GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

CLINICAL PHARMACY

SEMESTER: I

Subject Name: Clinical Research and Drug Development
Subject Code: MCP203T

Scope:
Objectives:

Sr No	Course Contents	Total Hrs
1	Drug development process: Introduction Various approaches to drug discovery Ethics in Biomedical Research: Ethical Issues in Biomedical Research – Principles of ethics in biomedical research Ethical committee [institutional review board] - its constitution and functions Challenges in implementation of ethical guidelines, ICH, CDSCO, GCP guidelines and ICMR guidelines in conduct of Clinical trials Drug Safety Reporting.	12
2	Types and Designs used in Clinical Research: Planning and execution of clinical trials Various Phases of clinical trials, Bioavailability and Bioequivalence studies Randomization techniques (Simple randomization, restricted randomization, blocking method and stratification) Types of research designs based on Controlling Method (Experimental, Quasi experimental and Observational methods) Time Sequences (Prospective and Retrospective), Sampling methods (Cohort study, case Control study and cross sectional study), Health outcome measures (Clinical & Physiological, Humanistic and economic) Clinical Trial Study team: 3Roles and responsibilities of Investigator, Study Coordinator, Sponsor, M4onitor, Contract Research Organization.	12
3	Clinical trial Documents: Guidelines to the preparation of following documents: Protocols, Investigator's Brochure, Informed Consent Form, Case report forms, Contracts and agreements, Dairy Cards Clinical Trial Start up activities: Site Feasibility Studies, Site/Investigator selection, Pre-study visit, Investigator meeting, Clinical trial agreement execution, Ethics committee document preparation and submission	12
4	New drug approval process: Clinical trial application in India: GCP inspection checklist, clinical trial registry, CMC-stability data requirement for approval. BA/BE studies: Approval of BA/BE centers, Regulatory requirements	12

	New drug approval in India: New drug application (NDA), common techniqual documents, new drug advisory committee, guidance for fixed dose combination (FDCs). New drug approval in USA: IND, NDA, INDA	
5	Quality Assurance and Quality Control in Clinical Trials: Types of audits, Audit criteria, Audit process, Responsibilities of stakeholders in audit process, Audit follow-up and documentation, Audit resolution and Preparing for FDA inspections, Data integrity in clinical research Data Management: Infrastructure and System Requirement for Data Management Clinical trial data management	12

REFERENCES:

1. Rick NG. Drugs From Discovery To Approval. John Wiley & Sons, Inc 2004
2. Allen Cato, Lynda Sutton Clinical Drug Trials and Tribulations Second Edition, Revised and Expanded. Marcel Dekker, Inc. 2002
3. Deborah Rosenbaum, Michelle Dresser. Clinical Research Coordinator Handbook Second Edition Practical Clinical Trials Series GCP Tools and Techniques Interpharm/CRC New York Washington, D.C.© 2002
4. Tamas Bartfai, Graham V. Lees. Drug Discovery from Bedside to Wall Street. Elsevier Academic Press. London 2006
5. Shayne C. Gad. Drug Safety Evaluation. A John Wiley & Sons, Inc., Publication
6. Bert Spilker. Guide to Clinical Trials.
7. Sandy Weinberg. Guidebook For Drug Regulatory Submissions. A John Wiley & Sons, inc.,2009
8. Duolao Wang and Ameet Bakhai Clinical Trials A Practical Guide to Design, Analysis, and Reporting. Remedica 2006
9. Textbook of Clinical Trial edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
10. Principals of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
11. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, 2000, Wiley Publications.
12. Various Guidelines like:

a) ICH – GCP- International Conference on Harmonisation of Technical requirements for registration of pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice. E6 1996.
b) ICMR Guideline – Ethical Guidelines for Biomedical Research on Human Subjects.
c) Indian GCP – Central Drugs Standard Control Organization. Good Clinical Practices
d) Guidelines for Clinical Trials on Pharmacuetical Products in India. New Delhi:
e) Ministry of Health; 2001.
f) Schedule Y