THEORY: (3 hours per week)

1. Clinical Research
   a. Basic concepts and introduction to Clinical Drug Development
   b. Clinical Trials

   Introduction to the fundamentals of the design and analysis of clinical trials. Ethical considerations intention-to-treat versus efficacy trials, principles of sampling and exclusion, methods of allocation and techniques of randomization, parallel versus cross over designs, monitoring treatment outcomes, adverse effects, stopping rules, data interpretation and logistical issues in the management of clinical trials FDA guidelines for clinical trials, reviews and approval of a clinical study. Clinical trials of Biological products.

2. Clinical pharmacokinetics and its applications in clinical research.
   Approval of New Drugs Principles of IND submission, format and content of IND, content of investigator brochure. General consideration of the NDA, specific requirements, content and format of NDA, manufacturing and control requirements of NDA, ANDA, the Orphan Drug.

BOOKS RECOMMENDED:

2. IND and NDA Guidelines of Various Regulatory Authorities