writing: strategies of developing good proposal • Publishing and peer review • Communication in the era of new media • Preparing oral and poster presentations
Suggested Reading	
1	A practical guide to quality management in clinical trial research by Graham D, Ogg;CRC Press ;2ND Edition
2	Clinical Trial Audit preparation: A guide for Good clinical practice by VM Madzarevic;ABC of Complementary medicine;2nd edition
3	Regulatory guidelines like ICH, USFDA, Indian GCP etc

MCR-DCC401:Research Methodology

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

Credits	Contact hours	Marks – 50	
2	32	Internal assessment	Semester examination
		15	35

Unit I: Research aptitude

1	• Research: Meaning, characteristics and types • Identifying a research problem, hypothesis • Steps of research • Ethical issues in research: Ethics involving use of animal and human subjects, professional ethics, publication ethics

Unit II: Communications Skills for research

	• Development of communication skills in presentation of scientific seminars, eye to eye contact, facing to audience, question & answer sessions etc. • 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.

Suggested Reading

1	Professional communication skills by Praveen S.R Bhatia,A.K Jain;S.Chand Publishing 2008
2	Communication: The Key to effective Leadership by Judith A Pauley 2009;ASQ quality press Communicating effectively; Tools for Educational Leaders by Michael B.Gilbert;3rd December 2012

MCR-DCC402:Dissertation/Project

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. The following broad units will be covered.

Credits	Contact hours	Marks – 450	
18	576	Internal assessment	Semester examination
		150	300

Unit I:

A project will be prescribed in the course structure in the 4th semester. Under this assignment a candidate shall be required to write a Dissertation/Drug Profile/Meta-analysis/Pharmacovigilance Report/Protocol Design/Standard Operating Procedure, of a minimum of 5000 words, on 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. Though for project work the topics shall be given in advance, the credits assigned for the project work shall be awarded at the end of 4th Semester. 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 the supervisor for project work. The student in consultation with the supervisor shall select a topic for the project work and inform the Head to the Department.