18BP104 METHOD TRANSFER, QUALITY CONTROL AND ASSURANCE

UNIT- I

INTRODUCTION: Concept and evolution of Quality Control and Quality Assurance, GLP, GMP, Overview of ICH Guidelines, QSEM-with special emphasis on Q-series guidelines.

UNIT- II

CGMP GUIDELINES: ICH, Pharmaceutical Inspection Convention(PIC), WHO and EMEA emphasizing on Organization and personnel responsibilities, training, hygiene and personal records, drug industry location, design, construction and plant lay out, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.

UNIT-III

ICH GUIDELINES: Analysis of raw materials, finished products, packaging materials, in process quality control (IPQC), developing specifications according to ICH for raw materials stores. In process quality control of finished products - tablets, capsules and parenterals in Pharmaceutical industry according to pharmacopoeia, Quality control test for containers, closures and secondary packing materials.

UNIT- IV

DOCUMENTATION IN PHARMACEUTICAL INDUSTRY: Three tier documentation, Policy, Procedures and Work instructions, and records (Formats), Basic principles of document maintenance, retention and retrieval etc. Standard operating procedures for preparing Master Formula Record, Batch Formula Record, Quality audit plan and reports. Specifications and test procedures, Protocols and reports. Distribution records and Electronic data.

UNIT-V

MANUFACTURING OPERATIONS AND CONTROLS: Sanitation of manufacturing premises, mix-ups and cross contamination, processing of intermediates and bulk products, packaging operations, IPQC, release of finished product, process deviations, chargein of components, time limitations on production, drug product inspection, expiry date calculation, calculation of yields, production record review, change control, sterile products, aseptic process control, packaging.