## Third Semester

| Subject code | Name of the Paper | Marks |
|---|---|---|
| CRT-301 | Regulatory Affairs | 50 |
| CRT-302 | Human Biology | 50 |
| CRT-303 | Special Regulatory Process | 50 |
| CRT-304 | Pharmacogenomics | 50 |
| CRP-V | Lab Course-V | 50 |
| CR-VI | Lab Course –VI | 50 |

## Fourth Semester

| Subject code | Name of the Paper | Marks |
|---|---|---|
| CRT-401 | Project management & Business Development | 50 |
| CRT-402 | Audit & Inspection | 50 |
| CRT-403 | Pharmacovigilance & Safety Monitoring | 50 |
| CRT-404 | Reporting & Medical writing | 50 |
| CRP-VII | Lab Corse VII | 50 |
| CRP-VIII | Lab Course-VIII | 50 |

**CRT-301 Regulatory Affairs** **Marks : 50**
**Hours : 45**

**Unit-1 Introduction regulatory affairs :**

Overview of judicial system in India, Medical Evidence, Legitimacy and Paternity, Privileged Communication and Professional Secrets, The Rights and Obligations of a Medical Professional to Patient, Medical Malpractice, Code of Medical Ethics

**Unit 2: The Drugs and Cosmetics Act & Schedule Y:**

Introduction to Drugs and Cosmetics Act, Aims and Objectives, Definitions, Administrative bodies, Schedules to Drug Rules, Import of drugs, Manufacture of drugs, Sale of drugs, penalties for offence regarding sale of drugs, labeling and packaging of drugs . Schedule Y, Clinical trials, Studies in special populations, Post Marketing Surveillance, special studies.Bioavailability and Bioequivalence studies, Amendment of Schedule Y

**Unit 3: Food and Drug Administration (FDA):**

Introduction to Food and Drug Administration, Laws Enforced by the FDA,Food and Drugs Act, Food Standards during 1930s, 40s and 50s, Center for Drug Evaluation & Research (CDER) Establishment-first step, Drug Inspection laboratory, functions and activities of CDER, post drug approval activities.

Center for Food Safety & Applied Nutrition (CFSAN)CFSAN-Mission, scope of responsibility, Organization of CFSAN, Applicability of Food Safety Law, precaution in regulating animal foods, authority to reconsider data, pesticides, plant and animal health regulations, FDA nutrition policy: labeling and fortification

**Unit 4 : Regulatory authorities & ICH:**

Regulatory authorities in India Indian FDA, DCGI, Schedule Y, ICMR, GEAC, AERB, DGFT, DTAB, DBT Guidelines and other important provisions, Indian regulatory approval process, regulatory timelines, approval timeline, approval letter.ICH and Process of Harmonization: History and structure of ICH, Process of Harmonization ICH Guidelines, Categories of ICH guidelines, Quality, Safety, and Efficacy Guidelines.

**Text & Reference:**


1.A guide book for regulatory submission: Sandy Weinberg.

2. A guide to clinical drug research: A.Cohen & J. Posner.

3. FDA Regulatory affairs: Dougles J. Posano & David Mantus.

4. Introduction to regulatory affairs: Vedjignesh.

5. Regulatory affairs: Fegodets.

**CRT-302 Human Biology** **Marks : 50**
**Hours : 45**

**Unit 1: Introduction to Human Anatomy :**

Body positions, Anatomy and physiology of a cell, transport mechanism across the cell, chemical messengers, ion channels in the cell membrane, types of intercellular junctions .

**Unit 2: Organs and Systems:**

Nervous(Nerve cells, supportive cells, electrophysiology of neurons, synapses)Heart(cardiac muscles & function of hurt,major blood vessels of the body, circulation)Respiratory( Functional anatomy of respiratory system, gas exchange in the lungs, hemoglobin and oxygen transport, Carbon dioxide transport and acid-base balance.)Digestive(structure,Secretion, digestion and absorption,)Excretory system, Reproductive (Male and female reproductive system ,Embryology and development )

**Unit 3:Basics of immunology :**

Introduction to immune system, organs of the immune system, cells associated with immune response, innate immunity, acquired immunity, immunoglobulin, complement system, antigen-antibody reactions, immune response.

**Unit 4:Basics & methods of hematology;**

Constituents of blood, methods of blood collection, anticoagulants, storage of blood specimens, precautions to prevent haemolysis, preparation of serum, universal precautions, blood smear preparation, labeling ,fixation, staining ,mounting and preservation of blood films Blood cell counting, RBC, WBC and platelet count by manual methods, absolute eosinophil count, automated blood cell counters, structure and types of hemoglobin, Methods of estimation of hemoglobin, haematocrit (packed cell volume), measurement of PCV in automated instruments, erythrocyte indices, Erythrocyte Sedimentation Rate, examination of blood films.

