

Scheme and Syllabus

First Semester

Course Code	Course Title	Teaching Load Allocation (hr.)			Marks Distribution			Exam (hr.)	Credit
		L	T	P	Internal	External	Total		
C R- 101	Pharmacology-101	3	1	-	40	60	100	3	4
CR - 102	Clinical Research-102	3	1	-	40	60	100	3	4
CR - 103	Medicine - 103	2	2	-	40	60	100	3	4
CR - 104	Biostatistics -104	2	2	-	40	60	100	3	4
CR-105	Practical Lab (Part I-IT & Part-II Communication and management)	-	-	8	40	60	100	3	4
		10	06	8	200	300	500	--	20

Second Semester

Course Code	Course Title	Teaching Load Allocation (hr.)			Marks Distribution			Exam (hr.)	Credit
		L	T	P	Internal	External	Total		
C R- 201	Pharmacology-201	3	1	-	40	60	100	3	4
CR - 202	Clinical Research-202	3	1	-	40	60	100	3	4
CR - 203	Medicine - 203	2	2	-	40	60	100	3	4
CR - 204	Biostatistics -204	2	2	-	40	60	100	3	4
CR-205	Practical Lab (Part I-IT & Part-II Communication and management)	-	-	8	40	60	100	3	4
		10	06	8	200	300	500	--	20

Punjab Technical University/MSc. Clinical Research

Third Semester

Course Code	Course Title	Teaching Load Allocation (hr.)			Marks Distribution			Exam (hr.)	Credit
		L	T	P	Internal	External	Total		
CR-301	Pharmacology- 301	3	1	-	40	60	100	3	4
CR-302	Clinical Research-I - 302	3	1	-	40	60	100	3	4
CR-303	Clinical Research-II- 303	3	1	-	40	60	100	3	4
CR-304	Medicine -304	3	1	-	40	60	100	3	4
CR-305	Practical Lab (Part I-IT & Part-II Communication and Management)	-	-	8	40	60	100	3	4
	Total	12	4	8	200	300	500	-	20

Fourth Semester

Course Title	Marks Distribution			Credits
	Dissertation Evaluation	Viva-Voce	Total	
Dissertation	100	200	300	12

The thesis/project report shall be presented by the candidate at the end of record academic year.

[Note: L- Lecture – Tutorial, P – Practical]

Total Credit: 20+20+20+12 = 72

Total Marks: 500 + 500 + 500 + 300 = 1800

Course Code	Course Title	Teaching Load Allocation (hr.)			Marks Distribution			Exam (hr.)	Credit
		L	T	P	Internal	External	Total		
CR - 101	Pharmacology-101	3	1	-	40	60	100	3	4

Introduction to Pharmacology – Definitions and brief – (pharmacology, pharmacokinetics, pharmacodynamics, drug, pharmacotherapeutics, clinical pharmacology, chemotherapy, pharmacy and toxicology), drug Nomenclature (chemical name, non-proprietary name and proprietary name) and essential drugs concepts

Routes of Drug Administration – Local routes (topical, deeper tissues and arterial supply etc.), systemic routes (Oral, sublingual, rectal, cutaneous, inhalation, nasal, parenteral etc.)

Dosage Forms of Drug – Definition and brief about the dosage forms – solid dosage forms (powder, tablets, capsules, lozenges, pills, cachets), liquid dosage forms (suspension, emulsion, elixirs, syrups, lotions, inhalations, eye drops, ear drops, enemas, mouth washes etc.), semisolid dosage forms (ointments, creams, pastes, gels, suppositories, etc.), sterile products (Injection, ophthalmic etc.), gas (aerosols, inhalations, sprays etc.) and novel drug delivery system (liposome, nanosome, nanoparticles, microspheres, osmotic pumps, transdermal, implants, intrauterine devices)

Sources of Drugs – Natural sources and synthetic sources

Pharmacodynamics – Principles of drug action and mechanism of drug action, dose response curve and adverse drug reaction

Factors Modifying Drug Action - Body size, age, sex, species and race, genetics, environmental factors, psychological factor, pathological states, other drugs, cummulation, tolerance, etc.

