GALGOTIAS UNIVERSITY

(Established under Galgotias University Uttar Pradesh Act No. 14 of 2011)

School of Biological and Biomedical Sciences

Program: B. Sc. Clinical Research

Scheme: 2019 – 2022

Date of BoS:

Curriculum

Semester 1									
Sl. No	**Course Code**	**Name of the Course**					**Assessment Pattern**		
			L	**T**	**P**	**C**	**IA**	**MTE**	**ETE**
1	BCRT 1001	Fundamentals of Clinical Research	4	0	0	4	20	50	100
2	BCRT 1002	Environmental sciences	3	0	0	3	20	50	100
3	BCRT 1003	Introduction to Healthcare	4	0	0	4	20	50	100
4	BCRT 1004	Anatomy and Physiology-I	4	0	0	4	20	50	100
5	PENG 1001	Communicative English - I	3	0	0	3	20	50	100
6	PENG 1002	Communicative English Lab - I	0	0	2	1	0	50	100
7	BCRP 1051	Anatomy and Physiology Lab	0	0	4	2	0	50	100
8	UHVE 1001	Universal Human Values and Ethics	3	0	0	3	0	50	100
		Total	**21**	**0**	**6**	**24**			

Semester II									
Sl No	**Course Code**	**Name of the Course**					**Assessment Pattern**		
			L	**T**	**P**	**C**	**IA**	**MTE**	**ETE**
1	BCRT 2001	Basic Biochemistry	3	0	0	3	20	50	100
2	BCRT 2002	Pharmacology-I	3	0	0	3	20	50	100
3	BCRT 2003	Microbiology	4	0	0	4	20	50	100
4	BCRT 2004	Anatomy and Physiology-II	3	0	0	3	20	50	100
5	BCRT 2005	Regulatory Affairs - I	4	0	0	4	20	50	100
6	PENG 1003	Communicative English - II	3	0	0	3	20	50	100
7	PENG 1004	Communicative English Lab - II	0	0	2	1	0	50	100
8	SNMC 0001	SWAYAM Moocs	2	0	0	2	0	0	100
		Total	**22**	**0**	**2**	**23**			

Semester III									
Sl No	**Course Code**	**Name of the Course**					**Assessment Pattern**		
			L	**T**	**P**	**C**	**IA**	**MTE**	**ETE**
1	BCRT 3001	Computer Fundamentals	3	0	0	3	20	50	100
2	BCRT 3002	Epidemiology	3	0	0	3	20	50	100
3	BCRT 3003	Biostatistics	3	0	0	3	20	50	100
4	BCRT 3004	Regulatory Affairs-II	4	0	0	4	20	50	100
5	BCRT 3005	Drug Discovery and Development	4	0	0	4	20	50	100
6	BCRT 3006	Aspects of Clinical Trials Operations	4	0	0	4	20	50	100
7	BCRT 3007	Pharmacology -II	3	0	0	3	20	50	100
8	BCRP 3051	Computer Lab	0	0	4	2	20	50	100

		Total	**24**	**0**	**4**	**26**			
Semester IV									
Sl No	**Course Code**	**Name of the Course**					**Assessment Pattern**		
			L	**T**	**P**	**C**	**IA**	**MTE**	**ETE**
1	BCRT 4001	Research Methodology	3	0	0	3	20	50	100
2	BCRT 4002	Clinical Trial Design and Project Management	4	0	0	4	20	50	100
3	BCRT 4003	Basics of Pharmacovigilance	4	0	0	4	20	50	100
4	BCRT 4004	Clinical Diagnostics	3	0	0	3	20	50	100
5	BCRT 4005	Ethical Guidelines in Clinical Trial	4	0	0	4	20	50	100
6	BCRT 4006	Basic Biotechnology	4	0	0	4	20	50	100
7	SNMC 0002	SWAYAM	0	0	4	2	0	0	100
		Total	**22**	**0**	**4**	**24**			
Semester V									
Sl No	**Course Code**	**Name of the Course**					**Assessment Pattern**		
			L	**T**	**P**	**C**	**IA**	**MTE**	**ETE**
1	BCRT 5001	Pharmacogenomics and Pharmacoeconomics	4	0	0	4	20	50	100
2	BCRT 5002	Clinical Data Management and SAS Training	4	0	0	4	20	50	100
3	BCRT 5003	Bioethics and Biosafety	3	0	0	3	20	50	100
4	BCRT 5004	Project Management	3	0	0	3	20	50	100
5	BCRT 5005	Hospital and Healthcare Administration	3	0	0	3	20	50	100
6	BCRT 5006	Pathophysiology and Disease Management	4	0	0	4	20	50	100
Electives									
7	BCRT 5007	Medical writing	4	0	0	4	20	50	100
	BCRT 5007	Clinical Trial Management							
		Total	**25**	**0**	**0**	**25**			
Semester VI									
Sl No	**Course Code**	**Name of the Course**					**Assessment Pattern**		
			L	**T**	**P**	**C**	**IA**	**MTE**	**ETE**
1	BCRT 6001	Soft skills & personality development	3	0	0	3	20	50	100
2	BCRT 6002	Hospital Management and Law	3	0	0	3	20	50	100

3	BCRT 6003	Medical Record management	3	0	0	3	20	50	100
4	BCRT 6004	ndustry Report	0	0	2	1	20	0	100
5	BCRP 6051	Budget	0	0	24	12	60	240	300
	BCRP 6051	Clinical Project							
		Total	**9**	**0**	**26**	**22**			

List of Electives

Basket-1

Sl No	Course Code	Name of the Electives					Assessment Pattern		
			L	T	P	C	IA	MTE	ETE
1	BCRT 5007	Medical writing	4	0	0	4	20	50	100
2	BCRT 5007	Clinical Trial Management	4	0	0	4	20	50	100

Basket-2

Sl No	Course Code	Name of the Electives					Assessment Pattern		
			L	T	P	C	IA	MTE	ETE
1	BCRP 6051	Budget	0	0	24	12	60	240	300
2	BCRP 6051	Clinical Project	0	0	24	12	60	240	300

Detailed Syllabus

Name of The Course	Fundamentals of Clinical Research			
Course Code	BCRT1001			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	4	0	0	4

Course Objectives: Students will be exposed to Clinical Research and their requirements, Pharmaceutical Industry, Bioavailability and Bioequivalence Studies.

Course Outcomes

On completion of this course the students will be able to understand

CO1	Historical Aspects of clinical research, clinical research terminologies
CO2	Phases of Clinical Trial and Types of Clinical Trial including Virtual Clinical Trials
CO3	Pharmaceutical Industry and concepts of Intellectual Property Rights
CO4	Modules of International Conference on Hormonization (Quality, Safety, Efficacy and Miscellaneous) and E6 Overview
CO5	Drug Regulation and Evidence based medicine

Text Book (s)

1. Indian GCP Guideline.
2. Schedule Y: Drug and Cosmetic Act 1940
3. Design and Analysis of Clinical Trials: Concepts and Methodologies, 3rd Edition. SheinChung Chow, Jen-Pei Liu. Publisher: Wiley.
4. Principles and Practice of Pharmaceutical Medicine, 3rd Edition. Lionel D. Edwards, Anthony W. Fox, Peter D. Stonier. Publisher: Wiley-Blackwell

Reference Book (s)

1. Methodology of Clinical Drug Trials, 2nd Edition. Spriet A., Dupin-Spriet T., Simon P. Publisher: Karger

Course Contents

Unit-1 Basic Introduction to Clinical Research **9 hours**
Overview, Opportunities & Career options in Clinical Research, Glossary of GCP. Historical Aspects of clinical research, Brief description of different phases, Stakeholders in clinical research, Need/Area for clinical research.
Unit-2 Phases and Types of Clinical Trials **9 hours**
Introduction to Clinical Trials - Phases of Clinical Trials, Types of Clinical Trials, Randomized/Non randomized Clinical Trial, Virtual-clinical trials, Drug discovery and development.
Unit-3 Pharmaceutical Industry & globalization **9 hours**
Overview of global and local players, Intellectual Property Rights: Introduction, Scope, Objectives and concepts of IPR, Tangible & Intangible property, scope & nature of patents, copyrights, trade mark, Indian Patent Act 1970, practical aspects of patent filing.
Unit-4 : ICH Introduction **9 hours**

ICH Introduction, Origin, Organization, Structure, Modules of ICH (Quality, Safety, Efficacy and Miscellaneous), E6 Overview
Unit-5: Introduction to Indian GCP and ICMR **9 hours**
Indian- good clinical practice and schedule Y, Overview of ICMR, evidence based medicine

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	Environmental Sciences			
Course Code	BCRT1002			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	3	0	0	3

Course Objectives:

1. To develop awareness about our environment.
2. To develop a concern about sustainable development.

Course Outcomes

On completion of this course the students will be able to understand

CO1	about environment and its components and Problems associated with natural resources and their sustainable use
CO2	Chemical Toxicity of the chemicals in the environment and Sources of pollution in air, water and soil and Solid waste management and natural Disaster management.
CO3	about social issues, Thermal, Nuclear hazards, Solid waste management.
CO4	role of information technology to address environmental issues and Environment Protection Act.
CO5	Application of sustained Chemistry, Tools of Green technology, zero waste technology

Text Book (s)

1. Environmental Studies, Anubha Kaushik, C P Kaushik, New Age International Publishers, 2008, ISBN:978-81-224-2159-0.
2. Environmental Studies, Suresh K. Dhameja, S.K. Kataria and Sons , 2008, ISBN: 81-88458-77-5
3. Text Book of Environmental Studies, Erach Bharucha, University Press (India) Private Limited, 2005,ISBN: 978 81 7371 540 2
4. Environmental Studies (From Crisis to Cure) Second Edition. , R. Rajagopalan, Oxford University Press, 2012, ISBN 0-19-807208-2.
5. Environmental Studies, Ranu Gadi, Sunitta Rattan, Sushmita Mohapatra, S.K. Kataria and Sons , 2008, ISBN: 81-89757-98-9.

Reference Book (s)

1. Environmental Studies , Benny Joseph , Tata McGraw Hill Education Private Limited, 2009, ISBN: 987-0-07-064813-5.
2. Environmental Studies, Anindita Basak, Pearson Education, 2009, ISBN: 978-81-317-2118-6.
3. Principles of Environmental Science (Inquiry and Applications), William P. Cunningham & Mary Ann Cunningham, Tata McGraw Hill Education Private Limited,2007, ISBN: 987-0-07-064772-0.

Course Contents

Unit-1: Environment & Natural Resources	**9 hours**
Definition, scope, importance, need for public awareness, Environmental Management Systems its objectives, components, EIA, forest resources – use, exploitation, deforestation, construction of multipurpose dams – effect on forests, Water resources – use of surface and subsurface water; effect of floods, drought, water conflicts, Mineral resources – Use and exploitation, environmental effects of extracting and using mineral resources, Food resources – food problems, advantage and disadvantage of fertilizers & pesticides, effect on environment, Energy resources – need to develop renewable energy, land resources – Land degradation, landslides, soil erosion, desertification & case studies.	
Unit-2: Chemical Toxicology	**9 hours**
Toxic chemicals in the environment, Impact of toxic chemicals on enzymes, biochemical effects of arsenic, cadmium, lead, chromium, mercury, biochemical effects of pesticides	
Unit-3: Environmental Pollution	**9 hours**
Definition – Causes, pollution effects and control measures of Air, Water, Soil, Marine, Noise, Thermal, Nuclear hazards. Solid waste management: causes, effects and control measures of urban and industrial wastes, pollution measures, case studies, Disaster management: floods, earthquake, cyclone and landslides..	
Unit-4 : Social Issues, Human Population and the Environment	**9 hours**
Urban problems related to energy & sustainable development, water conservation, problems related to rehabilitation – case studies, Consumerism and waste products - Environment Protection Act, Air, Water, Wildlife, Forest Conservation Act, Environmental legislation and public awareness. Population growth, variation among nations, Population explosion, Environment and human health, Value Education, Women and Child Welfare, Role of Information Technology – Visit to local polluted site /Case Studies.	
Unit-5: Green Chemistry	**9 hours**
Introduction, Basic principles of green technology, concept of Atom economy, Tools of Green technology, zero waste technology	

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	Introduction to Healthcare			
Course Code	BCRT1003			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	4	0	0	4

Course Objectives:

Introduction to Healthcare exposes a student to learn Healthcare system, Hospital Role, Infection control, and foundation of health.

Course Outcomes

On completion of this course the students will be able to understand

CO1	Healthcare systems and Ethical Roles and Responsibilities of a Health Care Worker
CO2	Holistic Health and Controlling Infection, Mental Health, Nutrition, Controlling Infection
CO3	Foundation of health and healthcare system, Community Medicine and Hospitals
CO4	Introduction to Primary healthcare, state & district level including Municipal Corporations & Councils
CO5	Role of Hospital in healthcare system, National Rural and Urban Health Mission

Text Book (s)

1. Health Care Reforms in India – Rajendra Pratap Gupta
2. Introduction to Health Care – SHARON B. BUCHBINDER & NANCY H. SHANKS
3. Innovation in Health Care Management- VK Singh n Paul Lillrank

Reference Book (s)

1. India's Healthcare Industry – Lawton Robert Burns

Course Contents

Unit-1: Healthcare Systems 9 hours
Careers in Health Care, Personal Qualities of a Health Care Worker/Health Care Providers, Measurement, Medical Terminology, Legal Obligations, Cultural Considerations, Medical Liability and Patient's Rights, Ethical Roles and Responsibilities of a Health Care Worker
Unit-2: Health Control 9 hours
Holistic Health, Mental Health, Nutrition, Controlling Infection, Measuring Vital Signs and other Clinical Skills, Injury and Prevention, First Aid/ CPR
Unit-3: Foundations of Health and Healthcare System 9 hours
Concept of health & disease: Concept of Prevention, Preventive Medicine, History of Hospitals. Characteristics Hospitals as industry, Community Medicine & Hospitals
Unit-4 : Introduction to Primary Health Care 9 hours
Definition, Principles, Functions, Evolution of Health Care System. Organisation of Health Services at central, state & district level including Municipal Corporations & Councils, Panchayat Raj institutions. Inter-sectoral linkages
Unit-5: Role of hospitals in health care system 9 hours

National health policy, National Rural and Urban Health Mission. National Health Programmes. International Health Agencies, Concepts of family welfare, National Family Welfare programme. MCH and RCH programmes

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	Anatomy and Physiology-I			
Course Code	BCRT1004			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	4	0	0	4

Course Objectives:
To understand the basic Human anatomy and Physiology

Course Outcomes

On completion of this course the students will be able to understand

CO1	Human Body as a whole, Epithelium and serous & mucous glands
CO2	Locomotion and support, names of bones, vertebral column, inter vertebral disc, fontanelles of fetal skull
CO3	Cardiovascular System, Blood supply of heart, Systemic & pulmonary circulation, Branches of aorta, common carotid artery
CO4	Gastrointestinal System including tonsil, dentition, pharynx, salivary glands, Oesophagus, stomach, small and large intestine
CO5	Respiratory System, Histology of trachea, lung and pleura

Text Book (s)

1. William Davis, *Understanding Human Anatomy and Physiology*, McGraw Hill
2. Chaursia's, *A Text Book of Anatomy*
3. Ranganathan, T.S., *A Text Book of Human Anatomy*

Reference Book (s)

1. Fattana, *Human Anatomy*, (Description and Applied), Saunder's & C P Prism Publishers, Bangalore
2. Ester. M. Grishcimer, *Physiology & Anatomy with Practical Considerations*, J.P. Lippin Cott. Philadelphia.