**Text & Reference:**


1. Human Biology: McGRAW-HILL.
2. Human Biology: Sylvia,S.Mader 10 & 11 Edition
3. Human Biology: Starr 6 Edition
4. Human Biology & Health: Padilla, Michaelt & Martha.
5. Human Biology & Healthy: Anthea Maton

**CRT-303 Special Regulatory Process** **Marks : 50**
**Hours : 45**

**Unit 1: IND Requirements for New Drugs, Biologics, Botanical Drug Products, Dietary Supplements (Nutraceuticals) :**

IND application, FDA's role in Drug Development, Types of INDs, Categories of INDs, Content of INDs, Resources for IND Applications, Guidance Documents for INDs, Manual of Policies and Procedures (MaPPs), Laws, Regulations, Policies and Procedures, IND Forms and Instructions, Emergency use of an Investigational Drug or Biologic, FDA's Drug Review Process: Ensuring Drugs are Safe and Effective, Stages of Drug Development and Review, The Quality of Clinical Data, Drug Safety Oversight Board (DSOB), Botanical Drug Products, Global Regulatory Standards For Dietary Supplements/Nutraceuticals

**Unit 2: Compliance of Chemistry, Manufacturing, Control (CMC) Information:**

a)CMC Information for IND applications for Exploratory Phase I Studies,
b)CMC Information for IND Applications for Phase II & Phase III Studies

**Unit 3: Regulatory Process for cosmetics,Medical Devices and Veterinary Products**

**Cosmetics Regulation:**

Indian Scenario-Prohibition of Import of Cosmetics, Standards of Quality, Import of Cosmetics, Manufacture of Cosmetic for Sale or for Distribution, Labeling, Packaging and Standards of Cosmetics

a) Medical Devices / Diagnostic Kits- US FDA Scenario, Indian Scenario

b) Veterinary Products- US FDA Scenario, Indian Scenario

**Unit 4: Biosimilars & Biopharmaceuticals:**

EMEA, background, Guideline on Similar Biological Medicinal Products ,Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance,Guideline on Similar Biological Medicinal Products containing Biotechnology-Derived Proteins as active Substance: Non-Clinical and Clinical Issues.Indian regulations and guidance of Biopharmaceuticals

Biopharmaceuticals – Regulatory bodies,Guidelines for generating preclinical and clinical data for r-DNA based vaccines, diagnostics and other biologicals.

**Text & Reference:**


1. FDA Regulatory affairs: Dougles J. Posano & David Mantus.
2. A guide to clinical drug research: A.Cohen & J. Posner.
3. Introduction to regulatory affairs: Vedjignesh.
4. A guide book for regulatory submission: Sandy Weinberg

**CRT-304 Pharmacogenomics** **Marks : 50**
**Hours : 45**

**Unit 1: Introduction to pharmacogenomics:**

History, Chronology of Events, Pharmacogenetics and Pharmacogenomics: The Difference, Benefits of Pharmacogenetics, Pharmacogenetics in Practice, Promise of Pharmacogenomics, Limitations, Pharmacogenomics drugs in the market, Future of pharmacogenomics

**Unit 2: Determinants of drug response & Bioinformatics tools for pharmacogenomics:**

Pharmacokinetics and pharmacodynamics of drug, drug properties that influence its pharmacokinetics and pharmacaodynamics .Bioinformatics, Divisions of Bioinformatics, Fields Related to Bioinformatics, Application of Bioinformatics in various disciplines/fields, Major categories of Bioinformatics Tools with examples

**Unit 3: Pharmacogenetics of enzymes and transporters:**

Xenobiotics -Phase I and II reactions Drug transporters-Structure and model of drug transporters, transport mechanisms, polarized expression of drug transporters, drug transporters in barrier epithelium, classification of drug transporters, ABC and SLC transporters, genetic variation and drug response, genetic variation in membrane transporters

**Unit 4: Clinical pharmacogenomics and clinical trials:**

Pharmacogenomics in clinical practice, the role of drug metabolizing enzymes in cardiovascular pharmacology,Pharmacogenetics and clinical trials-Issues in clinical trials ethical implications of pharmacogenomic research, guidance on pharmacogenomics data

**Text & Reference:**


1. Basic and Clinical Pharmacology :Bertrand Katzung
2. Essentials of Medical Pharmacology :K. D Tripathi
3. Pharmacology: Rang, Dale and Ritter
4. Pharmacology and Pharmacotherapeutics:Satoskar,18th ed, 2003
5. Public Health and Preventive Medicine:Appleton and Lange, California

**Lab Course-V**

**Case Studies - I**

The students should study suitable cases from any one hospital about the patients and do critical analysis, comments, observations and recommendations. This needs to be submitted in writing as well as a seminar presentation, which shall be evaluated by internal and university examiners.