Pharmacokinetics – brief of absorption, distribution, metabolism and excretion

Autonomic nervous system - Introduction, cholinergic system, anti-cholinesterase, anticholinergic, adrenergic system, alpha blocker, beta blocker

Reference Books

1. Rang & Dale's Pharmacology, 7th Edition. By Humphrey P. Rang, Maureen M. Dale, James M. Ritter, Rod J. Flower, and Graeme Henderson. Publisher: Elsevier.
2. Basic and Clinical Pharmacology, 12th Edition. By Bertram G. Katzung, Susan B. Masters, Anthony J. Trevor. Publisher: Lange.
3. Goodman and Gilman's The Pharmacological Basis of Therapeutics. 12th Edition. Laurence Brunton, Bruce Chabner, Bjorn Knollman. Publisher: Mc Graw Hill.
4. Essentials of Medical Pharmacology, 7th edition. By K D Tripathi. Publisher Jaypee.
5. Ganong's Review of Medical Physiology, 24th Edition. Authors: Kim E. Barrett, Susan M. Barman Scott Boitano, Heddwen Brooks. Publisher: Lange.

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		L	T	P	Internal	External	Total		
C R-102	Clinical Research-102	3	1	-	40	60	100	3	4

Introduction to Clinical Trials - Glossary of terms in clinical trials, history, requirements, new drug development process, need for new drug, selection of a chemical compound as a potential drug, screening of chemical compounds, translation medicine, assessment of preclinical data

Phases of clinical trials- Phase 1, Phase 2, Phase 3, Phase 4

Principles of controlled clinical trials- Clinical trial design (observational and interventional) protocol, consent in clinical trials, placebo, bias and methods to prevent bias, ethics in clinical trials, monitoring, problems and solutions of controlled clinical trials. Multicentre clinical trials- Requirements, regulations and feasibility. Improving patient enrolment and retention in Clinical Trials

Other Clinical Studies- Pharmacoepidemiology, pharmacovigilance, ADR monitoring, pharmacokinetic trials, quality of life studies

Legal issues in clinical trials

Drug regulations- National- good clinical practice and schedule Y

Critical evaluation of literature- Systematic review and meta analysis, evidence based medicine

Reference Books

1. Methodology of Clinical Drug Trials, 2nd Edition. Spriet A., Dupin-Spriet T., Simon P. Publisher: Karger.
2. Design and Analysis of Clinical Trials: Concepts and Methodologies, 3rd Edition. Shein-Chung Chow, Jen-Pei Liu. Publisher: Wiley.
3. Principles and Practice of Pharmaceutical Medicine, 3rd Edition. Lionel D. Edwards, Anthony W. Fox, Peter D. Stonier. Publisher: Wiley-Blackwell.

Course Code	Course Title	Teaching Load Allocation(hr.)			Marks Distribution			Exam (hr.)	Credit
		L	T	P	Internal	External	Total		
CR - 103	Medicine-103	2	2	-	40	60	100	3	4

Note: brief study of the following topics with their relevant applications

Introduction to clinical medicine – Science and art of medicine, global issues in medicine, screening and prevention of diseases

Basic climatic and environmental diseases

Diabetes mellitus - Functional anatomy, physiology, presenting problems in Diabetes mellitus, management, drugs-class effect and side effects, dietary management, long term complications in brief

Hypertension - Definition, types of hypertension, causative factors, pathophysiology, JNC classification of Hypertension, dietary management, treatment (different classes), class effect and side effects

Coronary artery diseases - Ischemic heart disease ; definition , types, causative factors, pathophysiology, life style modifications, treatment (different classes) ,class effect and side effects in brief

Cerebrovascular diseases- Stroke; etiology, management; life style modifications, treatment (different classes), class effect and side effects in brief

Reference Books

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.

Course Code	Course Title	Teaching Load Allocation(hr.)			Marks Distribution			Exam (hr.)	Credit
		L	T	P	Internal	External	Total		
CR - 104	Biostatistics-104	2	2	-	40	60	100	3	4

Introduction- Biostatistics and standard terminology

Basic knowledge about presentation of data - Type of diagram, one dimensional diagram, two dimension diagram, three dimensional, pie diagram and pictogram

Graphic representation of data - Histogram, frequency, polygon and frequency curve.