Course Contents

Unit-1: Introduction: Human body as a whole	**9 hours**
Definition of anatomy and its divisions, Terms of location, positions and planes, Cell and its organelles, Epithelium-definition, classification, describe with examples, Glands classification, describe serous & mucous glands with examples, Basic tissues – classification with examples	
Unit-2: Locomotion and Support	**9 hours**
Cartilage – types with example & histology, Bone – Classification, names of bone cells, parts of long bone, microscopy of compact bone, names of bones, vertebral column, inter vertebral disc, fontanelles of fetal skull, Joints – Classification with examples, synovial joint, Muscular system-Classification & histology, Names of muscles of the body.	
Unit-3: Cardiovascular System	**9 hours**

Heart-size, location, chambers, exterior & interior, Blood supply of heart, Systemic & pulmonary circulation, Branches of aorta, common carotid artery, subclavian artery, axillary artery, brachial, artery, superficial palmar arch, femoral artery, internal iliac artery, Peripheral pulse, Inferior venacava, portal vein.
Unit-4 : Gastro-intestinal System **9 hours**
Parts of GIT, Oral cavity (lip, tongue (with histology), tonsil, dentition, pharynx, salivary glands, Oesophagus, stomach, small and large intestine, liver, gall bladder, pancreas, Radiographs of abdomen
Unit-5: Respiratory System **9 hours**
Parts of RS, nose, nasal cavity, larynx, trachea, lungs, bronchopulmonary segments, Histology of trachea, lung and pleura, Names of paranasal air sinuses.

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	Communicative English –I			
Course Code	PENG1001			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	3	0	0	3

Course Objectives:

1. To help the students understand and communicate in English as used in day to day activities.
2. To help the students enhance their competence in the English language.

Course Outcomes

On completion of this course the students will be able to understand

CO1	Demonstrate the knowledge of the fundamental principles of communication
CO2	Write simple and meaningful sentences with proper punctuations
CO3	Apply the knowledge of functional and formal grammar
CO4	Compose different types of formal letters
CO5	Develop effective non verbal skills, Develop conversational and presentation skills for group discussion

Text Book (s)

1. Bhatnagar, R.P. & R. Bhargava, Law and language, New Delhi: Macmillan.
2. Cross, Ian et al. Skills for lawyers, Jordan Publishing Company., 1997 Bristol.
3. Madabhushi Sridhar, Legal Language, Asia Law House, Hyderabad.
4. Legal Language and Legal Writing – P.K. Mishra

Reference Book (s)

1. Murphy Raymond, Essential English Grammar, Cambridge Uni. Press.
2. Intermediate English Grammar. Raymond Murphy ISBN NO 978-81-7596-676-5
3. Essential English Grammar. Raymond Murphy ISBN: 9788175960299
4. Wallace, Michael J: Study Skills in English, Cambridge University Press, Cambridge, 1980.

Course Contents

Unit-1: Fundamentals of communication **9 hours**
Fundamentals of Communication; Effective listening strategies , Time, Tense and aspects ; Subject-Verb Agreement; Basic sentence structure
Unit-2: Analysis of sentences **9 hours**
Formal and Functional Analysis of sentences, Prepositions
Unit-3: Letter writing **9 hours**

Constituents of Formal Letter writing, Formats; Types of Letter (Enquiry, Complaint, Adjustment, Place an Order)
Unit-4 : Voices **9 hours**
Clauses, Active and Passive Voice; Homophones; Homonyms
Unit-5: Moded of communication **9 hours**
Non-Verbal Communication; Para linguistics; Group Discussion , Extempore

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	Communicative English-I (P)			
Course Code	PENG1002			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	0	0	2	1

Course Objectives:

1. To help the students understand and communicate in English as used in day to day activities.
2. To help the students enhance their competence in the English language

Course Outcomes

On completion of this course the students will be able to understand

CO1	write simple and meaningful sentences with proper punctuation
CO2	words, in isolation and in context
CO3	instructions, requests and class lectures
CO4	pronounce words correctly in everyday use
CO5	Presentation techniques

Text Book (s)

1. Cambridge Grammar for IELTS with answers. ISBN NO 9780521706117
2. Byne: Teaching Writing Skills, Longman, London 1989.
3. Cross, Ian et al. Skills for lawyers, Jordan Publishing Company., 1997 Bristol.
4. Jones Daniel, English Pronouncing Dictionary.

Reference Book (s)

1. Wallace, Michael J: Study Skills in English, Cambridge University Press, Cambridge,1980.
2. Kelkar, Ashok R. "Communication and Style in Legal Language", Indian Bar Review Vol. 10 (3): 1993.
3. English Vocabulary in Use. Michael McCarthy & Felicity O'Dell ISBN: 9780521684569

Course Contents

Topics
Basics of Pronunciation: Organs of Speech, Articulation System, Three Term Label, Consonant Sounds, Vowel Sounds; Introduction (Self and Lab Partners); Extempore; Presentation Techniques; Book Review, Newspaper Reading, Mock Lecture

Continuous Assessment Pattern

Internal Assessment (IA)	Mid Term Test (MTE)	End Term Test (ETE)	Total Marks

00	50	50	100

Name of The Course	**Anatomy and Physiology Practical**			
Course Code	**BCRP1051**			
Prerequisite				
Corequisite				
Antirequisite				
	L	**T**	**P**	**C**
	0	0	4	2

Course Objectives:

To understand the anatomy and physiology, concepts of health and disease of human body.

Course Outcomes

On completion of this course the students will be able to understand

Structure and functional characteristics of cells and tissues, skeletal system, skeletal and smooth muscles and compositions, functions of blood and its elements.

Text Book (s)

1. Ranade VG, "Text Book of Practical Physiology", Pune Vidyarthi Griha Prakashan, Pune. 2. Chatterjee C.C. "Human Physiology", Medical Allied Agency, Calcutta.
3. Ross & Wilson "Anatomy & Physiology in Health & Illness", Churchill Livingstone.
4. Parmar N.S. "Health Education & Community Pharmacy" CBS Publishers, Delhi.
5. Shalya Subhash "Human Physiology" CBS Publishers & Distributors

Reference Book (s)

1. Keele, C.A., Niel, E and Joels N, Samson Wright's Applied Physiology,
Oxford University Press
2.Tortora GJ, & Anagnodokos NP "Principles of Anatomy & Physiology", Harper & Row,
New Delhi.
3. Guyton AC, Hall JE., "Text book of Medical Physiology", WB Saunders Company.
4. Difore S.H. "Atlas of Normal Histology" – Lea & Febiger Philadelphia

Course Content

1. Study of human skeleton.
2. Microscopic study of different tissues.
3. Recording of body temperature, pulse rate and blood pressure, basic understanding of Electrocardiogram – PQRST waves and their significance.

Continuous Assessment Pattern

Internal Assessment (IA)	Mid Term Test (MTE)	End Term Test (ETE)	Total Marks
00	50	50	100

Name of The Course	Universal Human Values and Ethics			
Course Code	UHVE1001			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	3	0	0	3

Course Objectives:

1. To help students distinguish between values and skills, and understand the need, basic guidelines, content and process of value education.
2. To help students initiate a process of dialog within themselves to know what they 'really want to be' in their life and profession
3. To help students understand the meaning of happiness and prosperity for a human being.
4. To facilitate the students to understand harmony at all the levels of human living, and live accordingly.
5. To facilitate the students in applying the understanding of harmony in existence in their profession and lead an ethical life

Course Outcomes

On completion of this course the students will be able to understand

CO1	the significance of value inputs in a classroom and start applying them in their life and profession
CO2	the values and skills, happiness and accumulation of physical facilities, the Self and the Body, Intention and Competence of an individual, etc.
CO3	the value of harmonious relationship based on trust and respect in their life and profession
CO4	the role of a human being in ensuring harmony in society and nature
CO5	ethical and unethical practices, and start working out the strategy to actualize a harmonious environment wherever they work.

Text Book (s)

1. R R Gaur, R Sangal, G P Bagaria, 2009, A Foundation Course in Human Values and Professional Ethics.

Reference Book (s)

1. Ivan Illich, 1974, Energy & Equity, The Trinity Press, Worcester, and Harper Collins, USA
2. E.F. Schumacher, 1973, Small is Beautiful: a study of economics as if people mattered, Blond & Briggs, Britain.
3. Sussan George, 1976, How the Other Half Dies, Penguin Press. Reprinted 1986, 1991
4. Donella H. Meadows, Dennis L. Meadows, Jorgen Randers, William W. Behrens III, 1972, Limits to Growth – Club of Rome's report, Universe Books.
5. A Nagraj, 1998, JeevanVidyaEkParichay, Divya Path Sansthan, Amarkantak.
6. P L Dhar, RR Gaur, 1990, Science and Humanism, Commonwealth Publishers.

7. A N Tripathy, 2003, Human Values, New Age International Publishers.
8. SubhasPalekar, 2000, How to practice Natural Farming, Pracheen (Vaidik) KrishiTantraShodh, Amravati.
9. E G Seebauer& Robert L. Berry, 2000, Fundamentals of Ethics for Scientists & Engineers , Oxford University Press
10. M Govindrajran, S Natrajan& V.S. Senthil Kumar, Engineering Ethics (including Human Values), Eastern Economy Edition, Prentice Hall of India Ltd.
11. B P Banerjee, 2005, Foundations of Ethics and Management, Excel Books.
B L Bajpai, 2004, Indian Ethos and Modern Management, New Royal Book Co., Lucknow.Reprinted 2008.

Course Contents

Unit-1: Course Introduction - Need, Basic Guidelines, Content and Process for Value Education 9 hours
1. Understanding the need, basic guidelines, content and process for Value Education 2. Self Exploration–what is it? - its content and process; 'Natural Acceptance' and Experiential Validation- as the mechanism for self exploration 3. Continuous Happiness and Prosperity- A look at basic Human Aspirations 4. Right understanding, Relationship and Physical Facilities- the basic requirements for fulfillment of aspirations of every human being with their correct priority 5. Understanding Happiness and Prosperity correctly- A critical appraisal of the current scenario 6. Method to fulfill the above human aspirations: understanding and living in harmony at various levels
Unit-2: Understanding Harmony in the Human Being - Harmony in Myself 9 hours
1. Understanding human being as a co-existence of the sentient 'I' and the material 'Body' 2. Understanding the needs of Self ('I') and 'Body' - Sukh and Suvidha 3. Understanding the Body as an instrument of 'I' (I being the doer, seer and enjoyer) 4. Understanding the characteristics and activities of 'I' and harmony in 'I' 5. Understanding the harmony of I with the Body: Sanyam and Swasthya; correct appraisal of physical needs, meaning of Prosperity in detail 6. Programs to ensureSanyam and Swasthya
Unit-3: Understanding Harmony in the Family and Society- Harmony in Human-Human Relationship 9 hours
1. Understanding harmony in the Family- the basic unit of human interaction 2. Understanding values in human-human relationship; meaning of Nyaya and program for its fulfillment to ensure Ubhay-tripti; Trust (Vishwas) and Respect (Samman) as the foundational values of relationship 3. Understanding the meaning of Vishwas; Difference between intention and competence 4. Understanding the meaning of Samman, Difference between respect and differentiation; the other salient values in relationship 5. Understanding the harmony in the society (society being an extension of family): Samadhan, Samridhi, Abhay, Sah-astitva as comprehensive Human Goals 6. Visualizing a universal harmonious order in society- Undivided Society (AkhandSamaj), Universal Order (SarvabhaumVyawastha)- from family to world family!
Unit-4 : Understanding Harmony in the Nature and Existence - Whole existence as Co-existence 9 hours
1. Understanding the harmony in the Nature 2. Interconnectedness and mutual fulfillment among the four orders of nature- recyclability and self-regulation in nature 3. Understanding Existence as Co-existence (Sah-astitva) of mutually interacting units in all-

	pervasive space
4.	Holistic perception of harmony at all levels of existence
Unit-5: Implications of the above Holistic Understanding of Harmony on Professional Ethics 9 hours	
1.	Natural acceptance of human values
2.	Definitiveness of Ethical Human Conduct
3.	Basis for Humanistic Education, Humanistic Constitution and Humanistic Universal Order
4.	Competence in Professional Ethics: a) Ability to utilize the professional competence for augmenting universal human order, b) Ability to identify the scope and characteristics of people-friendly and eco-friendly production systems, technologies and management models
5.	Case studies of typical holistic technologies, management models and production systems
6.	Strategy for transition from the present state to Universal Human Order: a) At the level of individual: as socially and ecologically responsible engineers, technologists and managers b) At the level of society: as mutually enriching institutions and organizations.

