Gujarat Technological University
Master of Pharmacy
Semester – II

Specialization paper - IV
Clinical Research and Regulatory Affairs
Theory
(Four hours per week, 6 credits)

1. Introduction to Drug Discovery and drug Development

2. Clinical trials

Introduction and designing

Various phases of clinical trials

Post Marketing surveillance – methods

Principles of sampling

Inclusion and exclusion criteria

Methods of allocation and randomization

Informed consent process

Monitoring treatment outcome

Termination of trial

Safety monitoring in clinical trials

3 Documents in clinical study

Investigator Brochure (IB),

Protocol & Amendment in Protocol ,

Case Report Form (CRF),

Informed Consent Form (ICF) ,

Content of Clinical Trial Report

Essential Documents in Clinical Trial

4 Data Management in clinical Research

5 Ethical guidelines in clinical research

History

ICH-GCP & its Principles

Indian GCP (CDSCO Guidelines)

ICMR Guidelines - Ethical Guidelines for Biomedical Research on Human Subjects Schedule Y

6 Roles & Responsibility of various clinical trial personnel as per ICH GCP

Sponsor

Investigator

Monitor

Auditors

7 Institution Ethics Committee / Independent Ethics Committee

8 Quality Assurance in clinical Research

9 BA/BE studies: Introduction, Regulatory requirements and methodology

10 Clinical Trial Application in India

Import & Export of Drug in India

11 Investigational New Drug application (IND)

12 Abbreviated New Drug Application (ANDA)

13 New Drug Application (NDA)

ASSIGNMENTS

The students are required to submit a minimum of two written assignments selected from the topics given to them.

References Books:

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. Ronald D. Mann, Elizabeth B. Andrews. Pharmacovigilance. John Wiley & Sons Ltd, 2002

6. Shayne C. Gad. Drug Safety Evaluation. A John Wiley & Sons, Inc., Publication

7. Bert Spilker. Guide to Clinical Trials.

8. Sandy Weinberg. Guidebook For Drug Regulatory Submissions. A John Wiley & Sons, inc.,2009

9. Duolao Wang and Ameet Bakhai Clinical Trials A Practical Guide to Design, Analysis, and Reporting. Remedica 2006

10. Textbook of Clinical Trial edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.

11. Principals of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.

12. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, 2000, Wiley Publications.

13. Various Guidelines like:

- ✓ 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.
- ✓ ICMR Guideline – Ethical Guidelines for Biomedical Research on Human Subjects.
- ✓ Indian GCP – Central Drugs Standard Control Organization. Good Clinical Practices – Guidelines for Clinical Trials on Pharmacuetical Products in India. New Delhi: Ministry of Health; 2001.

Schedule Y