Syllabus

Module 01 **10 Hours**

Quality Assurance and Quality Management Concepts

- Definition and concept of Quality control, Quality assurance and GMP.

Total Quality Management (TQM)

- Definition, elements, philosophies.

ICH Guidelines

- Purpose, participants, process of harmonization, Brief overview of QSEM, with special emphasis on Q-series guidelines, ICH stability testing guidelines.

Quality by Design (QbD)

- Definition, overview, elements of QbD program, tools.

ISO 9000 & ISO14000

- Overview, Benefits, Elements, steps for registration.

NABL Accreditation

- Principles and procedures.

Module 02 **10 Hours**

Organization and Personnel

- Personnel responsibilities, training, hygiene and personal records.

Premises

- Design, construction and plant layout, maintenance, sanitation, environmental control, utilities and maintenance of sterile areas, control of contamination.

Equipments and Raw Materials

- Equipment selection, purchase specifications, maintenance, purchase specifications and maintenance of stores for raw materials.

Module 03 **10 Hours**

Quality Control

- Quality control test for containers, rubber closures and secondary packing materials.

Good Laboratory Practices

- General Provisions, Organization and Personnel, Facilities, Equipment, Testing Facilities Operation.
- Test and Control Articles.
- Protocol for Conduct of a Nonclinical Laboratory Study.
- Records and Reports.
- Disqualification of Testing Facilities.

Module 04 **08 Hours**

Complaints

- Complaints and evaluation of complaints, Handling of return good, recalling and waste disposal.

Document Maintenance in Pharmaceutical Industry

- Batch Formula Record, Master Formula Record, SOP, Quality audit, Quality Review and Quality documentation, Reports and documents, distribution records.

Module 05 **07 Hours**

Calibration and Validation

- Introduction, definition and general principles of calibration, qualification and validation, importance and scope of validation, types of validation, validation master plan.
- Calibration of pH meter, Qualification of UV-Visible spectrophotometer, General principles of Analytical method Validation.

Warehousing

- Good warehousing practice, materials management.

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