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
00	50	50	100

Name of The Course	Basic Biochemistry			
Course Code	BCRT2001			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	3	0	0	3

Course Objectives:

This course Biochemistry-1 deals with the acid base balance, biochemical nature of carbohydrates, proteins, minerals, vitamins, lipids etc. A detailed study of these, emphasizing on their chemical composition and their role in metabolism is the required aim of this course.

Course Outcomes

On completion of this course the students will be able to understand

CO1	Acid Base balance, Structure, function and interrelationship of bio molecule
CO2	Different types of carbohydrates and their structure and function
CO3	Amino acids & Proteins and Chemical bonds involved in protein Structure
CO4	Types of Lipids, properties & functions of fatty acids, Saturated and Unsaturated Fatty acids and biological significance of fats
CO5	Base Composition of Nucleic acids, deficiency disorders of Vitamins and Minerals

Text Book (s)

1. S. Ramakrishnan, K G Prasannan and R Rajan: Text book of Medical Biochemistry, Orient Longman, Madras, 1990

2 Das, Debajyothi, Biochemistry, Academic, Publishers, Calcutta.

3 A Text book of Medical Biochemistry by. Chatterjee,

4 A Text book of Biochemistry by Satyanarayan,U.

5 Fundamentals of Biochemistry- J L Jain, Sanjay Jain, Nitin Jain

Reference Book (s)

1. Varley, Clinical Chemistry

2. Teitz, Clinical Chemistry

3. Kaplan, Clinical Chemistry

Course Contents

Unit-1: Introduction of Acid, Base and Salt	9 hours
Introduction, Definition, Structure of Water molecule, basic concept of Acids, bases, salts & acid base balance, buffer System, Structure of cell & introduction to Atoms and chemical bonds.	

Unit-2: Carbohydrates	**9 hours**
Introduction, Sources, Classification, fischer projections, The artificial or synthetic sweeteners, Haworth perspective formula, Isomerism, important derivatives of monosaccharides, Structure and functions of sugars- disaccharides & polysaccharides.	
Unit-3: Amino Acids and Proteins	**9 hours**
Introduction, Classification, Properties of Proteins, Peptide bond, Amino acids, Peptides, Chemical bonds involved in protein Structure, Derived protein, Ramachandran plot, Myoglobin.	
Unit-4 : Lipids	**9 hours**
Introduction, sources, nomenclature, classification, structure, properties & functions of fatty acids, Saturated and Unsaturated Fatty Acids, Derived Lipids, steroids, biological significance of fats ,cholesterol and phospholipids	
Unit-5: Nucleic Acid, Vitamins and Minerals	**9 hours**
Introduction, Definition and Base Composition of Nucleic acids, helical Structure, Nomenclature and Classification of Enzymes, deficiency disorders of Vitamins and Minerals.	

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	PHARMACOLOGY – I			
Course Code	BCRT2002			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	3	0	0	3

Course Objectives:

This subject deals with the pharmacology of cardiac glycoside drugs e.g. digitoxin, digoxin, antianginal drugs e.g. nitrates, antihyperlipidemic drug e.g. statins, antiarrhythmic drugs e.g. lidocaine, Anticoagulants e.g. heparin, Fibrinolytics e.g. streptokinase, Antiplatelet drugs e.g. Aspirin, Antiasthmatic drugs e.g. bronchodilators, Anti-tussive drugs- opioids(codeine). It also deals with the anti-inflammatory, analgesic, antipyretic drugs and drugs used for migraine treatment e.g. NSAIDS. Drugs acting on GIT antacids- sodium bicarbonate, anti ulcer drug- cimetidine, omeprazole, antiemetics- hyoscine.

Course Outcomes

On completion of this course the students will be able to understand

CO1	Introduction to human body and detailed structure of cell membrane
CO2	Anatomy and Physiology of Skeletal and Smooth Muscles and energy Metabolism
CO3	Pharmacology of Cardiovascular system and drugs acting on CVS
CO4	Drugs acting on Haemopoietic system and Respiratory system
CO5	Drugs acting on GIT and NSAIDS & Anti-gout Drugs

Text Book (s)

1 Tripathi K.D., *Essentials of Medical Pharmacology*, Jay Pee Publishers, New Delhi.

2. Rang M.P., Date M.M., Riter J.M., *Pharmacology*, Churchill Livingstone.

3. Katzung, B.G., *Basic & Clinical Pharmacology*, Prentice Hall, International.

4. Barar F.S.K., *Text Book of Pharmacology*, Interprint, New Delhi.

5. Satoskar & Bhandarkar, *Pharmacology & Pharmacotherapeutics*, Popular Prakashan Pvt. Ltd., Bombay

Reference Book (s)

1. Laurence D.R. & Bannet P.N., *Clinical Pharmacology*, Churchill Livingstone.

2. Goodman & Gilman, *The Pharmacological Basis of Therapeutics*, Editors:-J.G. Hardman, L.E. Limbird, P.B. Molinoss, R.W. Ruddon & A.G. Gil, Pergamon Press.

3. Craig, C.R. & Stitzel R.R., *Modern Pharmacology*, Little Brown and Co., 1994.

Course Contents

Unit-1: Introduction to human body **9 hours**
Functional & structural characteristics of cell and cell membrane, Structural & functional characteristics of tissues- epithelial, connective, muscle and nerve, Functions of skeleton. Classification of joints, types of movements of Joints
Unit-2: Anatomy and Physiology of Muscles **9 hours**

Skeletal & smooth muscle, neurotransmission, physiology of skeletal muscle contraction, energy metabolism, types of muscle contraction, muscle tone
Unit-3: Pharmacology of CVs **9 hours**
Cardiac glycosides, Antihypertensive drugs, Antianginal drugs Antiarrhythmics, Antihyperlipidemics, Therapy of shock.
Unit-4 : Hemopoeitic System and Respiratory system **9 hours**
Drug Acting on Hemopoeitic System: Haematinics, Vit. K & anticoagulants, Fibrinolytics & antiplatelet drugs, Plasma Volume expanders **Drugs Acting on Respiratory System**: Anti-asthmatic drugs, Expectorants, Respiratory Stimulants
Unit-5: Drugs acting on GIT **9 hours**
Antacids and Antiulcer drugs, Laxatives and Anti diarrhoeal Agents, Emetics and Antiemetics

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	MICROBIOLOGY			
Course Code	BCRT2003			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	4	0	0	4

Course Objectives:

Pharmaceutical microbiology deals with common pathogenic microorganisms, their cultivation methods, sterilization methods, assays. The micro org. causes diseases & contamination the subject deal with all these.

Course Outcomes

On completion of this course the students will be able to understand

CO1	different types of microorganisms and their structure
CO2	Identification of Microbes and types of staining techniques
CO3	staining, cultivation of microbes and methods of sterilization & sterility testing
CO4	Microbial Physiology and Genetics including Microbiology of soil, Aquatic Microbiology and Industrial Microbiology
CO5	Control of microbial contamination during manufacture and sterility testing

Text Book (s)

1. Aneja K.R. Experiments in Microbiology, Plant Pathology, Tissue Culture & Mushroom Cultivation, Vishwa Prakashan.
2. Gunasekaran P, Lab Mannual of Microbiology, New Age Publishers
3. Davis, Dulbetco, Eisen Microbiology.
4. Stanier R.Y., Ingraham, J.L., Wheelis M.L. & Painter P.R. General Microbiology, Macmillan Press Limited.
5. Hugo and Russell, Pharmaceutical Microbiology, Black Well Scientific Publication, Oxford. 6. Prescott L.M., Harley J.P. & Klien D.A. Microbiology, McGraw Hill.
7. Sykes, Disinfection and Sterilization.

Reference Book (s)

1. Pelczar & Reid, Microbiology, Tata Mc Graw Hill, Delhi.
2. Virella G. Microbiology and Infectious Diseases, William & Wilkins.
3. Ananthanarayan R & Paniker CKJ, Textbook of Microbiology, Orient Longman

Course Contents

Unit-1: INTRODUCTION	**9 hours**
Introduction to the scope of microbiology, Structure of bacterial cell, Classification of microbes and their taxonomy, Bacteria and viruses	
Unit-2: IDENTIFICATION OF MICROBES	**9 hours**

Identification of Microbes: Stains and types of staining techniques, electron microscopy. Reproduction and Growth of Microbes, cultivation & isolation of bacteria & viruses
Unit-3: CONTROL OF MICROB 9 hours
Control of microbes by physical and chemical methods, Disinfection, disinfectants and antiseptics and their evaluation, Sterilization, different methods, validation of sterilization methods & equipments
Unit-4 : MICROBIAL PHYSIOLOGY AND GENETICS 9 hours
Enzymes and their regulation, Microbial Metabolism: Energy Production, Bacterial Genetics, Microbiology of soil, Aquatic Microbiology, Industrial Microbiology
Unit-5: MICROBIAL ASSAYS 9 hours
Microbial assays of antibiotics, Factory and hospital hygiene, manufacture of sterile products, nosocomial infection, control of hospital infections, Sterility testing as per I.P.

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	Anatomy and Physiology- II			
Course Code	BCRT2004			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	3	0	0	3

Course Objectives:
This subject will develop an understanding of the Structure & Function of organs and Organ systems, in normal Human Body– Urinary system, Endocrine, Nervous system, Reproductive system, & sensory organs.

Course Outcomes

On completion of this course the students will be able to understand

CO1	the Structure and function of Cytoplasmic Organelles
CO2	Anatomy and Physiological functions of Kidney and Renal Blood circulation
CO3	Anatomy & Physiology of all Endocrine Glands
CO4	Fundamental parts of brain: Hind Brain, Mid Brain, Fore Brain and Nervous system
CO5	Male and female reproductive system and abnormalities

Text Book (s)

1. William Davis, *Understanding Human Anatomy and Physiology*, McGraw Hill
2. Chaursia's, *A Text Book of Anatomy*
3. Ranganathan, T.S., *A Text Book of Human Anatomy*

Reference Book (s)

1. Fattana, Human Anatomy, (Description and Applied), Saunder's & C P Prism Publishers, Bangalore
2. Ester. M. Grishcimer, Physiology & Anatomy with Practical Considerations, J.P. Lippin Cott. Philadelphia
3. Guyton, Arthur, Text Book of Physiology, Prism Publishers
4. Chatterjee, C C, Human Physiology, Medical Allied Agency.

Course Contents

Unit-1: Cell **9 hours**
Definition, Structure and function of cell, Skin, Eye, Ear, Reproduction-Meosis, Mitosis
Unit-2: Execratory System **9 hours**
Identification of Microbes: Stains and types of staining techniques, electron microscopy. Reproduction and Growth of Microbes, cultivation & isolation of bacteria & viruses
Unit-3: Endocrines system **9 hours**
Anatomy & Physiology of all Endocrine Glands; Thyroid, Parathyroid, Pituitary & Adrenal Glands, Gonads & Islets of Langerhans
Unit-4 : Nervous System **9 hours**

CNS: Brain: Fundamental parts of brain, Location, & coverings of brain. Spinal cord: Anatomy, functions, CSF: Formation, circulation, properties, Composition, & Functions; Lumbar Puncture
Unit-5: Reproductive system **9 hours**
Male Reproductive system: Testis, Duct system, Functions. Semen-secretion, composition, Oligozoospermia. **Female Reproductive system:** Ovaries, Duct system & Accessory Organs, Functions. Ovulation, Menstrual Cycle, Pregnancy, Parturition

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	Regulatory Affairs-I			
Course Code	BCRT2005			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	4	0	0	4

Course Objectives:
Students will be exposed to Indian Drug and Cosmetic Act and Ethical Guideline

Course Outcomes

On completion of this course the students will be able to understand

CO1	Indian Good Clinical Practice Guideline for conducting Clinical Trial.
CO2	Indian Drug and Cosmetic Act 1940 and Data required to be submitted with application for permission to market a new drug
CO3	National Ethical Guidelines For Biomedical And Health Research Involving Human Participants
CO4	Investigational new drug, New Drug application and Abbreviated new drug application Submission procedure and 21 Code of Federal Regulation
CO5	Informed Consent process in special Population or Vulnerable patient

Text Book (s)

1. Indian Council of Medical Research Guideline
2. Drug and Cosmetic Act 1940 Schedule Y
3. Indian Good Clinical Practice Guideline

Reference Book (s)

1. Principles and Practice of Clinical research by John I, Gallin;Academic Press Inc;3rd Edition

Course Contents

Unit-1: Indian Good Clinical Practice 9 hours
Overview of ICH GCP, Glossary, Prerequisites for the study, Responsibilities of Sponsor, Monitor, Investigator, Statistics, Special Concern, Basic Principles for all Medical Research.
Unit-2: Schedule Y 9 hours
Data Required to be submitted with application for permission to market a new drug, Clinical Study Report, Informed Consent, Undertaking by the Investigator, Ethics Committee, Protocol, Data Elements for reporting Serious Adverse Event.
Unit-3: Guidelines and Ethical Issues of Medical Research 9 hours
Introduction to ICMR and centers, Statement of general principles, Human genetics testing and research, Biological materials
Unit-4 : Clinical Research Regulatory Submission & Approval Process 9 hours

Food and Drug Administration- Investigational new drug, New drug application and Abbreviated new drug application Submission Procedure, Medical Device Regulation in India, Vaccine Regulation, Biologics Regulation, 21 CFR
Unit-5: General ethical Consideration 9 hours
Ethical review procedures, Informed consent process, Vulnerability, Clinical trials of drugs and other interventions, Assisted reproductive technology

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	Communicative English -II			
Course Code	PENG1003			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	3	0	0	3

Course Objectives:

1 To help the students understand and communicate in English as used in day to day activities.
2. To help the students enhance their competence in the English language.