Sampling - Definition, selection of samples, merit and limitation of sampling, methods of sampling.

Measures of central tendency - Mean, median, mode and relation between arithmetic mean, geometric mean and harmonic mean.

Measures of dispersion - Mean deviation, advantage and disadvantage of mean deviation, coefficient of mean deviation, standard deviation, application of standard deviation and coefficient of variation.

Definition and application - Correlation, regression, Chi-square test and t-test.

Reference Books

1. Biostatistics, 1st Edition. Sai Subramanian. Publisher: Career Publications.
2. Pharmaceutical Biostatistics, 1st Edition. Shadab Ahmed Khan, Ismaili, Ahmed and Husain. Publisher: Birla Publications.
3. Biostatistics for Pharmacy, 1st Edition. Khan and Khanum. Publisher: Ukaaz Publication.
4. Basic & Clinical Biostatistics, 4th Edition. Beth Dawson, Robert G. Trapp. Publisher: Lange.

Course Code	Course Title	Teaching Load Allocation (hr.)			Marks Distribution			Exam (hr.)	Credit
		L	T	P	Internal	External	Total		
CR - 105	Practical Lab (Part I-IT & Part-II Communication and management)	-	-	8	40	60	100	3	4

MS- Excel – Introduction to excel and RDBMS

Clinical Data Management – Overview, regulation, data management plan, data acquisition and CRF designing, database designing and implementation, data entry and verification and data analysis.

Soft Skills - Introduction and definition, motivation, SWOT analysis, goal setting, business etiquettes, business dressing, business communication, understanding body language and gestures, listening skill, giving and accepting feedback, group discussion.

Communication – Types of communication, pronunciation; consonants and vowel sounds. Grammar; noun, adjectives, use of definite and indefinite articles, tenses. Vocabulary; antonyms, synonyms, homonyms, one word substitution, common phrases and idiomatic expressions. Vocabulary power; words related to various concepts of life and activities.

Reference Books

1. Practical Computer Literacy, 3rd Edition. June Jamrich Parsons, Dan Oja. Publisher: CENGAGE Learning.

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		L	T	P	Internal	External	Total		
CR - 201	Pharmacology- 201	3	1	-	40	60	100	3	4

Histamine – Classification of drugs, prototype drug- actions, prototype drug- class effect and side effect, peculiar effect and side effect of some important drugs

Antihistamine - Prototype drug- class effect and side effect, peculiar effect and side effect of some important drugs

Drugs acting on kidneys and GIT:

Diuretics - Classification of drugs, prototype drug- actions, class effect and side effect, peculiar effect and side effect of some important drugs

Antidiuretics- Classification of drugs, prototype drug- actions, class effect and side effect, peculiar effect and side effect of some important drugs

Drugs for peptic ulcer - Introduction to disease in brief, classification of drugs, prototype drug- actions, class effect and side effect, peculiar effect and side effect of some important drugs

Cardiovascular Pharmacology:

Hypertension - Introduction to disease in brief, classification of drugs, prototype drug- actions, Prototype drug- class effect and side effect, peculiar effect and side effect of some important drugs

CHF - Introduction to disease in brief, classification of drugs, prototype drug- actions, Prototype drug- class effect and side effect, peculiar effect and side effect of some important drugs

Coronary Artery Disease- - Introduction to disease in brief, classification of drugs, prototype drug- actions, Prototype drug- class effect and side effect, peculiar effect and side effect of some important drugs

Arrhythmia - Introduction to disease in brief, classification of drugs, prototype drug- actions, Prototype drug- class effect and side effect, peculiar effect and side effect of some important drugs

Endocrine Pharmacology:

Diabetes Mellitus- Introduction to disease in brief, insulin – types of insulin, class effect and side effect, methods to deliver insulin, management of acute complication of diabetes, oral hypoglycemic drugs- classification of drugs, class effect and side effect, peculiar effect and side effect of some important drugs

Thyroid hormone and Thyroid inhibitors- Anatomy & physiology of thyroid in brief, classification of drugs, prototype drug- actions, Prototype drug- class effect and side effect, peculiar effect and side effect of some important drugs

