MPH2C.1 QUALITY ASSURANCE OF PHARMACEUTICALS THEORY **3 Hrs/Week**

UNIT-I

1. Concept of total quality management, philosophy of GMP, CGMP and GLP.
2. Organization and personnel, responsibilities, training hygiene.
3. Premises: Location, design, plan layout, construction, maintenance and sanitations, environmental control, sterile areas, control of contamination.

UNIT-II

4. Equipments: Selection, purchase specifications, maintenance, clean in place, sterilize in place.
5. Raw materials: Purchase specifications, maintenance of stores, selection of vendors, controls and raw materials.
6. Manufacture of and controls on dosage forms: Manufacturing documents master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities.

UNIT-III

7. In process quality control on various dosage forms sterile, biological products and non-sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfection, sterilization, membrane filtration etc. Guidelines for Quality assurance of Human Blood products and Large volume parenterals.
8. Packaging and labeling controls, line clearance and other packaging materials.
9. Quality control laboratory: Responsibilities, good laboratory practices, routine controls, instruments, protocols, non-clinical testing, controls on animal house, data generation and storage, quality control documents, retention samples, records, audits of quality control facilities.

UNIT-IV

10. Finished products release: Quality review, quality audits, batch release document.
11. Distribution and distribution-records: Handling of returned goods recovered materials and reprocessing.
12. Complaints and recalls, evaluation of complaints recall procedures, related records and documents.

REFERENCES :

1. The International Pharmacopoeia Vol 1,2,3,4, 3rd Edition General methods of analysis and quality specifications for pharmaceutical substances, excipients, dosage forms.
2. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials Vol.1 and Vol.2, WHO, (1999)
3. Basic tests for pharmaceutical substances – WHO (1988)
4. Basic tests for pharmaceutical dosage forms – WHO (1991)
5. GMP-Mehra
6. How to Practice GMPs – P.P.Sharma
7. The Drugs and Cosmetic Act 1940 – Vijay Malik
8. Pharmaceutical Process Validation by Berry and Nash.
9. Q.A. Mannual by D.H.Shah
10. SOP Guidelines by D.H.Shah
11. Quality Assurance Guide by OPPI