Course Outcomes

On completion of this course the students will be able to understand

CO1	simple and meaningful sentences with proper punctuation
CO2	words, in isolation and in context
CO3	instructions, requests and class lectures
CO4	pronounce words correctly in everyday use
CO5	Fundamentals of Report Writing; Essay Writing

Text Book (s)

1. Murphy Raymond, Essential English Grammar, Cambridge Uni. Press.
2. Intermediate English Grammar. Raymond Murphy ISBN NO 978-81-7596-676-5
3. Essential English Grammar. Raymond Murphy ISBN: 9788175960299

Reference Book (s)

1. Wallace, Michael J: Study Skills in English, Cambridge University Press, Cambridge, 1980.
2. Bhatnagar, R.P. & R. Bhargava, Law and language, New Delhi: Macmillan.
3. Cross, Ian et al. Skills for lawyers, Jordan Publishing Company., 1997 Bristol.
4. Madabhushi Sridhar, Legal Language, Asia Law House, Hyderabad.
5. Legal Language and Legal Writing – P.K. Mishra

Course Contents

Unit-1: The Art of Condensation **9 hours**
The Art of Condensation; Reading Comprehension; Introduction to Adjectives; Adverbs, Reported Speech; Word Formation
Unit-2: Effective Writing **9 hours**
Constituents of Effective Writing; Modals; Letter Writing (Sales Letter, Cover letter); Resume Writing
Unit-3: Vocabulary **9 hours**
Vocabulary (Antonyms, Synonyms, One Word Substitution)

Unit-4 : Presentation Techniques	**9 hours**
Presentation Techniques	
Unit-5: Fundamentals of Report Writing	**9 hours**
Fundamentals of Report Writing; Essay Writing, E-mail and Telephonic Etiquettes	

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	Communicative English -II (PRACTICAL)			
Course Code	**PENG1004**			
Prerequisite				
Corequisite				
Antirequisite				
	L	**T**	**P**	**C**
	0	0	2	1

Course Objectives:

1. To help the students understand and communicate in English as used in day to day activities.
2. To help the students enhance their competence in the English language.

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Course Outcomes

On completion of this course the students will be able to understand

CO1	Able to write simple and meaningful sentences with proper punctuation
CO2	Able to understand words, in isolation and in context
CO3	Able to understand instructions, requests and class lectures
CO4	Able to pronounce words correctly in everyday
CO5	

Text Book (s)

1. Cambridge Grammar for IELTS with answers. ISBN NO 9780521706117
2. Byne: Teaching Writing Skills, Longman, London 1989.
3. Cross, Ian et al. Skills for lawyers, Jordan Publishing Company., 1997 Bristol.
4. Jones Daniel, English Pronouncing Dictionary.

Reference Book (s)

1. Wallace, Michael J: Study Skills in English, Cambridge University Press, Cambridge,1980.
2. Kelkar, Ashok R. "Communication and Style in Legal Language", Indian Bar Review Vol. 10 (3): 1993.
3. English Vocabulary in Use. Michael McCarthy & Felicity O'Dell ISBN: 9780521684569

Course Contents

Unit-1: Basics of Pronunciation **9 hours**
Basics of Pronunciation: Phonemes, Allophones, Syllables, Stress, Accent, Intonation,' Phonetic Transcription;
Unit-2: Effective Discussion **9 hours**
Group Discussion, Do's and Don'ts of GD; Debate; Role Play
Unit-3: Review **9 hours**
Live Presentations ; Movie Review; Book Review, Newspaper Reading
Unit-4 : Presentation Techniques **9 hours**
Mock Lecture; Mock Interview; Skit ; Picture Interpretations; Powerpoint Presentations

Continuous Assessment Pattern

Internal Assessment (IA)	Mid Term Test (MTE)	End Term Test (ETE)	Total Marks

00	50	50	100

Name of The Course	Current regulatory requirements for conducting clinical trials in India for investigational new drug/new drug (Version 2.0)				
Course Code	**SNMC0001**				
Prerequisite					
Corequisite					
Antirequisite					
		L	**T**	**P**	**C**
		2	0	0	2

Course Objectives:
Students will be exposed to Clinical Trial Regulatuion, BA/BE requirement, GCP and Ethical consideration.

Course Outcomes

On completion of this course the students will be able to understand

CO1	Indian drug regulatory system, Schedule Y and Indian GCP.
CO2	Preclinical trial, Types of clinical trial and rule governing clinical trial
CO3	Generic drug, BA/BE studies and Regulations
CO4	Good Clinical Practice and Ethical Guideline Consideration
CO5	Special consideration in clinical trial
CO6	Protocol, content of protocol and importance of Protocol
CO7	Dossier preparation and submission to regulatory bodies
CO8	SUGAM and CTRI

Text Book (s)

1. Fundamentals of Clinical Trials textbook by David L. DeMets and Lawrence M. Friedman
2. Clinical Trials: Study Design, Endpoints and Biomarkers, Drug Safety, and FDA and ICH Guidelines Book by Tom Brody

Reference Book (s)

1. Challenges and Prospects for Clinical Trials in India: A Regulatory Perspective (Academic Foundation)

Course Contents

Unit-1: Drug and Cosmetic Act and Rule 3 hours
Course Overview, Overview of Indian drug regulatory system, Overview of drugs & cosmetics Act and Rules thereunder, Overview of New Drug and Clinical Trials Rules Rules, 2019
Unit-2: Phases of Clinical Trial 3 hours
Pre-clinical data requirements, Rules governing clinical trials, Phases of clinical trial, forms, and fees, Regulatory pathway and data requirements for NDCT, 2019
Unit-3: Bioavailability and Bioequivalence studies 3 hours
BA/BE study and study centres: Legal provisions, Guidelines to conduct BA/BE studies, Ethics Committee registration and re-registration

Unit-4 : Good clinical practice	**3 hours**
Ethical considerations, Good Clinical Practice, Requirements for import/manufacture of new drug/IND for conducting clinical trials in India, Requirements for import/manufacture of new drug/IND for sale/distribution and unapproved new drug for patients	
Unit-5: Clinical trial guideline	**3 hours**
Important issues, Special concerns, Clinical trial related guidelines (NDCT Rules)	
Unit-6: Protocol	**3 hours**
Content of proposed clinical trial protocol, Content of a clinical trial report, Post marketing assessment and clinical trial compensation	
Unit-7: Drug development process	**3 hours**
Common observations during submission of CT/BA/BE protocol, Common observations during CT/BA/BE centre inspections, Drug development process: Overview	
Unit-8: CDSCO and SUGAM	**3 hours**
Salient feature of NDCT 2019 (What's new in NDCT?), Online submission (SUGAM), Online submission (CTRI), Tables given in NDCT 2019 and its content	

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
25	00	75	100

Name of The Course	Computer Fundamentals			
Course Code	BCRT3001			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	3	0	0	3

Course Objectives:
The basic objective of this course is to get familiar with computers and programming Language.

Course Outcomes

On completion of this course the students will be able to understand

CO1	Definition and Overview of Computer and different kinds of Networks
CO2	Single and Multi user operating system and function
CO3	Introduction to MS Office including Editing and Important Functions
CO4	ways of delivering Presentation, main components of Access tables, Queries, Reports, Forms and table handling
CO5	Computer applications in Medical studies and uses of Internet in Clinical Research Industry

Text Book (s)

1. Mendhanm J, Denny R.C., Barnes J.D., Thomas M, Jeffery G.H., "Vogel's Textbook of Quantitative Chemical Analysis", Pearson Education Asia.
2. Conners K.A., "A Text book of Pharmaceutical Analysis", Wiley Inter-science.

Reference Book (s)

1. Beckett, A.H., and Stenlake, J.B., Practical Pharmaceutical Chemistry, Vol. I&II. The Atherden Press of the University of London.
2. Alexeyev V. "Quantitative Analysis". CBS Publishers & Distributors.

Course Contents

Unit-1: Definition and Overview of Computer **9 hours**
Computer classification, Computer Organization, Computer code, Input Devices, Output devices, Storage devices. Computer Software, LAN, MAN, WAN, Internet, Intranet.
Unit-2: Operating system and function **9 hours**
Evolution of operating system, Single User and Multi-user Operating system, Compare MS-DOS vs. UNIX, Various window features. Internal and External commands in MS-DOS
Unit-3: Introduction to MS-OFFICE **9 hours**
MS word, Document creation, Editing, formatting table handling, mail merge, Excel-2003, working Retrieval, Important functions, short cut keys used in EXCEL
Unit-4 : Ways of delivering presentation **9 hours**
MS-Power point, Elements of Power point, concept of Four P's (Planning , Preparation, Practice and Presentation), Data models schema and instance. Database language, working on Query and use of database

Unit-5: Computer Application	**9 hours**
Computer applications in Medical studies, uses of Internet in Clinical Research Industry	

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	Epidemiology			
Course Code	BCRT3002			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	3	0	0	3

Course Objectives:
This course Basic Epidemiology deals with the scope of epidemiology in clinical research.

Course Outcomes

On completion of this course the students will be able to understand

CO1	Scope of epidemiology, definition and calculation of prevalence, incidence, risk, rate, basic and net reproductive rate
CO2	risk ratio, rate ratio, odds ratio, absolute risk, assumptions and limitations of these measures and Measures of dynamics of infectiousness
CO3	Ecological/geographical studies, Cohort Studies, Intervention studies and RCTs
CO4	mortality, sociodemographic information, samples size and statistical power
CO5	Bias: definition, information and selection, definitions, detection and control of Confounding Bias

Text Book (s)

1. Hospital Administration — Tabish (O.U.P.)
2. Epidemiology & Management of Health Care for all-P.V. Sathe & A.P. Sathe
3. Elementary Statistics for Medical Workers, Indervir Singh, Jaypee Brothers
4. Element of Health Statistics-Rao NSN

Reference Book (s)

1 Text Book of Preventive and Social Medicine — Park.
2 A Short Text Book of Medical Statistics-Hill A.B, 10th Ed, ELBS

Course Contents

Unit-1: Scope of epidemiology **9 hours**
definition, descriptive and analytical epidemiology, contribution to population health, Measures of disease frequency, Prevalence, incidence, risk, rate, basic and net reproductive rate, choosing suitable measures.
Unit-2: Measures of association **9 hours**
Definition and calculation of risk ratio, rate ratio, odds ratio, absolute risk and rate differences, attributable risk and fraction, net reproduction rate and the basic reproduction rate, infection and transmissibility periods.
Unit-3: Ecological/geographical studies **9 hours**
Uses and interpretation of ecological studies, ecological fallacy and ecological bias. Case control studies, Cohort studies, Intervention studies and RCTs, bias, Migrant studies: design strategies

Unit-4 : Routine data sources	**9 hours**
Mortality, sociodemographic information, Disease trends and standardization, Mortality ratio, Random error/chance: samples size and statistical power, type I and II errors, regression dilution, confidence intervals	
Unit-5: Bias	**9 hours**
Definition, information and selection, Confounding bias, Interaction and effect modification: definition and detection, Association and Causation: causal paradigms and criteria for causality. Validity and reliability, positive and negative predictive value of a test	

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	Biostatistics			
Course Code	BCRT3003			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	3	0	0	3

Course Objectives:

This course Basic Biostatic collaborates with scientists in nearly every area related to healthcare and clinical research.

Course Outcomes

On completion of this course the students will be able to understand

CO1	Test of Hypothesis, Study design, Role of Statistics in Preventive Medicine
CO2	Measures of central tendency, Absolute and relative measures of dispersion
CO3	Elements of Probability, Properties of probability. Illustrations and applications
CO4	Analysis and Interpretation of Data, Preparing Data for Computer Analysis and presentation
CO5	Types of Test, Comparison of data between different groups

Text Book (s)

1. Wiley Des Raj and Chandhok (1998).
2. Sampling Theory, Narosa. Murthy, M.N. (1967).
3. Sampling Theory and Methods. Statistical Publishing Company, Calcutta. Sampath S.(2005). Sampling Theory and Methods.

Reference Book (s)

1 Cochran, W.G. (2002). Sampling Techniques.

Course Contents

Unit-1: Scope of Statistical Methods In Medicine **9 hours**
Test of Hypothesis, Study design, Role of Statistics in Clinical Medicine, Role of Statistics in Preventive Medicine, and Observations in Medicines.
Unit-2: Measures of Central Tendency **9 hours**
Arithmetic mean, median, mode, geometric mean, harmonic mean, Absolute and relative measures of dispersion, range, standard deviation, mean deviation, quartile deviation, coefficient of variation.
Unit-3: Elements of Probability **9 hours**
Random experiments, sample space, events, related results. Classical, empirical, and axiomatic approaches to probability, Addition theorem, Conditional probability, independence of events. Law of total probability, Bayes theorem and applications
Unit-4 : Analysis And Interpretation of Data **9 hours**

Plan for Data Analysis: Quantitative and Qualitative, Preparing Data for Computer Analysis and Presentation, Statistical Analysis, Interpretation of Data, Summary and Discussion, Confidence interval, SD, SE, Regression and correlation
Unit-5: Types of Test **9 hours**
Null hypothesis and test of significance (t-test, paired t-test, Analysis of variance, Analysis of covariance, Coefficient of Variation, chi-square test, Fischer exact, Mann-Whitney, Wilcoxin, McNeman test, Kruskal Wallis.

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	Regulatory Affairs - II			
Course Code	BCRT3004			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	4	0	0	4

Course Objectives:

The students will be familiarized with international rules and regulations pertaining to Clinical Research.

Course Outcomes

On completion of this course the students will be able to understand

CO1	International Conference on Hormonization Good Clinical Practice guideline
CO2	Regulatory requirement in US and European Union and their different committees
CO3	Regulatory requirement in China, Japan, Australia and Brazil including the working Procedure
CO4	Regulatory requirement for Medical Devices, Classification of medical Devices, Regulations for Biological products Trial
CO5	Common Technical Document: Purpose, structure and contents, Investigator Investigational new drug, Treatment Investigational new drug.

Text Book (s)

1. Principles and Practice of Clinical research by John I, Gallin;Academic Press Inc;3rd Edition
2. Textbook of Pharmaceutical Medicine. Edited by John. P. Griffin;Wiley Blackwell;10th Edition
3. Guidelines like GCP, USFDA, EMEA, MHRA, TGA, Indian GCP etc.
4. Good clinical practice: Consolidated guideline, ICRI
5. Basic Principles of Clinical research, S.K.Gupta, ICRI
6. MRC Guidelines for Good Clinical Practice in Clinical Trials, ICRI
7. Guidance for Investigational New Drug Applications, ICRI

Reference Book (s)

1. Principles and practice of Clinical Research by John. I Gallin.;Academic Press;3rd Edition
2. Medical Devices: Regulations, Standards and Practices (Woodhead Publishing series in biomaterials; Ist Edition.

