GUJARAT TECHNOLOGICAL UNIVERSITY
PHARM.D (PB)
2nd Year

Subject Name: Clinical Research
Subject Code: 828901

Scope: This course is designed to make the students to understand the principles and gain adequate knowledge regarding the various approaches to drug discovery including clinical phase of development. Also enables the students to understand and implement all regulatory and ethical requirements that are required during the process of drug development.

Objectives: At completion of this course, it is expected that students will be able to:

- Know the concept of new drug development process.
- Understand the regulatory and ethical requirements.
- Conduct the clinical trials in accordance to regulatory and ethical requirements.
- Coordinate the clinical trials and promote quality drug trial research

Teaching scheme and examination scheme:

Teaching Scheme				Evaluation Scheme				Total Marks
Theory	Tutorial	Practical	Total	Theory		Practical		
				External	Internal	External	Internal	
3	1	0	4	70	30	0	0	100

	Topics	Hrs
1	**1. Drug development process:** Introduction Various Approaches to drug discovery 1. Pharmacological 2. Toxicological 3. IND Application 4. Drug characterization 5. Dosage form	**06**
2.	**Clinical development of drug:**	
	1. Introduction to Clinical trials.	**02**
	2. Various phases of clinical trial.	**04**
	3. Methods of post marketing surveillance.	**02**
	4. Abbreviated New Drug Application submission.	**02**
	5. Good Clinical Practice – ICH, GCP, Central drug standard control organisation (CDSCO) guidelines.	**06**
	6. Challenges in the implementation of guidelines.	**02**
	7. Ethical guidelines in Clinical Research.	**01**
	8. Composition, responsibilities, procedures of IRB / IEC.	**01**
	9. Overview of regulatory environment in USA, Europe and India.	**08**

	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	**05**
	11. Designing of clinical study documents (protocol, CRF, ICF, PIC with assignment).	**04**
	12. Informed consent Process.	**01**
	13. Data management and its components.	**03**
	14. Safety monitoring in clinical trials.	**03**

Text Books:

1. Principles and Practice of Pharmaceutical Medicine. Lionel D. Edward, Aadrew J. Flether, Anthony W. Fos, Peter D. Sloaier. Publisher- Wiley. Latest edition.

2. Handbook of clinical research. Julia Lloyd and Ann Raven Ed. Publisher- Churchill Livingstone. Latest edition.
3. Principles of Clinical Research. Giovanna di Ignazio, Di Giovanna and Haynes. Publisher- Ergode books. Latest edition.
4. Essentials of Clinical Research. Glasser. Publisher- Springer. Latest edition.

Reference books:

1. Textbook of Clinical Trials. David Machin, Simon Day and Sylvan Green. Publisher- John Wiley and Sons. Latest edition.
2. Clinical Data Management. R K Rondels, S A Varley, C F Webbs. Publisher- Wiley. Latest edition.
3. Goodman & Gilman: JG Hardman, LE Limbard, Publishers- McGraw Hill. Latest edition.

Other references:

1. Central Drugs Standard Control Organization. Good Clinical Practices-Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health (Latest guidelines).
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6. (Latest guidelines).
3. Ethical Guidelines for Biomedical Research on Human Subjects. Indian Council of Medical Research, New Delhi. (Latest guidelines).
4. Websites of regulatory bodies of different countries.
5. Clinical research journal