**Lab Course-VI**

**Case Studies - II**

The students should make case study from different hospitals by taking single case and do critical analysis, comments, observations and recommendations. This needs to be submitted in writing as well as a seminar presentation, which shall be evaluated by internal and university examiners.

**CRT-401 Project management & Business Development** **Marks : 50**
**Hours : 45**

**Unit 1: Introduction to Project Management :**

The triple constraints in Project Management, Project management activities, Project objectives, Project management Documents, Project control variables, Project Management & Clinical Trials, Role of Project Management in Clinical Trials, Major Roles of a Project Manager in a CRO, Ensuring Project Success

**Unit 2 : Project Management Process & Project Development Plan in clinical research:**

Initiating, Planning, Executing, Monitoring & Controlling, Closing .Preparation of Clinical Project Development Plan, Contents of Clinical Project Development, Plan, Review and Approval of CPDP

**Unit 3 : Business Development in the Clinical Research Industry :**

Introduction & Stages of Business Development-Start-up Phase, Growth Phase, Maturity Phase, Decline Phase. Outsourcing in Clinical Research, Reasons for outsourcing to contract research organizations, The India Advantage, Scope and Future of CRO, List of Clinical Research Organizations in India, List of IT companies offering services in Clinical Research. Role of business development manager:

**Unit 4 : Clinical Research outsourcing & Services Offered by CROs :**

Benefits of outsourcing, Out/In-Sourcing of Clinical Services, Process of outsourcing Phase I to Phase IV studies, Acute, Sub-acute, Chronic animal studies, Bioequivalenceand Bioavailability, Clinical Trial Management, Clinical Trial Monitoring, Pharmacovigilance - Drug Safety, Data Management, Regulatory Affairs, Protocol Development, Site Management, Clinical Trial Supplies, Centralized Lab Management, Centralized ECG reading services, Centralized Imaging Services.

**Text & Reference:**


1. Project Management - The Managerial Approach: Clifford Gray and Erik W. Larson
2. Principles of project management: Richard A. Billows.
3. Principles of project management & risk management: R.Max Wideman.
4. Business development: the expanding role of the project management: Lew Ireland

**CRT-402 Audit & Inspection** **Marks : 50**
**Hours : 45**

**Unit 1 : Introduction to Audits and quality assurance :**

Quality Assurance, Definition, Quality system, The Quality Plan, Quality Assurance (QA), Quality Control (QC), Differentiating quality control and quality assurance, Structuring the quality assurance function, Critical Issues For Organizing The Quality Assurance Function, Overview Of QA Activities Audits: Definition of audit, Quality Assurance Audits In Clinical Research, Motives For Process Audit, Objectives Of Process Audit, Auditors, Conducting A Clinical Research Department Process Audit, Audit findings, Research Fraud and misconduct, site audits, FDA inspections, PL 483 warning letters, Auditing clinical data management function

**Unit 2: Site audits, fraud and misconduct:**

Definition of audits as per ICH GCP, Goals and objectives of study site audits, Types of clinical trial site audits, Criteria for onsite audits, The audit process, Audit preparation activities, Common audit findings.

**Unit 3 : FDA Inspections, PL 483, and warning letters :**

Definitions, Differentiating inspection from audits, Types of inspections, Purpose of regulatory inspections, The process of inspection, forms, warning letters, Selection of the study site for inspection, Forms, warning letters

**Unit 4: Auditing CDM function:**

Types of audits in CDM, Audit process, Activity-specific audits, Protocol audit, CRF audit, Audit of the Study Database Build, DMP review, Study-specific audit, Common findings during a data management audit.

**Text & Reference:**


1. Clinical trials audit-David machin
2. Introduction to Audit & inspection-DJ Cockbuern
3. Clinical trials audit preparation:a guide for good clinical practice inspection: Vera mihajlovic & madzarevic**.**

**CRT-403 Pharmacovigilance & Safety Monitoring** **Marks : 50**
**Hours : 45**

**Unit 1: Introduction to Pharmacovigilance :**

Introduction, Definition, requirement of Pharmacovigilance needed, Objectives of Pharmacovigilance, Agencies concerned with Pharmacovigilance, Reporting ADRs,changes to recommendations for use, Methods involved in Pharmacovigilance,Pharmacovigilance plans, Scope of Pharmacovigilance, Indian scenario, Pharmacovigilance and pharmacogenomics