Course Contents

Unit-1: International conference on Hormonization Good Clinical Practice 9 hours
Background of drug regulations, International Conference on Harmonization, ICH Guidelines, Principle of GCP, Ethics Committee, Investigator, Sponsor, Investigational Brochure, Protocol, Essential Documents.

Unit-2: Regulatory Requirements in US and European Union 9 hours
Food and Drug Act (USFDA), Organization structure and Functions, EU regulations, EMEA Structure and Functions, England Regulation (MHRA).
Unit-3: Other Country Regulati 9 hours
China Regulatory System (SFDA), Australia Regulation (TGA), Japan Drug Regulation (MHLW, PMDA), Brazil Guideline (ANVISA).
Unit-4 : Medical Device and Biological prod 9 hours
Global Regulations for Medical Devices, Classification, Regulatory agencies and regulations, Biological products Trial, Types of Biological products, Drug Development for Orphan diseases and Drug legislation.
Unit-5: Common technical Document and types of Investigational new drug 9 hours
Investigational new drug Application :requirements forms , contents, application form, Types, Emergency use, review process, actions, Guidance documents, application procedure for ANDA filing, Basic Regulation of Bioavailability/Bioequivalence Studies, Common Technical Document: Purpose , structure and contents

Continuous Assessment Pattern

Internal Assessment (IA)	Mid Term Test (MTE)	End Term Test (ETE)	Total Marks
20	30	50	100

Name of The Course	Drug Discovery and Development			
Course Code	BCRT3005			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	4	0	0	4

Course Objectives:
To understand the Drug Discovery and Development process

Course Outcomes

On completion of this course the students will be able to understand

CO1	In vitro preclinical studies, Selection of animal models, Mutagenicity, teratogenecity and carcinogenicity
CO2	High through put screening and Problems in extrapolating data from animals to humans
CO3	Introduction to Preclinical Studies and role of regulatory body in preclinical trial
CO4	Drug evaluation and clinical development, Phases of developmental Clinical Trial
CO5	Investigational new drug, New drug application and abbreviated new drug application submission procedure

Text Book (s)

1. Drug Design to Clinical Research – ICRI.
2. A Comprehensive Guide to Toxicology in Preclinical Drug Development, Ali S. Faqi, Second Edition, 2013.
3. Pre-Clinical evaluation of new drugs, S K Gupta.

Reference Book (s)

1 Preclinical Drug Development, Edited by Mark Rogge, David R. Taft, Second Edition, 25th Sep 2009.

Course Contents

Unit-1: Drug Evaluation and Clinical Development **9 hours**
Introduction, Factors to be considered for animal studies, Phase 0, Phase 1, Phase II, Phase III, Phase IV, Placebo, Significance of Adverse event, Serious Adverse event and End point.
Unit-2: HIGH THROUGH PUT SCREENING (HTS) 9 hours
Introduction, Advantages and Disadvantages, Uses, Methodology, Combinatorial Chemistry, Lead optimization, target-centered drug design.
Unit-3: INTRODUCTION TO PRE-CLINICAL STUDIES 9 hours
Objectives, Importance of Pre-Clinical trials, Steps involved in Pre-clinical studies, Drug Development process, Types of Pre-Clinical Studies, GLP, Toxicity Studies.
Unit-4 : IN VITRO PRE-CLINICAL STUDIES 9 hours

Introduction to toxicology, Organ specific toxicity, Bioassays, Animal models of certain diseases, Overview of study types, Differences between in vitro study and in vivo study.
Unit-5: NON CLINICAL DRUG DEVELOPMENT 9 hours
Global submission of IND, NDA, ANDA. Investigation of medicinal products dossier, dossier (IMPD) and investigator brochure (IB).

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	Aspects of clinical trial operation			
Course Code	BCRT3006			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	4	0	0	4

Course Objectives:
Students will be exposed to all aspects of Clinical Trial operation.
Course Outcomes

On completion of this course the students will be able to understand

CO1	the Operational Introduction of Clinical Trial, Site selection, Patient recruitment and Retention
CO2	Responsibility, Composition and basic function of Instituitional Ethics Committee, NABH accreditation process
CO3	Clinical Trial Stakeholders, Roles & Responsibilities of Clinical Research Coordinator, Clinical Data Manager, Project Manager, LAB selection Procedure
CO4	Filing of Case report form or electronic Case report form, Documentation procedure in Informed consent form
CO5	Site selection procedure and Contingency planning to prepare for unexpected situations

Text Book (s)

1. Guidelines like GCP, USFDA, EMEA, Indian GCP etc.
2. Good clinical practice: Consolidated guideline, ICRI
3. White book for Clinical Research, ICRI
4. CRA handbook, ICRI
5. Basic Principles of Clinical research, S.K.Gupta, ICRI

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Reference Book (s)

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

Course Contents

Unit-1: Operational Introduction **9 hours**
Site Selection parameters: Location, ICH-GCP compliance, Patient Recruitment and Retention, Single/Multi Centre Trial, Investigator Selection and agreement, Undertaking by the Investigator.
Unit-2: Operation of IRB/IEC **9 hours**
Introduction, Defining Scope of IRB/IEC, Responsibilities, Composition of IRB/IEC, Basic Functions, NABH Accreditation of EC, EC role in Special Population Studies.
Unit-3: Clinical Trial Stakeholders **9 hours**

Roles & Responsibilities Sponsor, Investigator, Hospital, CROs/SMOs, CRA/CRC, Auditor, Inspector, Clinical Data Manager, LAB selection Procedure, Budgeting and Contracting
Unit-4 : Documentation **9 hours**
Investigator's Brochure, Source data verification, Study Protocol, CRF & e-CRF, ICF Process, Clinical Study Report, SOP, Essential Documents, Conflict of interest in Research, Record retention.
Unit-5: Site Management **9 hours**
Monitoring visits, audits and inspections, Total quality Management, termination of a trial, Handling missing data, query and resolution Database lock, Site close-out report, CSR, submission to ethics committee and regulatory agency, publication of results.

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	PHARMACOLOGY II			
Course Code	BCRT3007			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	3	0	0	3

Course Objectives:
The basic objective of this course is to get familiar with pharmacology.

Course Outcomes

On completion of this course the students will be able to understand

CO1	Hypothalamic & pituitary hormones, Calcitonin & Vitamin D, Insulin, oral hypoglycaemic agents & glucagon
CO2	ACTH & Corticosteroids and Drugs acting on Uterus
CO3	General Principle of Chemotherapy and Introduction of Immunomodulators and chemotherapy of Cancer
CO4	Principle of Toxicology and general principles of treatment of poisoning with particular reference to barbiturates and opioids
CO5	Haemopoitic System and Disease causing agents & prevention of disease

Text Book (s)

1. Tripathi, K.D., *Essentials of Medical Pharmacology*, Jay Pee Publishers, New Delhi.
2. Satoskar & Bhandarkar, *Pharmacology & Pharmacotherapeutics*, Popular Prakashan Pvt. Ltd.,Bombay.
3. Katzung, B.G., *Basic & Clinical Pharmacology*, Prentice Hall, International.
4. Rang M.P., Dale M.M., Riter J.M., *Pharmacology*, Churchill Livingstone.
5. Barar F.S.K., *Text Book of Pharmacology*, Interprint, New Delhi.
6. Kulkarni S.K., *Hand Book of Experimental Pharmacology*, Vallabh Prakashan, Delhi.

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Reference Book (s)

1. Goodman & Gilman, *The Pharmacological basis of Therapeutics*, Pergamon Press.
2. Laurene, D.R. & Bennet P.N., *Clinical Pharmacology*, Churchill Livingstone

Course Contents

Unit-1: Pharmacology of Endocrine System	**9 hours**
Hypothalamic & pituitary hormones, Thyroid hormones & Thyroid Drugs, Parathyroid, Calcitonin & Vitamin D, Insulin, oral hypoglycaemic agents & glucagon	
Unit-2: ACTH & CORTICOSTEROIDS	**9 hours**
Androgens & anabolic steroids, Estrogens, Progesterone & Oral Contraceptives, Drugs acting on uterus	
Unit-3: Chemotherapy	**9 hours**

General Principles, Antibiotics, Chemotherapy of Parasitic infections, Tuberculosis, Fungal infections, viral diseases, Immunomodulators and chemotherapy of Cancer
Unit-4 : Principles of Toxicology **9 hours**
Definition of poison, general principles of treatment of poisoning with particular reference to barbiturates, opioids, organo phosphorous & atropine poisoning, Heavy metal Antagonists.
Unit-5: Haemopoietic system **9 hours**
Composition & function of blood & its elements, erythopoesis, blood groups, blood coagulation, Concepts of health & disease, Classification of food requirements

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	Computer Fundamentals (Practical)			
Course Code	BCRP3051			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	0	0	4	2

Course Objectives:
The basic objective of this course is to get familiar with computers and programming Language.
Course Outcomes

Students will learn about basics of computer, programming.

Text Book (s)

1. Mendhanm J, Denny R.C., Barnes J.D., Thomas M, Jeffery G.H., "Vogel's Textbook of Quantitative Chemical Analysis", Pearson Education Asia.
2. Conners K.A., "A Text book of Pharmaceutical Analysis", Wiley Inter-science.

Reference Book (s)

1. Beckett, A.H., and Stenlake, J.B., Practical Pharmaceutical Chemistry, Vol. I&II. The Atherden Press of the University of London.
2. Alexeyev V. "Quantitative Analysis". CBS Publishers & Distributors.

Practical to be conducted

Software Lab to be used for the following:-

1. Windows, Managing Windows, Working with Disk , Folders and files.

2. MS-Office 2003 (MS Word, MS Power point, MS Excel, MS Access).

3. Computer Operating System Like DOS and Windows.

4. Internet Features (E-mail, Browser etc)

Continuous Assessment Pattern

Internal Assessment (IA)	Mid Term Test (MTE)	End Term Test (ETE)	Total Marks
00	50	50	100

Name of The Course	Research Methodology			
Course Code	BCRT4001			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	3	0	0	3

Course Objectives:
This course deals with the study of Literature Review and Research Methodology.

Course Outcomes

On completion of this course the students will be able to understand

CO1	Research Methods, definition, objectives, role, scope in management research
CO2	Ethical Issues in Research, Choice of Research Design and Sources of Experimental Errors
CO3	Basic concept of Biostat, Research tools and Data collection methods
CO4	Sampling and Data Collection, Probability sampling techniques, Sampling and non sampling errors.
CO5	Developing a Research Proposal, Data Preparation and Analysis and Report writing

Text Book (s)

1. The Analysis of Biological Data (2nd edition) by Whitlock & Schluter
2. TB of Biostatisics and Research methodology by Karthikeyan,R.M .Chathurvedi,R.M.Bhosale
3. C.R. Kothari : Research Methodology, New Age International Publishers
4. Srivastava and Rego : Business Research Methodology Tata McGraw Hill
5. Rajinder Nargundhkar : Marketing Research, Tata McGraw Hill

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Reference Book (s)

1. Cooper and Schindler, Business Research Methods, Tata McGraw Hill
2. Textbook of Methods in Biostatistics by B.K.Mahajan 7th Edition
3. Textbook of Biostatistics by B.Annadural

Course Contents

Unit-1: Research Methods	**9 hours**
Introduction to research methods, identifying research problem, definition, objectives, role, scope in management research, process of research, limitations & types	
Unit-2: Issues	**9 hours**
Ethical issues in research, Research design, Choice of Research Design, Types of Research Design, Sources of Experimental Errors	
Unit-3: Biostat	**9 hours**

Basic Concepts of Biostatistics, Types of Data, Research tools and Data collection methods
Unit-4 : Sampling **9 hours**
Sampling methods, Advantages and Limitation, Sampling process, Types of Sampling, Probability and Non Probability sampling techniques, errors, Data collection, observation methods and survey method
Unit-5: Developing a research proposal **9 hours**
Data Preparation and Analysis: Editing, Coding, Cross Tabulation and Practices **Report Writing:** Types of Research Reports, Guidelines for Writing a Report

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	Clinical Trial Design and Project management			
Course Code	BCRT4002			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	4	0	0	4

Course Objectives:
Students will be exposed to Clinical Trial Designing and Project Management

Course Outcomes

On completion of this course the students will be able to understand

CO1	Types of Clinical Trial Study, Cohort study and superiority trials and non-inferiority trials
CO2	Clinical Study Designing, Advantage and disadvantage of Placebo and Biomarker
CO3	Types of Designing and Trials for special population: pediatric, geriatric, pregnant women
CO4	Trials Designing based on Disease, Training in Clinical Research, Project auditing, Inspection, Fraud and Misconduct
CO5	Clinical Trial Management, Managing projects through teamwork, conflict in projects.

Text Book (s)

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. Basic principles of Clinical Research and Methodology: S K Sharma
4. Project Management: the Managerial Process. McGraw-Hill

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Reference Book (s)

1. Decision Modeling for Health Economic Evaluation by Andrew Briggs, KarlClaxton, Mark Sculpher, Published by the Oxford University Press 2006
2. Project Management, Tools and Trade-offs. John Wiley & Sons, Inc.Gray, C.F. and Larson, E.W. (2006

Course Contents

Unit-1: Types of Studies	9 hours
Definitions, Introduction and types of trial, Designing phase I, II, III and IV trials, cross over, case control study, cohort study, equivalence trials, superiority trials and non-inferiority trials.	
Unit-2: Study Planning and Strategy	**9 hours**
Define study population, control study, Randomized trial, blinding, their characteristics and parameter to measure endpoints, Subject Screening, Placebo, Biomarker, Efficacy and Safety endpoints.	
Unit-3: Tools used in Clinical Trial designing	**9 hours**

Inclusion and exclusion criteria, Trials for special population, Quality of life trial, Logs and Forms, Subject Diaries, Visual Analog scales, Subject Recruitment and Advertisement.
Unit-4 : Documentation and Management **9 hours**
Clinical Trial stakeholders, Selection of an Investigator and Site, Managing projects, conflict in projects, Documentation in Clinical Trials, Regulatory Binder, Record Retention, Project auditing, Inspection, Fraud and Misconduct
Unit-5: Clinical Trial Management **9 hours**
Project budgeting, Project risk, Trial designs of common diseases like CVS, CNS, Cancer and metabolic disorders, BA-BE study designs, Data entry management, Ethical and Regulatory submission.

