15PH706: Professional Elective-I

DRUG REGULATORY AFFAIRS & INTELLECTUAL PROPERTY RIGHTS

15PH706.E.1. THEORY 3 Hrs/Week

MODULE-I

1. Documentation in Pharmaceutical industry: MFR (Master Formula Record), DMF (Drug Master File), BPR (Batch Processing Record), Packaging and Distribution records, BRR (Batch Release Record).
2. Generic drugs product development: Introduction to generic & brand name of drugs, drug development process.

MODULE-II

1. Total Quality Management (TQM) - Introduction, Basic Principles, Benefits.
2. ISO 9000, 9001 and 9002 documentation: Introduction: Guidance on the terminology used in ISO 9000:2000, ISO 9001:2000.

MODULE-III

1. Introduction to Intellectual Property Rights (IPR) & basic terminology of Copyright, Trademark and Patents.
2. Regulatory requirement for product approval: API, novel therapies obtaining IND, NDA, ANDA process.

MODULE-IV

1. Clinical trials: Developing clinical trial protocols. Requirement to clinical study process, Introduction to pharmacovigilance.

MODULE-V

1. Stability Studies: ICH guidelines and WHO guidelines and stability testing protocols for dosage forms.

REFERENCES

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143.
2. New Drug Approval Process: Accelerating Global Registrations by Richard a Guarino, MD, 5th edition, Drugs and the Pharmaceutical Sciences, Vol.190.
3. ISO 9000 and Total Quality Management by S.K.Ghosh.
4. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance by Fay A. Rozovsky and Rodney K. Adams.
5. How to Practice GMP by P.P.Sharma.
6. GMPs by Mehra.
7. Validation of analytical procedure: methodology**, ICH harmonized tripartite guideline**, (1996).