Corticosteroids- Anatomy & physiology of adrenal gland in brief, classification of drugs, prototype drug- actions, Prototype drug- class effect and side effect, peculiar effect and side effect of some important drugs

Estrogen, Progestins and Contraceptives- Classification of drugs, prototype drug- actions, class effect and side effect, peculiar effect and side effect of some important drugs

Oxytocin and other drugs acting on uterus- Classification of drugs, prototype drug- actions, class effect and side effect, peculiar effect and side effect of some important drugs,

Drug affecting calcium balance- Physiology of calcium balance in brief, classification of drugs, prototype drug- actions, class effect and side effect, peculiar effect and side effect of some important drugs

Reference Books

1. Rang & Dale's Pharmacology, 7th Edition. By Humphrey P. Rang, Maureen M. Dale, James M. Ritter, Rod J. Flower, and Graeme Henderson. Publisher: Elsevier.
2. Basic and Clinical Pharmacology, 12th Edition. By Bertram G. Katzung, Susan B. Masters, Anthony J. Trevor. Publisher: Lange.
3. Goodman and Gilman's The Pharmacological Basis of Therapeutics. 12th Edition. Laurence Brunton, Bruce Chabner, Bjorn Knollman. Publisher: Mc Graw Hill.
4. Essentials of Medical Pharmacology, 7th edition. By K D Tripathi. Publisher Jaypee.
5. Ganong's Review of Medical Physiology, 24th Edition. Authors: Kim E. Barrett, Susan M. Barman Scott Boitano, Heddwen Brooks. Publisher: Lange.

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C R-202	Clinical Research-202	3	1	-	40	60	100	3	4

Toxicity studies – Acute, sub acute and chronic toxicity studies, Detail of Acute, sub acute and chronic toxicity studies, Mutagenicity, Carcinogenicity and Teratogenicity

Quality Assurance/Quality Control studies: Guidelines and operational techniques

Drug regulations: International: Food and Drug Administration and European Medicine Agency.

- a) Introduction of FDA
- b) History of FDA and Departments in FDA
- c) Regulations in FDA
- d) Regulations in FDA
- e) How FDA works
- f) introduction of European Medicine Agency

Clinical Data Management- Introduction, planning of trial, database, flow of data, creating database, Data Validation, system validation, data entry, E- data capture.

Therapeutic drug monitoring - Efficacy and safety measurement, endpoints

Auditing: Research Auditing & Inspections

Preparing Clinical Trial Report: Interim study report, close out report

Case Record Form: Introduction to CRF, Format and Sponsor Needs, guidelines related to CRF filling

Research ethics and research audits: Declaration of Helsinki

Ethical issues in Genetic Research: Genetic engineering, Gene mapping, cloning and ethical issues

Behavioral Research: Studies – case study discussion, psycho-social issues

Research methodology (laboratory and clinical) - Definition, objectives, concept, variable

Research process, research question – Hypothesis, features of a good research design.

Experimental Design- Concept of independent & dependent variables

Exploratory Research Design – Descriptive vs analytical Research, applied vs fundamental research, qualitative vs quantitative research

Use of tools / techniques for research- Methods to search required information effectively and teaching of latest software to search data and facilitate writing for publications e.g. Endnote

Funding Medical Research – Budgeting of a clinical trial in detail

Business Process Outsourcing and Contract Research Organization- Organizational structure, Types, Relationships with various stakeholders in the Clinical trial process

Overview of Pharma. Business- India and worldwide: Introduction, Major Pharma players: global & Indian, their area of research market scenario of health care products

Business Development- Introduction, methodology and importance

Translational medicine- Introduction, methodology and importance

Conflicts of Interest- Investigator, sponsor, publisher

Community based Qualitative Research and Research Ethics- Ethical Principles, informed consent, confidentiality of information shared and anonymity of research participants, no harm to participants, beneficence and reciprocity

Facilitating Best Practices

- a. Introduction to Standard operating procedures (SOP's) & need for SOP
- b. Training and decision making

FDA and DCGI guidelines to conduct trials- vaccine trials, medical device trials, diagnostic trials, surgical trials

Reference Books

1. Methodology of Clinical Drug Trials, 2nd Edition. Spriet A., Dupin-Spriet T., Simon P. Publisher: Karger.
2. Design and Analysis of Clinical Trials: Concepts and Methodologies, 3rd Edition. Shein-Chung Chow, Jen-Pei Liu. Publisher: Wiley.
3. Principles and Practice of Pharmaceutical Medicine, 3rd Edition. Lionel D. Edwards, Anthony W. Fox, Peter D. Stonier. Publisher: Wiley-Blackwell.