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	Basics of Pharmacovigilance			
Course Code	BCRT4003			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	4	0	0	4

Course Objectives:
Students will be exposed to Pharmacovigilance and their requirements, Adverse Drug Reaction Reporting and signal detection.

Course Outcomes

On completion of this course the students will be able to understand

CO1	the need and importance of Pharmacovigilance, Standard terms and terminologies in Pharmacovigilance
CO2	Medical evaluation of Adverse event in Pharmacovigilance, Definitions and classification of ADRs, Detection and reporting
CO3	Case Processing and Medical Dictionary, Global Perspective of Pharmacovigilance and Single Case Processing
CO4	signal detection and management process, Managements and Risk Assessments & Evaluation
CO5	Pharmacovigilance Laws and Guideline, PV Auditing and Inspection

Text Book (s)

1. Essentials of Pharmacovigilance, ICRI
2. Recommended text: An Introduction to Pharmacovigilance by Patrick Waller (2010)

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Reference Book (s)

1. Targeted Regulatory Writing Techniques: Clinical Documents for Drugs and Biologics by Linda Fossatti Wood and MaryAnn Foote

Course Contents

Unit-1: Introduction of Pharmacovigilance **9 hours**
Definitions, Overview and Scope, Importance of Pharmacovigilance, Pharmacovigilance Regulations in India, WHO Drug monitoring Programme and Uppsala Monitoring centre.
Unit-2: Medical Evaluation of Adverse Events In Pharmacovigilance 9 hours
AE Reporting System And Form, Diagnosis And Managements of ADRs, Definitions and classification of ADRs Detection and reporting, Causality assessment, Severity and seriousness assessment

Unit-3: Case Processing and Medical Dictionary 9 hours
Global Perspective of Pharmacovigilance, Single Case Processing, Case Narrative Writing, Medra
Unit-4 : Pharmacovigilance Reporting Database , Signal Detection , Managements And Risk Assessments & Evaluation 9 hours
Quality System In PV, Expedited Reporting Criteria, PSUR & PBRER, PV Database And Signal Detection
Unit-5: PV laws And Guideline 9 hours
Regulatory Guideline & Laws In PV, SOPS In PV, PV Auditing And Inspection, Regulatory Aspects In PV.

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	**Clinical Diagnostic**				
Course Code	**BCRT4004**				
Prerequisite					
Corequisite					
Antirequisite					
		L	**T**	**P**	**C**
		3	0	0	3

Course Objectives:
The basic objective of this course is to get familiar with Clinical diagnostic of various body systems.

Course Outcomes

On completion of this course the students will be able to understand

CO1	Introduction to Clinical Medicine, global issues in medicine, screening and prevention of diseases
CO2	Basic climatic and environmental diseases, Functional anatomy, physiology, presenting problems in Diabetes mellitus
CO3	Definition, types of hypertension, Pathophysiology and dietary management
CO4	Coronary artery diseases, definition , types, causative factors, pathophysiology and treatment
CO5	Cerebrovascular diseases and Autoimmune disease, Definition, pathophysiology, treatment - different classes of drugs

Text Book (s)

1 . Harrison's Principles of Internal Medicine, 18th Edition. Dan Longo, Anthony Fauci, Dennis Kasper, Stephen Hauser, J. Jameson, Joseph Loscalzo. Publisher: McGraw-Hill.
2. Davidson's Principles and Practice of Medicine, 22nd Edition. Brian R. Walker, Nicki R Colledge, Stuart H. Ralston, Ian Penman. Publisher: Churchill Livingstone, Elsevier.
3. Oxford Handbook of Clinical Medicine, 9th Edition. Murray Longmore, Ian Wilkinson, Andrew Baldwin, and Elizabeth Wallin. Oxford Medical Handbooks.
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Reference Book (s)

1. Laurence D.R. & Bannet P.N., *Clinical Pharmacology*, Churchill Livingstone.
2. Goodman & Gilman, *The Pharmacological Basis of Therapeutics*, Editors:-J.G. Hardman, L.E. Limbird, P.B. Molinoss, R.W. Ruddon & A.G. Gil, Pergamon Press.
3. Craig, C.R. & Stitzel R.R., *Modern Pharmacology*, Little Brown and Co., 1994

Course Contents

Unit-1: Introduction to clinical medicine	**9 hours**
Science and art of medicine, Types and forms of Drugs, global issues in medicine, screening and prevention of diseases	

Unit-2: Basic climatic and environmental diseases	**9 hours**
Diabetes mellitus, drugs-class effect and side effects, dietary management	
Unit-3: Hypertension	**9 hours**
Definition, types, causative factors, pathophysiology, JNC classification of Hypertension, dietary management, treatment (different classes), class effect and side effects	
Unit-4 : Coronary artery diseases	**9 hours**
Ischemic heart disease ; definition , types, causative factors, pathophysiology, life style modifications, treatment (different classes) ,class effect and side effects	
Unit-5: Cerebrovascular diseases and Autoimmune disease	**9 hours**
Stroke; etiology, management; life style modifications, treatment (different classes), class effect and side effects, Arthritis, Definition, pathophysiology, treatment - different classes of drugs, class effect & class side effect & non-pharmacological treatment	

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	Ethical Guideline in Clinical Trial			
Course Code	BCRT4005			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	4	0	0	4

Course Objectives:
To understand the Ethical Guideline in Clinical Trial

Course Outcomes

On completion of this course the students will be able to understand

CO1	Evaluation of Ethics in clinical research, Tuskegee experiment, Thalidomide disaster, Kefauvers Harris amendments act.
CO2	ICMR Guideline, Statement of general principles, General ethical issues, Responsible conduct of research
CO3	Legal Liability in Clinical Research, Legal obligations of the investigator, Compensation to subjects/patients for clinical trial related injuries
CO4	Overview of IRB/IEC, Ethics review procedure and Approval, Importance of Inform Consent Document
CO5	Fraud and Misconduct in clinical research, Violations of ethics in research

Text Book (s)

1. Basic Principles of Clinical Research and Methodology by S.K Gupta;Jaypee Brothers and Medical Publishers; First Edition

.

Reference Book (s)

1. Oxford Text Book of Clinical Research Ethics by Ezekiel J. Emanuel, Christine C. Grady, Robert A. Crouch; OUP USA; 2008 Edition

Course Contents

Unit-1: Evolution of Ethics -I **9 hours**
Statement of general principles, Tuskegee experiment, Thalidomide disaster, Kefauvers Harris amendments act, Declaration of Helsinki, Belmont report, Establishment of CIOMS and NIH
Unit-2: Evolution of Ethics - II **9 hours**
General ethical issues, Nuremberg Code, Ethical review procedures, Informed consent process, Vulnerability, Clinical trials of drugs and other interventions, Public health research, Biological materials
Unit-3: Legal Liability **9 hours**

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-4 : Overview of IRB/IEC **9 hours**
Definition, Composition, Role and Responsibility, Ethics review procedure and Approval, Importance of Inform Consent Document; Patient Information Sheet & Inform Consent Form
Unit-5: Fraud and Misconduct **9 hours**
Fraud and misconduct, detection of fraud in clinical research, Ethics in academia, Violations of ethics in research

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	**Basic Biotechnology**				
Course Code	**BCRT4006**				
Prerequisite					
Corequisite					
Antirequisite					
		L	**T**	**P**	**C**
		4	0	0	4

Course Objectives:
The students will be familiarized with Genetics, Molecular Biology, Biotechnolgy and Immunology.

Course Outcomes

On completion of this course the students will be able to understand

CO1	Genetic of Inheritance, interaction between traits and quantitative inheritance
CO2	Molecular Biology, transcription, translation. Mutation and mutagenesis
CO3	Genetic Engineering, vectors & enzymes used in recombinant technology
CO4	Applications and Ethical aspects of Biotechnology, Stem cell and its application
CO5	Active, passive, Humoral and Cellular immunity, Monoclonal & Polyclonal antibodies

Text Book (s)

1. Elements of Genetics; Phundan singh
2. Genetics: B D Singh
3. A textbook of molecular biology: 3rd edition: Mohan p arora and Himanshu Arora
4. Basic Biotechnology: B D Singh
5. Basic and Clinical Immunology: Mark Peakman and Diego Vergani

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Reference Book (s)

1. Genome the autobiography of a species in 23 chapters: Matt Ridley
2. The double helix: The discovery of the structure of DNA: James D Watson.
3. Basic Biotechnology: 3rd Edition: Colin Ratledge and Bjorn Kristiansen
4. Immunology: Kuby

Course Contents

Unit-1: Genetics	**9 hours**
Genetics of Inheritance - Laws of inheritance, recombination and segregation of traits, segregation ratio, interaction between traits and quantitative inheritance	
Unit-2: Molecular Biology	**9 hours**
Molecular Biology - The genetic material. RNA as genetic material, fidelity of DNA replication, transcription, translation. Mutation and mutagenesis. Ames test	
Unit-3: Genetic Engineering	**9 hours**

Genetic Engineering - Essentials of gene manipulation, vectors & enzymes used in recombinant technology.
Unit-4 : Biotechnology **9 hours**
Biotechnology: Applications and Ethical aspects: Stem cell and its application, Concept of GM Crops and their relevance to society
Unit-5: Immunology **9 hours**
Active, passive, Humoral and Cellular immunity; Clonal selection theory, Cells of immune system; Immunoglobulins, Haptens, Antigens and Immunogens; Monoclonal antibodies

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	Current regulatory requirements for conducting clinical trials in India for investigational new drug/new drug (Version 2.0)			
Course Code	**SNMC0001**			
Prerequisite				
Corequisite				
Antirequisite				
	L	**T**	**P**	**C**
	2	0	0	2

Course Objectives:
Students will be exposed to Clinical Trial Regulatuion, BA/BE requirement, GCP and Ethical consideration.

Course Outcomes

On completion of this course the students will be able to understand

CO1	Indian drug regulatory system, Schedule Y and Indian GCP.
CO2	Preclinical trial, Types of clinical trial and rule governing clinical trial
CO3	Generic drug, BA/BE studies and Regulations
CO4	Good Clinical Practice and Ethical Guideline Consideration
CO5	Special consideration in clinical trial
CO6	Protocol, content of protocol and importance of Protocol
CO7	Dossier preparation and submission to regulatory bodies
CO8	SUGAM and CTRI

Text Book (s)

3. Fundamentals of Clinical Trials textbook by David L. DeMets and Lawrence M. Friedman
4. Clinical Trials: Study Design, Endpoints and Biomarkers, Drug Safety, and FDA and ICH Guidelines Book by Tom Brody

Reference Book (s)

2. Challenges and Prospects for Clinical Trials in India: A Regulatory Perspective (Academic Foundation)

Course Contents

Unit-1: Drug and Cosmetic Act and Rule	**3 hours**
Course Overview, Overview of Indian drug regulatory system, Overview of drugs & cosmetics Act and Rules thereunder, Overview of New Drug and Clinical Trials Rules Rules, 2019	
Unit-2: Phases of Clinical Trial	**3 hours**
Pre-clinical data requirements, Rules governing clinical trials, Phases of clinical trial, forms, and fees, Regulatory pathway and data requirements for NDCT, 2019	
Unit-3: Bioavailability and Bioequivalence studies	**3 hours**

BA/BE study and study centres: Legal provisions, Guidelines to conduct BA/BE studies, Ethics Committee registration and re-registration
Unit-4 : Good clinical practice 3 hours
Ethical considerations, Good Clinical Practice, Requirements for import/manufacture of new drug/IND for conducting clinical trials in India, Requirements for import/manufacture of new drug/IND for sale/distribution and unapproved new drug for patients
Unit-5: Clinical trial guideline 3 hours
Important issues, Special concerns, Clinical trial related guidelines (NDCT Rules)
Unit-6: Protocol 3 hours
Content of proposed clinical trial protocol, Content of a clinical trial report, Post marketing assessment and clinical trial compensation
Unit-7: Drug development process 3 hours
Common observations during submission of CT/BA/BE protocol, Common observations during CT/BA/BE centre inspections, Drug development process: Overview
Unit-8: CDSCO and SUGAM 3 hours
Salient feature of NDCT 2019 (What's new in NDCT?), Online submission (SUGAM), Online submission (CTRI), Tables given in NDCT 2019 and its content

Continuous Assessment Pattern

Internal Assessment (IA)	Mid Term Test (MTE)	End Term Test (ETE)	Total Marks
25	00	75	100

Name of The Course	Pharmacogenomics and Pharmacoeconomics			
Course Code	BCRT5001			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	4	0	0	4

Course Objectives:
The students will be familiarized with Pharmacogenomics and Pharmacoeconomics.

Course Outcomes

On completion of this course the students will be able to understand

CO1	Measures of disease occurrence and disease association, Instruction in the research implications of evidence-based clinical medicine
CO2	Molecular and Genetic Project, Human Genome Project, Framework for interpreting
CO3	Pharmacoeconomics, costs and consequences in pharmacoeconomic studies
CO4	Health related quality of life, health utilities index, Measuring benefits
CO5	Health Technology Assessment, Models of HTA agencies, Structure of the HTA report

Text Book (s)

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

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Reference Book (s)

1. Methods by Brian MacMahon and Thomas F. Pugh;Lippinkot William and Wilkins;2nd Edition
2. Decision Modeling for Health Economic Evaluation Andrew Briggs, Karl Claxton, Mark Sculpher, Published by the Oxford University Press 2006

Course Contents

Unit-1: Epidemiology	9 hours
Mortality indicators, Morbidity indicators, The different mechanisms of bias in clinical research and a conceptual approach to multivariable analysis, evidence-based clinical medicine, Pharmacoepidemiological studies	
Unit-2: Molecular and Genetic Project	**9 hours**

Introduction, principles and use of molecular and genetic methods in epidemiology and clinical research, Human Genome Project, race, ethnicity, social class, and culture, Pharmacogenomics and its application in clinical research, GWAS
Unit-3: Introduction to Pharmacoeconomics 9 hours
Definitions, costs and consequences in pharmacoeconomic studies, perspectives, difference between pharmacoeconomics and outcomes research, Types of pharmacoeconomic analysis: cost-effective and cost-minimization analysis
Unit-4 : Cost- benefit analysis 9 hours
Cost-utility analysis, cost-offset analysis, Health related quality of life, health utilities index, Measuring benefits
Unit-5: Health Technology Assessment 9 hours
HTA system: practice and process, Models of HTA agencies, Structure of the HTA report: principles, practice and process

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	Clinical Data Management and SAS Training			
Course Code	BCRT5002			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	4	0	0	4

Course Objectives:
To understand the Clinical Data Management in Clinical Trial.

