GUJARAT TECHNOLOGICAL UNIVERSITY

M PHARM

QUALITY ASSURANCE AND REGULATORY AFFAIRS

SEM II

Subject Name: GMP, GLP AND VALIDATION (Specialization paper – IV)

Subject Code: 2921502

Theory (Four hours per week, 8 Credits)

1. Concepts of Philosophy of QA, GMP, GLP .
2. Good Manufacturing Practices: |
a. Organization & Personnel, responsibilities, training, hygiene.
b. Premises: Location, design, Plant Layout, Construction, Maintenance and Sanitation, Environmental control, utilities and services like gas, water, maintenance of sterile areas and control of contamination.
c. Equipments: Selection, purchase specifications, maintenance, clean in place, sterilize in place, Methods (TP & STP).
d. Raw Materials: Purchase specifications, maintenance of Stores, selection of Vendors, control on raw materials and finished dosage forms.
e. Manufacture of & control on dosage forms: manufacturing documents, master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities.
f. In Process quality controls on various dosage forms: Sterile and non sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfections, sterilization, membrane filtration etc.
g. Packaging and labelling control, Line clearance, reconciliation of labels, cartons and other packaging materials.
h. Quality control Laboratory: Responsibilities. Routine controls instruments, reagents, sampling plans, standard test Procedures, protocols, data generation and storage, quality control documents, retention samples, records, audits of quality control facilities.
i. Finished product release, quality review, quality audits and batch release documents.
j. Warehousing, design, construction, maintenance and sanitation; good warehousing practice, materials and management.
k. Distribution and distribution records, handling of returned goods, recovered materials and reprocessing.
l. Complaints and recalls, evaluation of complaints, recall procedures, related records and documents.
m. Waste disposal, scrap disposal procedures and records.
3. Good Laboratory Practices.
4. Introduction to Pharmaceutical Validation:
Definition, Manufacturing Process Model, scope of Validation, Advantage of Validation, Organization for Validation, Validation Master Plan, Types of process validation, Design Qualification, Installation Qualification, Operational Qualification & Performance Qualification of facilities.
5. Cleaning Validation: Cleaning of Equipment, Cleaning of Facilities.
6. Analytical Method Validation.

General principles of analytical method validation. Validation of following analytical Instruments

- HPLC
- Dissolution test apparatus
- U.V./Visible spectrophotometers

7. Process Validation

Prospective, concurrent, retrospective & revalidation, Process validation of following formulations

- Coated tablets
- Capsules
- Ointment/Creams
- Liquid Orals

8. Computer System Validation

Reference Books:

1. Sidney H. Willig, "Good Manufacturing Practices for Pharmaceuticals", Drugs and Pharm. Sci. Series, Vol. 109, Marcel Dekker Inc., N.Y.
2. S. Bolton, "Pharmaceutical Statistics: Practical & Clinical Applications", Drugs and Pharm. Sci. Series, Vol. 135, 4th Ed., Marcel Dekker Inc., N.Y
3. G. S, Banker & C.T. Rhodes, "Modern Pharmaceutics", Drugs and Pharm. Sci. Series, Vol. 121, 4th Ed., Maracel Dekker Inc., N.Y.
4. P. P .Sharma “How to practice GMPs”, 3rd edition Vandana Publication.
5. P. P. Sharma “How to practice GLP” Vandana Publication.
6. S. Weinberg, “Good Laboratory Practice Regulation” Drugs and Pharm. Sci. Series, Vol. 124, 2nd Ed., Maracel Dekker Inc., N.Y.
7. WHO’s “Drug” Bulletins.
8. Remingtons “Pharmaceutical Sciences”.
9. GMP practices for pharmaceutical-James Swarbrick.