QUALITY ASSURANCE IN PHARMACEUTICAL INDUSTRIES

Unit-1

- Basics of Advanced GMP
  - History of cGMP's
  - The Code of Federal Regulations, Pharmacopoeias, and Guidance
  - Documents as source information
  - Who is the FDA and what power do they have?
  - How employees should act during an FDA inspection
  - How FDA communicates with the company
  - Why FDA considers all products not made by cGMP's to be adulterated
  - Roles and responsibilities of Manufacturing, Quality Assurance, Management and Employees
- Introduction to various Regulatory bodies and regulation in force for manufacturing, holding and distribution of pharmaceutical products
- Introduction to ICH Guidelines and CFR

Unit-2

- Detail study on requirements stated in…
  - ICH Q7 CFR 210-211 and Schedule M
- Quality Control: Good Laboratory System
  - Analytical Methods & Its Validation
  - Reagents ,Reference & Working Standard Management
  - Sampling
  - Instruments Calibration
  - Good Weighing practices
  - Self-life
  - Documentation
- Good Documentation Practices

Unit-3

- Storage & Distribution : Good Warehousing Practices
- Stability Requirements & Regulation in place
- Validation, Qualification & Calibrations
  - Equipment Qualification
  - Process Validation
  - Cleaning Validation
- Introduction to Clean Room, Its requirements of pharmaceutical Manufacturing and Validation of Clean area
- Water for Pharmaceutical use : Need, Necessity and Validation concepts
- Pharmaceutical Product Life Cycle : Drug development, Technology Transfer, Scale up and Commercialization of Product

Unit-4

- OOS & OOT : Failure Investigation System and Techniques
- Regulatory Filing and FDA Inspection System
  - DMF/ANDA/NDA approval Flow
  - Post Approval Changes DMF/ANDA – SUPAC
  - Generic Drugs Law
  - Pre-approval Inspections and periodic Inspections
- Statistical Quality Control
- Regulation of Training: Compliance

- Quality Management System
  - Chang Management
  - Deviation Handling
  - CAPA System
  - FG Testing and release system
  - Reprocess & Reworking
  - Annual Product Review
  - Site Master File
  - Validation Master File
  - Recall and rejection Management
  - Self-Inspection