

Course contents for the proposed course Pharmaceutical GMP Audits and Self-Inspections.

I. Regulatory audit/inspections: Preparing ,Initiating and Conducting

- Materials management
- Documentation systems
- Pharmaceutical quality systems
- Sterile products
- Oral solid dose
- Packaging and many more

II. Regulatory Audit Principles and Planning

- Planning and preparation
- Audit types and techniques
- Establishing an audit program for suppliers, contractors and company sites
- Internal vs. external audits
- The audit process

III. Auditor Skills and Competencies

- What makes a good auditor
- Communication skills, questioning and listening
- Body language and non-verbal communication
- Overcoming apathy, resistance and aggression
- Effective note taking
- Auditor continuing professional development
- Assessing the auditor
- Managing auditors

IV. Concluding the Audit