Fourth Semester

PC-401: Basic Principles of Clinical Research

UNIT – I: Introduction of Clinical research
History, terminology, events: serious adverse events (SAE), investigational new drug safety reports (INDSR), reporting, investigational product (IP), principles & precaution and risk minimization, post marketing surveillance, managing blinded therapy cases, consent: informed consent, compensation: compensation for participation.

UNIT – II: Clinical trials & Good clinical practices (GCP), guidelines and related management.
GCP guidelines, principles of ICH GCP, ethical principles related to GCP, clinical trials, SOPs, regulation: obtaining clinical trial permission, application for permission, report: clinical trial report, trial management: data monitoring committee (DMC).

UNIT – III: Bioethics, devices, essential documents in clinical research
Ethics committee: independent EC & institutional EC, EC approval, quorum in EC, EC review & records, applied ethics & healthcare, contribution to clinical practices, devices: devices in clinical trials, essential documents: essential documents for the conduct of a clinical trial.

UNIT – IV: Generic drugs, herbal products, investigator in clinical trials
Comparing generic brands with original brand, herbal product: clinical trial of herbal product, investigators, laboratory, phases of trial.

UNIT – V: Bioequivalence, bioavailability & pharmacovigilance
General concepts, therapeutic equivalence evaluations: methods for determining bioequivalence, minimizing the need for bioequivalence studies, bioequivalence testing: evaluation of bioequivalence data, bioequivalence assessment and data evaluation, criteria for bioequivalence, study design, pharmacoepidemiology and pharmacovigilance.

Books Recommended

UNIT – I: Concepts of Industrial Management


UNIT – II: Intellectual Property Rights

TRIPs – Its scope and options, the changing R & D processes and IPR, The IPR tool kit, patents, the patenting process, patent cooperation treaty.

UNIT – III: Intellectual Property Protections of Living Species

Compatibility between conventions, protecting inventions in biotechnology, protections of traditional knowledge, biopiracy and documenting traditional knowledge, some case studies: The basmati rice issue, revocations of turmeric patent, revocation of neem patent.

UNIT – IV: Exercising and Enforcing of Intellectual Property Rights

Rights of an IPR owner, licensing agreements, criteria for patent infringement, case studies of patent infringement, IPR – a contract, unfair competitions and control, provisions in TRIPs, some case studies.

UNIT – V: Role of Patents in the Pharmaceutical Industry

Recent changes in IPR laws impacting pharmaceutical industry, intellectual cooperation in the pharmaceutical industry, some case studies

Books Recommended