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		L	T	P	Internal	External	Total		
CR - 203	Medicine-203	3	2	-	40	60	100	3	4

Arthritis- Rheumatoid arthritis, osteoarthritis- Definition, pathophysiology, treatment - different classes of drugs, class effect and class side effect, pharmacological- classification of drugs, class effect & class side effect & non-pharmacological treatment

Shock - Definition, pathophysiology, types of shock, presenting features, diagnostic investigation in brief, pharmacological- classification of drugs, class effect & class side effect and non-pharmacological treatment

Inflammatory Bowel Disease and Irritable Bowel Syndrome- Definition, pathophysiology, presenting features, management, investigation, pharmacological- classification of drugs, class effect & class side effect & non-pharmacological treatment

Heart failure, Coronary artery diseases: drugs, surgical treatment in brief & stents

Common infections:

- a) **Tuberculosis** – causative agents, diagnostic criteria, etiological agents in brief, categories of tuberculosis, classification of drugs, first line drugs in detail different classes of drugs, class effect and class side effect , DOTS therapy, multidrug resistant tuberculosis
- b) **AIDS** - Etiological agents in brief, causative agents, diagnostic criteria, treatment, different classes of drugs, class effect and class side effect treatment regimes, prophylactic therapy, therapy in pregnancy
- c) **Malaria-** Life cycle of causative agent, types of malaria, causative agents, diagnostic criteria, treatment, different classes of drugs, class effect and class side effect treatment of relapsing malaria, treatment of cerebral malaria, multi drug resistant malaria

Reference Books

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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		L	T	P	Internal	External	Total		
CR - 204	Biostatistics-204	3	2	-	40	60	100	3	4

1. **Probability:** Definition and Application
2. **Parametric Tests:** Definition and Application
Analysis of variance-One Way and Two Way
 - a) McNemar's test
 - b) Exact probability test
3. **Rank score tests** – Definition and Application
 - a) Wilcoxon signed rank test,
 - b) Wilcoxon two sample rank test,
 - c) The Mann Whitney Test,
 - d) The Spearman Test,
 - e) The Friedman Test.
4. F-test – testing of two population variances
5. Study design and choosing a statistical test Design-Assignments

Reference Books

1. Biostatistics, 1st Edition. Sai Subramanian. Publisher: Career Publications.
2. Pharmaceutical Biostatistics, 1st Edition. Shadab Ahmed Khan, Ismali, Ahmed and Husain. Publisher: Birla Publications.
3. Biostatistics for Pharmacy, 1st Edition. Khan and Khanum. Publisher: Ukaaz Publication.
4. Basic & Clinical Biostatistics, 4th Edition. Beth Dawson, Robert G. Trapp. Publisher: Lange.

Course Code	Course Title	Teaching Load Allocation (hr.)			Marks Distribution			Exam (hr.)	Credit
		L	T	P	Internal	External	Total		
CR - 205	Practical Lab (Part I-IT & Part-II Communication and management)	-	-	8	40	60	100	3	4

I. INFORMATION TECHNOLOGY

STATISTICAL ANALYSIS SYSTEM (SAS)

1. Introduction
2. Working with SAS Data Sets
3. Working with Raw Data Files
4. Creating Variables
5. Manipulating Data
6. Generating Reports
7. Getting started with SAS
8. Getting familiar with SAS Data Sets
9. Producing List Reports
10. Enhancing output
11. Creating SAS Data Sets
12. Data step Programming
13. Combining SAS Data sets
14. Producing Summary Reports