Course Outcomes

On completion of this course the students will be able to understand

CO1	Introduction to CDM, Data Management team, Roles and responsibilities of key team members and sponsor
CO2	CRF Design and Medical Coding, Clinical data entry process, Data entry screen validation
CO3	Study setup and Guideline, Laboratory Data and Range checks, creating reports and transferring data
CO4	Data Management and Query Management, Discrepancy Management and Introduction to data transfer procedure
CO5	SAS Training and Overiew of Argus and ORACLE

Text Book (s)

1. Society for Clinical Data Management, Good clinical Data Management Practices version 3. Sep 2003
2. Colleen M Cox. Planning the data Management Process for a clinical trial, Technology and Data Management. Monitor, Sep 2005.
3. Louis Pozzo, Glen de Vries. Applied Clinical Trials, Oct 5 2005
4. Paul Bliecher, Applied Clinical Trials, Apr 1, 2005
5. Rondel, R. Varley, S. Webb, C. Clinical Data Management. New York: John Wiley and Sons LTD. 2000

Reference Book (s)

1. Database Management and Design. By Gary W. Hansen, James V. Hansen, Prentice Hall, 2nd edition, 2002.
2. Fundamentals of Database Systems. By Ramez Elmasri, Shamkant B. Navathe, T. Benjamin. 2nd edition, 2002.
3. Database System Concepts By Henry F. Korth, Abrabam Silberchatz, Mc Graw Hill. 4th edition, 2002.

Course Contents

Unit-1: Introduction to Clinical Data Management and SOPs	9 hours

Introduction, history and overview of CDM, Data validation, System validation, Clinical Data Management flow, Data Management team, Roles and responsibilities of key team members and sponsor, SOPs of data Management.
Unit-2: CRF Design and Medical Coding 9 hours
Procedure for CRF design, elements of CRF, Tracking CRF data, data base validation. Clinical data entry process, Data entry screen validation, symbols, Data Standards, Data base closure, Types of dictionaries, Clinical Data Coding and Coding Checks.
Unit-3: Study setup and Guideline 9 hours
Electronic Data Capture, Laboratory Data and Range checks, Data Storage and Archival, Collecting Adverse event data, Remote data entry, QA and QC, Creating reports and transferring data, Guideline and Regulation in Clinical Trial Data.
Unit-4 : Data Management and Query Management 9 hours
Introduction to data base lock, minimum standards, procedure, Discrepancy Management, errors found after database closure, freezing, SOPs for Data management, Types of queries, Management of queries, SAE reconciliation.
Unit-5: SAS Training 9 hours
Software Training: Argus, Oracle, Recent advancement in CDM

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	Bioethics and Biosafety			
Course Code	BCRT5003			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	3	0	0	3

Course Objectives:
To understand the Bioethics and Biosafety

Course Outcomes

On completion of this course the students will be able to understand

CO1	Biosafety-Regulatory Framework for GMO's In India, the Food Safety and Standards Bill
CO2	Biosafety-Regulatory Framework for GMO's At International level, Objectives and silent features of Cartagena Protocol
CO3	Fundamentals of Bioethics, The legal and socioeconomic impacts of biotechnology
CO4	IPR, International conventions patents and methods of application of patents
CO5	Patents and patent laws, Legal development-Patentable subjects

Text Book (s)

1. Beier, F.K., Crespi, R.S. and Straus, T. Biotechnology and Patent protection-Oxford and IBH Publishing Co. New Delhi
2. Bioethics and Biosafety- M.K. Sateesh
3. Bioethics and Biosafety- Rajmohan

Reference Book (s)

1. IPR, Bioethics and Biosafety- Deepa Goel and Shomini Parashar.

Course Contents

Unit-1: BIOSAFETY-REGULATORY FRAMEWORK FOR GMO's IN INDIA 12 hours
Regulatory framework in India governing GMOs-Recombinant DNA Advisory Committee, Institutional Biosafety Committee, Review Committee on Genetic Manipulation, State Biosafety Coordination Committee, District Level Committee, Seed Policy, The Food Safety and Standards Bill, Plant Quarantine Order, National Environment Policy.
Unit-2: BIOSAFETY-REGULATORY FRAMEWORK FOR GMO's AT INTERNATIONAL LEVEL 9 hours
Convention of Biological Diversity (1992), Cartagena Protocol on Biosafety, risk assessment-risk management-handling, transport, packaging and identification of GMOs- Biosafety Clearing House-unintentional transboundary movement of GMOs

Unit-3: BIOETHICS	**9 hours**
Fundamentals of bioethics- The legal and socioeconomic impacts of biotechnology, ethical concerns of biotechnology research and innovation.	
Unit-4 : INTELLECTUAL PROPERTY RIGHTS	**9 hours**
Intellectual property rights-TRIPS, GATT-International conventions patents and methods of application of patents-Legal implications-Biodiversity and farmer rights	
Unit-5: PATENTS AND PATENT LAWS	**9 hours**
Objectives of the patent system, patent law-biotechnological inventions and patent law-Legal development-Patentable subjects and protection, the patenting living organisms	

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	Project Management			
Course Code	BCRT5004			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	3	0	0	3

Course Objectives:

1. The students will be familiarized with learn to project management techniques in order to achieve completion within timelines.
2. The Students will understand the importance of control systems

Course Outcomes

On completion of this course the students will be able to understand

CO1	Introduction of Project Management, concepts and terminology, History of project management, Project life cycle
CO2	Initiation and Problem Selection, Problem selection criteria
CO3	Project Organization, Managing projects through teamwork, Managing conflict in projects
CO4	Project Planning and Scheduling, Program evaluation and review technique, Project risk and responses
CO5	Project Control, Earned value analysis, Performance analysis

Text Book (s)

1. Klastorin, T. (2004), Project Management, Tools and Trade-offs. John Wiley & Sons, Inc.

Reference Book (s)

1. Gray, C.F. and Larson, E.W. (2006), Project Management: the Managerial Process. McGraw-Hill

Course Contents

Unit-1: Project Management Introduction	**9 hours**
Characteristics of projects. constraints and tradeoffs, concepts and terminology. History of project management. Project life cycle. Success factors.	
Unit-2: Problem selection and Initiation	**9 hours**
Problem selection criteria. Numerical methods. Qualitative methods. Project plan and Work break down structure.	
Unit-3: Project Organization	**9 hours**
Organisational structures. Project stakeholders. Roles and responsibilities. Managing projects through teamwork. Managing conflict in projects. Communication and coordination.	

Unit-4 : Project Planning and Scheduling	**9 hours**
Precedence Network. Critical path method. Program evaluation and review technique. Cost estimation. Project budgeting, Time cost trade off and Linear programming. Resource allocation and analysis	
Unit-5: Project Control	**9 hours**
Establishment of control systems, Earned value analysis, Performance analysis, Project auditing. Project termination. Information Support, Computer tools.	

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	Hospital and Healthcare Administration			
Course Code	BCRT5005			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	3	0	0	3

Course Objectives:

The students will be familiarized with to know about Indian healthcare system: The Indian healthcare sector is expanding rapidly, with an estimated market value of US$ 280 billion by 2020.
This course will provide strategic insights and business skills for those working across the worldwide health sector.

Course Outcomes

On completion of this course the students will be able to understand

CO1	Basic concepts of Health, Natural history of disease and role of hospitals to offer various levels of care
CO2	Introduction to Hospital Management, Concepts of Healthcare industry, Department and organization structure of different types of hospitals
CO3	Hospital's Department, Supportive and Ancillary service Departments
CO4	Basics of Drug Management, Computerized Drug management system
CO5	Procurement of Drugs, Procedure of drug indenting

Text Book (s)

1. Hospital Management: Principle, Theory and Practice by Amit Virmani
2. Hospital Management: An Evaluation – by A.K. Malhotra
3. Principles of Hospital Administration & Planning: B.M. Sakharkar (Jaypee)

Reference Book (s)

1. Hospital Administration: C.M. Francis (Jaypee)
2. Management of Hospital (4 Vols), S.L Goel & R. Kumar, Deep & Deep Publications Pvt. Ltd.
3. Hospital Mgmt. In Tropics & Subtropics, James A. William, Mc Millan, London,1991

Course Contents

Unit-1: Basic Concepts of Health	9 hours

Concept of health & disease and well-being, Prevention aspect of diseases, Dynamics of disease transmission, Changing pattern of diseases, Common pathological conditions, Basic concepts of interpretation of investigations reports
Unit-2: Introduction to Hospital Management **9 hours**
Concepts of Healthcare industry and its ever-changing character, terminal planning, design and operation, Concept of hospitals, space required for separate functions, overview, design & planning of different types of hospitals, Problems and constraints in hospitals.
Unit-3: Deparmentation in Hospital **9 hours**
Organization, Structure, Vertical and Horizontal, Clinical and Non- Clinical, Supportive and Ancillary service Departments, Department and organization structure of different types of hospitals.
Unit-4 : Basics of Drug Management **9 hours**
Drug Management, Hospital Pharmacy License and Drug License, Narcotics drug storage, Pharmacy billings, Computerized Drug management system, Rational use of Drugs and Prescription Audits, Spurious Drugs, Banned Drugs
Unit-5: Procurement of Drugs **9 hours**
Purchase of drugs and other consumable materials, Procedure of drug indenting, On time drug dispensing inventory control, Methods of ordering – two bin system (lead time, buffer stock, reorder level) cyclic system

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	PATHOPHYSIOLOGY AND DISEASE MANAGEMENT			
Course Code	BCRT5006			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	4	0	0	4

Course Objectives:
The basic objective of this course is to get familiar with pathophysiology of human system.
Course Outcomes

On completion of this course the students will be able to understand

CO1	Introduction to Pathology, Alternations in Vascular permeability and blood flow
CO2	Cell injury and Adaptation, intracellular accumulation & pathophysiology of Neoplasm
CO3	Basic mechanisms involved in the process of inflammation and repair, Communicable diseases
CO4	Pathophysiology of disorders related to digestive system, Ulcerative colitis, Crohn's disease
CO5	Pathophysiology of joints disorders-Arthritis, gout, myasthenia gravis

Text Book (s)

1. Chaurasia B.D, Human Anatomy, Regional & Applied Part I, II & III, CBS Publishers & Distributors, New Delhi.
2. Parmar N.S., Health Education & Community Pharmacy CBS Publishers, Delhi.
3. Shalya Subhash, Human Physiology, CBS Publishers & Distributors.
4. Chatterjee C.C. Human Physiology, Medical Allied Agency, Calcutta.
5. Ross & Wilson, Anatomy & Physiology in Health & Illness, Churchill Livingstone.
6.Tortora GJ, & Anagnodokos NP, Principles of Anatomy & Physiology, Harper & Rave Publishers, New Delhi.

Reference Book (s)

1. Keele, C.A., Niel, E and Joels N, Samson Wright's Applied Physiology, Oxford University Press.
2. Dipiro JL, Pharmacotherapy – A Pathophysiological Approach, Elsevier.
3. Guyton AC, Hall JE., Text book of Medical Physiology, WB Saunders Company.
4. Difore SH, "Atlas of Normal Histology" Lea & Febiger Philadelphia.

Course Contents

Unit-1: Introduction to Pathology	9 hours

Normal Cell injury and cell death ,Basic mechanisms involved in the process of inflammation and repair, Alternations in Vascular permeability and blood flow, breif outline of the process of repair.
Unit-2: Cell injury & Adaption 9 hours
Courses of cell injury, pathogenesis & morphology of cell injury. Cellular adaptation- Atrophy, hypertrophy, hyperplasia, dysplasia, metaplasia, intracellular accumulation & pathophysiology of Neoplasm
Unit-3: Basic mechanisms involved in Inflammation 9 hours
Alterations in vascular permeability and blood flow, repair, Communicable diseases, modes of transmission and prevention(Chicken pox, measles, influenza, diphtheria, whooping cough, tuberculosis, poliomyelitis, helminthiasis, malaria, filariasis, rabies, leprosy, syphillis, gonorrhea and AIDS).
Unit-4 : Digestive system 9 hours
Pathophysiology of disorders related to digestive system- Peptic Ulcer, Ulcerative colitis, Crohn's disease, Zollinger-Ellison syndrome, Amoebiasis, Typhoid, Hepatitis, Cirrhosis of liver, Pancreatitis
Unit-5: Pathophysiology of joints disorders and Eye System 9 hours
Pathophysiology of joints disorders-Arthritis, gout, myasthenia gravis, spasticity, tetany, fatigue, pathophysiology of anaemia, allergic conditions, psychosis, Pathophysiology of cataract, glaucoma etc.

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	Clinical Trial Management				
Course Code	BCRT5007				
Prerequisite					
Corequisite					
Antirequisite					
		L	T	P	C
		4	0	0	4

Course Objectives:
Students will get exposure on Clinical Trial start up process that includes budgeting, vendor selection, Project Milestone and documentation management.

Course Outcomes

On completion of this course the students will be able to understand

CO1	the introduction and importance of Clinical Trial study start up process and procedure
CO2	Methodology of clinical trial operation and Monitoring process
CO3	about basic concepts of project mile stones and their management
CO4	about checklist of budgeting, types of Cost, payment planning and controls and vendor selection
CO5	feasibility of project, regulatory aspects, documents before the clinical trial commence.