**Unit 2 : Safety monitoring process & good Pharmacovigilance Practices (GPP) :**

The Monitoring Process, The Role of Institutional Review Boards and Data Safety Monitoring Boards, Quality Assurance Monitoring, Ending Trials Early: Protecting the Interests of Participants and the Public.GPP, Overview of Risk Management Goals and Guidance, Adverse events, serious adverse events, Reporting of AE & SAE, Pharmacovigilance

**Unit 3: Good reporting practices and safety signals:**

Risk management process, Signals, Case report, Case series, Causality, Data mining, Reporting rates Vs incidence rates, Pharmacovigilance plans, Pharmacoepidemiologic safety studies

**Unit 4 : Pharmacoepidemiology, Registers, Surveys :**

Pharmacoepidemiology, Guidelines for Good Pharmacoepidemiology Practices (GPP), Pharmacovigilance Methods, Use of health care databases in pharmacoepidemiology, Registries, Surveys, Pharmacoeconomics and pharmacoepidemiology, Pharmacoepidemiology and pharmacokinetics, International drug monitoring, Using eHealth information for comprehensive Pharmacovigilance surveillance, Pharmacoepidemiology in India, Pharmacovigilance and India

**Text & Reference:**


1. Textbook of therapeutics Drug and Disease Management: Eric T Herfindel, Dick R. Gourley, 6th ed.
2. Assuring Data Quality And Validity In Clinical Trials For Regulatory Decision Making : Janet Woodcock, Frederick Ognibene, John Overbeke.2003;Welly Publication.
3. Medical Transcription Guide: Do's and Don'ts (Medical Transcription Guide) : Marilyn Takahashi Fordney, Marcy Otis Diehl.

**404 Reporting & Medical writing :** **Marks : 50**
**Hours : 45**

**Unit 1: Fundamentals of Medical Writing & Data interpretation and presentation:**

The Scope of Medical Writing, Qualities of effective medical writer, Types of Data, Tools of data presentation Graphical methods for qualitative data: Frequency Tables, Pie Charts, Bar charts, Comparing Distributions, Graphical methods for quantitative data: Stem and leaf plots, Histograms, Line GraphsError! Bookmark not defined. Dot plotsError! Bookmark not defined.Box Plot, Scatter Plot.

**Unit 2 : The Clinical Study Report & Reporting clinical laboratory tests :**

Structure of CSR and possible modifications, study patients, efficacy evaluation, safety evaluation, discussion and overall conclusions, tables, figures and graphs referred to but not included in the text, reference list, appendices.Reference ranges (normal ranges), Interpretation of normal values, Units of measurement, Factors Affecting interpretation of test.

**Unit 3 : Preparation of Investigator's Brochure, clinical summaries and global submission dossiers:**

Contents of the Investigator's Brochure, Table of Contents, Summary, Introduction, Physical, Chemical, and Pharmaceutical Properties and Formulation, Non-clinical Studies, Effects in Humans, Summary of Data and Guidance for the Investigator Components of the CTD, Global Submission Dossiers, Electronic Common Technical Document

**Unit 4 : Bibliography preparation ,Computer skills & Language for medical writers :**

Types of referencing – Primary and secondary, standard referencing. Different styles of referencing – Focus on Vancouver style.MS word ,MS Excel & MS PowerPoint skills –complete knowledge & skills for typing, tabulation, slide show & animation preparation. Basic language orientation-Sentence Structure and Patterns, Choice of active or passive voice, proper use of tenses. Punctuation for Clarity and Style–types of punctuation, capitalization, use of hyphens, quotation marks, apostrophes, commas, and differences between British and American

English. Techniques to improve simplicity and clarity ofstyle-linking of passages and construction of paragraphs, building of strong sentences.

**Text & Reference:**


1. Clinician's Guide to Medical Writing :Robert B. Taylor. 1st ed. 2004. Springer Publications.
2. Guidebook to Better Medical Writing :Robert L. Iles (Author), Debra Volkland. Iles
3. Medical writing & clinical reporting: Beltas.
4. Medical writing: Cam Johns tan.
5. Medical writing & reporting:Dr.Nancy Snyder man.


**CRP-VII**

**Seminars & Report Writing**

Students should prepare & submit the report of seminars for at list two topics given by their guide.
Seminar report should be computer typed & evaluated by guide, internal & university examiners'.

**CRP-VIII Project Work**

The students should do their project on any related topics of the above syllabus or study suitable cases from the hospitals, pharmaceutical industries etc. This needs to be submitted in writing, which shall be evaluated by internal and university examiners.