II. MANAGEMENT

1. **ACCOUNTING** - Basic accounting, Accounting principles & conventions, Accounting Terms, Types of accounts, Accounting Rules , Double Entry, Ledger Posting, Trial Balance, Final Accounts
2. **MARKETING** - Marketing Concept, Marketing environment, Marketing mix, Market Segmentation, Consumer behavior, Advertisement, Pricing policy, Ethical and social marketing, e-marketing

III. COMMUNICATION

English

- a) **Grammar usage** – Pronoun, Problems in grammar usage, Transitive and Intransitive Verb, Singular and plural verbs, Adverb
- b) **Vocabulary usage**- How to Keep Your Sanity with transitive and intransitive verbs
- c) **Interview Skills**
- d) **Reading Assignments**
- e) **Writing Assignments**
- f) **Personality development programs**

Reference Books

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CR-301	Pharmacology – 301	3	1	-	40	60	100	3	4

Introduction, classification, mechanism of action and side effect of the following categories of drugs:

- a) General Anesthetics
- b) Sedative and Hypnotics
- c) Antiparkinsonian
- d) Antipsychotic
- e) Antidepressant

Opioid analgesic and antagonist - introduction to pain pathway in brief and classification of drugs, prototype drug- actions, side effect of some important drugs

Antimicrobials — introduction, classification, mechanism of action and side effect of the following categories of drugs:

- a) Sulfonamides
- b) Cotrimoxazole and Quinolones
- c) Beta-Lactam Antibiotics
- d) Tetracycline & Chloramphenicol
- e) Aminoglycosides antibiotics
- f) Macrolide, lincosamide, glycopeptides, & other Antibacterial Antibiotics
- g) Antitubercular drugs
- h) Antileprotic drugs
- i) Antiviral drugs
- j) Antimalarial drugs
- k) Antiamoebic drugs
- l) Antiprotozoal
- m) Antihelmenthic drugs

Immunomodulatory drugs- introduction, classification, mechanism of action and side effect of Immunomodulatory drugs

Anti-cancer drugs - introduction, classification, mechanism of action and side effects of anti-cancer drugs

CPCSEA guidelines: ethics and handling of laboratory animals

Introduction to epidemiology and epidemiological typing methods

Reference Books

1. Rang & Dale's Pharmacology, 7th Edition. By Humphrey P. Rang, Maureen M. Dale, James M. Ritter, Rod J. Flower, and Graeme Henderson. Publisher: Elsevier.
2. Basic and Clinical Pharmacology, 12th Edition. By Bertram G. Katzung, Susan B. Masters, Anthony J. Trevor. Publisher: Lange.
3. Goodman and Gilman's The Pharmacological Basis of Therapeutics. 12th Edition. Laurence Brunton, Bruce Chabner, Bjorn Knollman. Publisher: Mc Graw Hill.
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Punjab Technical University/MSc. Clinical Research

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CR-302	Clinical Research-I - 302	3	1	-	40	60	100	3	4

Bioavailability /Bioequivalence Studies - introduction, terminology, concepts, characteristics and regulatory guidelines in India.

Introduction to GLP and GCP, Declaration of Helsinki

Regulations for pre-clinical and clinical studies and drug regulation:

- a. DCGI
- b. Indian Council of Medical Research
- c. FDA
- d. OECD
- e. WHO
- f. National Institute for Clinical Excellence (NICE), European Medicines Agency

Pharmaceutical marketing - introduction to

- a. Medico marketing
- b. Industry scenario
- c. Pharmacoeconomics

Special clinical trials and trial related issues - special population, trials on special population, and trials on life threatening diseases (ICH Guidelines).

Micro-dosing - Phase 0 and importance in relation to clinical research

Biomarkers – definitions, importance, surrogate biomarkers

Health Insurance Portability and Accountability Act (HIPAA) - introduction to HIPAA, titles under HIPAA, privacy rule, PHI.

Reference Books

1. Methodology of Clinical Drug Trials, 2nd Edition. Spriet A., Dupin-Spriet T., Simon P. Publisher: Karger.
2. Design and Analysis of Clinical Trials: Concepts and Methodologies, 3rd Edition. Shein-Chung Chow, Jen-Pei Liu. Publisher: Wiley.