Text Book (s)

1. Guide to Clinical Trials (Volume-I &II), ICRI

2. LachmanL, Liberman H.A and Kanig J.L., "Theory and Practice of Industrial Pharmacy", Lea and Febiger.

Reference Book (s)

1. Clinical trials: a practical approach. John Wiley 1983, by Pocock SJ
2. Clinical trials. Remedica 2006, by Wang D and Bakhai A (Ed)

Course Contents

Unit-1: Study Start up Process	**9 hours**
Introduction, Definition, Project Kick off Meeting, Vendors selection, Duties delegation, Formation of team, Site selection, Investigator selection Procedure and requirement, Data Management handling, Selection of Lab, IP Management	
Unit-2: Clinical Trial Monitoring and Audit	**9 hours**

Overall objectives, Importance, personnel, types of monitoring, pre-study, initiation study, Routine Monitoring Visit, close-out visits and their purpose, checklist, monitoring report, procedure, audit, type of audit, purpose of audit.
Unit-3: Overview of Project mile stones and Management 9 hours
Overview of project, mile stones, planning, scope, checklist, terminologies & definitions used in clinical research project management, project forecast.
Unit-4 : Budgeting and outsourcing of Clinical Research Project 9 hours
Objectives and scope, definition and types of costs, procedures and checklist, terminologies, specific item, agreements, payment planning and controls, cost measures, Insurance, complexity, Indemnification, Outsourcing
Unit-5: Clinical Trial Documents and development 9 hours
Introduction, Essential clinical trial documents, development, regulatory aspects, documents before the clinical trial commence, during clinical trial conduct and post-trial or termination of the trial, forms, logs, Patient diary, source document, questionnaires.

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	**Medical Writing**			
Course Code	**BCRT5007**			
Prerequisite				
Corequisite				
Antirequisite				
	L	**T**	**P**	**C**
	4	0	0	4

Course Objectives:

1) Creating documents for medical records & reference retrieval
2) To understand the different aspects of medical writing

Course Outcomes

On completion of this course the students will be able to understand

CO1	Importance of Medical Writing in Clinical Trial, Letter writing for editorial process, Reviewing, editing and publishing
CO2	Writing Article, Research report and paper writing, systematic review
CO3	Software for medical writing, Literature search and Pubmed search, Meta analysis
CO4	Documents in Clinical Research, Designing and development of clinical research documents
CO5	Guidelines for medical writing, Guidelines and Checklists of relevant to medical writing in diverse medical fraternities

Text Book (s)

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
4. Asher R. How to present your article. BMJ, 2: 502, 1958.
5. Stephen Lock Thornes's better medical writing, Pitmen Medical, 2nd Ed. 6. 1977.
6. Fraser HS. Writing a scientific paper. West Indian Med J; 44 (4): 114-24, 1995.

Reference Book (s)

1. Bradford Hill A. Logical order for a scientific paper. BMJ; 2: 870, 1965.
2. Gustavii B. How to write and illustrate a scientific paper. Cambridge Univ P.BMA 2003.
3. Hall GM. How to write a paper. BMJ Books. BMA 2003.

Course Contents

Unit-1: Introduction to Medical Writing	**9 hours**
Introduction, exercises and examples, Good Publication Practices, Overview of scientific articles, Reviews, Research and submission, journal and selection, Letter writing for editorial process	
Unit-2: Fundamentals of Manuscript	**9 hours**
Basic introduction to medical terminology and fundamentals of medical writing, Literature survey-Use of books and journals and internet, Research report and paper writing, systematic review, Patient narrative preparation	
Unit-3: Software application in medical writing	**9 hours**
Introduction to Software, Objective, Scope, article writing and plagiarism software, Literature search and search engine, analytical tools	
Unit-4 : Documentation and Development	**9 hours**
Clinical study report, Designing and development of clinical research documents i.e. protocol, ICF, CRF, SOP on various functional clinical trial procedures, Pharmacovigilance writing: ICSR, SAE reporting, Narratives, PSUR, DSUR, etc.	
Unit-5: Guidelines	**9 hours**
Duties of Author and disputes, Publication policy, Editor, Reviewer, Common technical document (CTD), dossier writing, ICMJE and other bodies, Checklists, Ethical consideration, Journal quality and impact assessment and Citation	

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	**Soft Skill and Personality Development**			
Course Code	**BCRT6001**			
Prerequisite				
Corequisite				
Antirequisite				
	L	**T**	**P**	**C**
	3	0	0	3

Course Objectives:
To understand the Soft Skill and Personality Development Training.
Course Outcomes

On completion of this course the students will be able to understand

CO1	the process of Professional Communication and modern tool of communication
CO2	Expression Development, Parts of Speech and synonyms and antonyms homophones.
CO3	Personality Development Training, Development of expression through paragraph writing, proposal writing, report writing
CO4	interpersonal and intra-personal relationships, stress management
CO5	need of soft skills and components of soft skills

Text Book (s)

1. Professional Communication: The Corporate Insider's Approach to Business Communication by Daniel L.Plung and Tracy
2. Professional communication by Malti Agarwal

Reference Book (s)

1. Professional Communication: The Social Perspective by Nancy Roundy Blyler

Course Contents

Unit-1: Professional Communication 9 hours
Definition, Communication: Meaning and definition, the process of communication, levels of communication, barriers of communication, modern tools of communication: Fax, email, telephone, voice mails etc.
Unit-2: Functional Grammar 9 hours
Functional Grammar: parts of speech, tense, correct usage, synonyms and antonyms homophones.
Unit-3: Expression Development 9 hours
Development of expression through paragraph writing, proposal writing, report writing, application of job, resume, letter writing: Formal and informal
Unit-4 : Personality Development 9 hours
Personality Development, Types of personality, concept of emotional quotient, importance of positive thinking, interpersonal and intra-personal relationships, stress management

Unit-5: Soft Skills	**9 hours**
Soft skills: the Bedrock of career growth, need of soft skills, components of soft skills	

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	**Hospital Management and Law**
Course Code	**BCRT6002**
Prerequisite	
Corequisite	
Antirequisite	

	L	**T**	**P**	**C**
	3	0	0	3

Course Objectives:
Students will be exposed to understand the importance of medical ethics.
Course Outcomes

On completion of this course the students will be able to understand

CO1	the company's act, Constitution for the Hospital, relevant State Act
CO2	to learn different acts like the Maternity Benefit Act, The Payment of Wages Act
CO3	Medical Malpractice, Negligence, Legal Issue in Death Cases, Legal Testimony in Medico-legal cases
CO4	Narcotics Law, Blood Transfusion, the Medical Termination of Pregnancy Act
CO5	Hospital Management and Law, Copyright, Patent, Trade Marks, Designs, Geographic indication

Text Book (s)

1. Kapoor, N.D; 2004: Mercantile Law – Sultan Chand & Sons: New Delhi(Chapter 1-5)
2. Kuchhel, M.C. 2003, Mercantile Law; Vikas Publishing Private Ltd. New Delhi (chapter 1-5)
3. Pathak, Legal Aspect of Business, TMH
4. P.L Mallick – Industrial Law – Eastern Book Company – Lucknow.
5. Bio-Medical Waste Management Handling Rule 1998.

Reference Book (s)

1) Law & Ethics in Nursing & Health Care, Nelson Thrones

Course Contents

Unit-1: Companies Act	**9 hours**
The Companies Act, Law of Partnership A Sample Constitution for the Hospital, relevant State Act, Factories Act, Shops and Establishment Act, The Workmen's Compensation Act, The Employee's State Insurance Act, The Employees Provident Funds Act, The Payment of Gratuity Act.	
Unit-2: Miscellaneous Acts	**9 hours**
The Maternity Benefit Act, The Payment of Wages Act; The Minimum Wages Act, The Industrial Disputes Act, The Industrial Employment Act, The Trade Union Act, The Apprentices Act The	

Employment Exchanges Act, The Collection of Statistics Act, Medical Licensure Law, Doctors Patient Relationship.
Unit-3: Medical Malpractice 9 hours
Quality and Standard of Medical Care, Negligence, Medical Consent Emergency Care, The Consumer Protection Act, Patients Rights and Responsibilities, Medical Ethics, Mental Illness, Tuberculosis, Drugs Addicts and Alcoholics, Legal Issue in Death Cases, Legal Testimony in Medico-legal cases.
Unit-4 : The Drugs and Cosmetic Act 9 hours
Narcotic Laws, Drug Control Policy, Clinical Investigation, Blood Transfusion, the Medical Termination of Pregnancy Act, The Prenatal Diagnostic Techniques Act.
Unit-5: Intellectual Property (IP) and Trade related aspects of Intellectual property rights (TRIPS) 9 hours
Meaning of property, is Intellectual Property a property, Justifications for protection of IP, Major forms of IP, Copyright, Patent, Trade Marks, Designs, Geographic indication, Plant varieties, protection of IP, Berne Convention, Paris Convention, Trade related aspects of Intellectual property rights.

Continuous Assessment Pattern

Internal Assessment (IA)	Mid Term Test (MTE)	End Term Test (ETE)	Total Marks
20	30	50	100

Name of The Course	Medical Record management			
Course Code	BCRT6003			
Prerequisite				
Corequisite				
Antirequisite				
	L	T	P	C
	3	0	0	3

Course Objectives:

Students will be exposed to learn about Utility & functions of Medical Records in Health care delivery System and Quality Management will provide students with a good foundation in some of the theory behind patient safety as well as structured information about how to carry out a successful quality improvement project.

Course Outcomes

On completion of this course the students will be able to understand

CO1	Medical Records Management, Computerization of record, Report and returns by the record department, Statistical information
CO2	to learn about medical record management, storage, scope and significance, Role of Hospital managers & Medical Record Department personnel in Medical record keeping
CO3	to have basic knowledge about legal aspects of medical records, Procedures of Medical Auditing & its importance
CO4	to know Quality in Healthcare, Clinical Quality Complication and Infection Rate Admission
CO5	to know Total Quality Management, Quality Audit and Review Techniques and Performance Indicators

Text Book (s)

1) A framework for managing patients medical records
2) Handling the medical claim- Catherine Cochran
3) Functions of a Tertiary Care Hospital – Md. Kamal Hussain
4) Raandi Schmidt J. Trumbo and R. Jonson, Quality in Health Care Sector – ASQC Quality – Press.

Reference Book (s)

1. Quality Improvement in Health Care,2nd Ed, Nelson Thrones

Course Contents

Unit-1: Medical Record	9 hours

Definition and Types of medical record, Importance of medical record, Flow chart of function, Statutory requirements of maintenance, coding, indexing and filing, Computerization of record, Report and returns by the record department, Statistical information and International classification of Diseases
Unit-2: Operational Function of Medical Record Dept. 9 hours
Utility & functions of Medical Records in Health care delivery System, Organizations & management of Medical Records Department, Role of Hospital managers & Medical Record Dept. personnel in Medical record keeping, Reports & returns in Medical Record System
Unit-3: Legal Aspects of Medical Record 9 hours
Basic knowledge of legal aspects of Medical Records including Factories Act, Workmen Compensation Act & Consumer Protection Act, Procedures of Medical Auditing & its importance. Government Regulations & requirements
Unit-4 : Quality 9 hours
Customer Service, Customer Experience: Core Service & Delivery of Service, Excellent Customer Service,Stress, Communication and Interpersonal Relationship Patient Satisfaction, Rights and Responsibilities of Patients, Satisfaction and Delight Quality Indicators of Patient Satisfaction, Clinical Quality Complication and Infection Rate Admission
Unit-5: Total Quality Management (TQM) 9 hours
Continuity of Care Measuring Quality Setting Objectives and Performance Indicators Feedback: Customers, Staff, Suppliers, etc. Quality Audit and Review Techniques, Definition of TQM, comparison of quality, Developing quality specification, Quality Cost department, Six sigma methodology, ISO 9000 certification, external benchmarking for quality improvement, service quality measurement.

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
20	30	50	100

Name of The Course	**Industry Report**				
Course Code	**BCRT6004**				
Prerequisite					
Corequisite					
Antirequisite					
	L	**T**	**P**	**C**	
	0	0	2	1	

Course Objectives:
The students will be familiarized with Clinical Research Industry.

Course Outcomes

On completion of this course the students will be able to understand

CO1	Students need to write a report on what they learnt from Industry during Industry Visit.

Unit-1: Industrial Report	**9 hours**
Students need to write a report on what they learnt from Industry during Industry Visit.	

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
30		70	100

Name of The Course	**Internship/Project**				
Course Code	**BCRP6051**				
Prerequisite					
Corequisite					
Antirequisite					
		L	**T**	**P**	**C**
		0	0	24	12

Course Objectives:
The Procedure to finalize the clinical trial budget.

Course Outcomes

On completion of this course the students will be able to understand

CO1	The Procedure to finalize the clinical trial budget

Course Contents

Unit-1: Clinical trial budget **9 hours**
Exposure to various components of planning, co-ordination and conduct of Objectives and scope, definition and types of costs, procedures and checklist, terminologies, specific item, agreements, payment planning and controls, cost measures, Insurance, complexity, Indemnification, Outsourcing Clinical Supplies materials cost- overview, concepts, definition, planning, partnership, future trends, Cost finalization on per subject, Lab Costing, Custom Clearance, Compensation towards serious adverse event, Ethics committee submission cost, Regulatory submission cost, Dossier preparation cost, Institutional Overhead cost, Patient travelling reimbursement cost in Clinical Research.

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
60		240	300

Name of The Course	**Internship/Project**				
Course Code	**BCRP6051**				
Prerequisite					
Corequisite					
Antirequisite					
		L	**T**	**P**	**C**
		0	0	24	12

Course Objectives:

1. Working Procedure in Clinical Research Industry
2. Global Regulations of Clinical Trials
3. different countries regulatory requirement

Course Outcomes

On completion of this course the students will be able to understand

CO1	Clinical trial Project

Course Contents

Unit-1: Clinical trial Project **9 hours**
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

Continuous Assessment Pattern

Internal Assessment (IA)	**Mid Term Test (MTE)**	**End Term Test (ETE)**	**Total Marks**
60		240	300