

## **Fifth year**

### **5.1 CLINICAL RESEARCH (THEORY)**

**Theory : 3 Hrs. /Week**

#### **1. Drug development process:**

Introduction

Various Approaches to drug discovery

1. Pharmacological
2. Toxicological
3. IND Application
4. Drug characterization
5. Dosage form

#### **2. Clinical development of drug:**

1. Introduction to Clinical trials
2. Various phases of clinical trial.
3. Methods of post marketing surveillance
4. Abbreviated New Drug Application submission.
5. Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines
6. Challenges in the implementation of guidelines
7. Ethical guidelines in Clinical Research
8. Composition, responsibilities, procedures of IRB / IEC
9. Overview of regulatory environment in USA, Europe and India.
10. Role and responsibilities of clinical trial personnel as per ICH GCP
  - a. Sponsor
  - b. Investigators
  - c. Clinical research associate
  - d. Auditors
  - e. Contract research coordinators
  - f. Regulatory authority
11. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment)
12. Informed consent Process
13. Data management and its components
14. Safety monitoring in clinical trials.

**References :**

- a. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; 2001.
- b. International Conference on Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
- c. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
- d. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
- e. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
- f. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
- g. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.