3. Principles and Practice of Pharmaceutical Medicine, 3rd Edition. Lionel D. Edwards, Anthony W. Fox, Peter D. Stonier. Publisher: Wiley-Blackwell.

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CR-303	Clinical Research - II 303	3	1	-	40	60	100	3	4

Clinical Data Management - communication, query process, coding dictionaries, locking of database, process after database locked, publishing, data management: career prospectus

Intellectual Property rights (IPR) - copyright, trademarks, patents: requirement, objectives, patent implications, recent scenario and case studies

Patents Regulations - trade related aspects of intellectual property rights (TRIPS), patent extension rules, implications

Pharmacovigilance:

- a.) Methods of pharmacovigilance , causality assessment
- b.) International Guidelines – US, UK and timelines of ADR reporting

Medical Transcription – introduction, process of transcription in context of clinical

Inspection - introduction, responsibilities of clinical trial staff, and actions: before, during and after completion, action item list

CONSORT: Consolidated Standards of Reporting Trial

Trial master file - contents of master file, source document, compilation, documentation, ways and importance

Publishing Research Studies: publication of research paper/report in National and International scientific journals and ethics

Confidentiality and competitiveness in clinical trials guidelines

Reference Books

1. Methodology of Clinical Drug Trials, 2nd Edition. Spriet A., Dupin-Spriet T., Simon P. Publisher: Karger.
2. Design and Analysis of Clinical Trials: Concepts and Methodologies, 3rd Edition. Shein-Chung Chow, Jen-Pei Liu. Publisher: Wiley.

3. Principles and Practice of Pharmaceutical Medicine, 3rd Edition. Lionel D. Edwards, Anthony W. Fox, Peter D. Stonier. Publisher: Wiley-Blackwell.

Punjab Technical University/MSc. Clinical Research

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		L	T	P	Internal	External	Total		
CR-304	Medicine - 304	3	1	-	40	60	100	3	4

Alzheimer's disease- definition, pathophysiology, presenting clinical feature, management: non-pharmacological and pharmacological

Parkinson's disease- definition, pathophysiology, presenting clinical feature, management: non-pharmacological and pharmacological

Osteoarthritis- definition, pathophysiology, presenting clinical feature, management: non-pharmacological and pharmacological

Malignancies- cell cycle, principal of treatment, incidence of various cancers, risk factors for carcinoma. Presenting feature, investigation and treatment, treatment regimes of:

- a) Oral cancer
- b) Lung cancer
- c) Breast cancer
- d) Lymphoma
- e) Leukemias
- f) Renal Carcinoma

Other renal diseases- anatomy and physiology of kidney, definition of renal failure, presenting features and management.

Hepatitis- definition, etiologic, classification, treatment regimes and management

Reference Books

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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		L	T	P	Internal	External	Total		
CR-305	Practical Lab Part –Information Technology Part -II Management	-	-	8	40	60	100	3	4

I. INFORMATION TECHNOLOGY

Statistical Analysis System (SAS)

1. Understanding DATA Step Processing
2. Creating and Applying User-Defined
3. Creating Enhanced List and Summary Reports using Proc SQL
4. Producing Descriptive Statistics
5. Producing HTML Output
6. Reading SAS Data Sets
7. Transforming Data with SAS Functions
8. Processing Variables with Arrays
9. Reading Free-Format Data
10. Reading Date and Time Values
11. Creating a Single Observation from Multiple Records
12. Performing Queries Using PROC SQL
13. Performing Advanced Queries Using PROC SQL
14. Creating and Managing tables using PROC SQL

II. MANAGEMENT

Accounting – final accounts

Human Resource Management – organizational behavior, organizational culture, conflict, motivation.

Business Entities – sole prop, partnerships, companies, societies and trusts

Financial Management- sources of capital, capital budgeting, introduction to direct and indirect taxes

Reference Books

1. SAS® Certification Prep Guide: Base Programming for SAS® 9, Third Edition.
2. PROC TABULATE by Example, Second Edition Lauren Haworth Lake, Julie McKnight.
3. Financial Management and Policy, Shashi K. Gupta, Kalyani Publishers
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