ITEC PROGRAMME ON
PHARMACEUTICAL GMP AUDITS AND SELF-INSPECTIONS
DATE: 09-01-2023 to 20-01-2023

About the Training Course:

A GMP audit is a process by which an external or internal individual or team verifies that a manufacturer is following its documented Good Manufacturing Practices. Audits are performed to ascertain the validity and reliability of information; also to provide an assessment of a system's internal control. A company that makes medications today must be able to prove that it does so with absolute reliability, under optimal secure conditions, and with extreme uniformity to allow for exact reproduction. Pharmaceutical auditing expertise includes writing and review of validation policies, guidelines and SOP from design qualification to performance qualification steps.

The self inspection is one of the key factors in pharmaceutical industry, to identify known and unknown non-compliance of the process, procedure, equipments, storage conditions, utilities etc., and will be regularized as per the current standard operating procedure or regulatory requirements.

Target Participants:

- Bachelor degree in pharmacy or equivalent or Master's degree in Pharmacy with relevant experience.
- Professionals having Experience about 5 years in the relevant field.
- Professionals from regulatory authorities.

Projected outcome of the course:

The aim of this training course is to learn how to perform better audits and have the opportunity to become familiar with audit process. Training will be provided by highly experienced pharmaceutical professionals and regulatory agency inspectors; this training course provides you the knowledge, understanding, skills and confidence to audit all aspects of pharmaceutical manufacture and control. This course will cover the following areas.

- Manufacturing operations
- Contract manufacturing organizations
- API suppliers
- Excipients suppliers
- Packing component suppliers
- Service providers

Key Learning Objectives

- Understand the GMP context for pharmaceutical quality system.
- Plan, conduct, report and follow up an audit of a GMP PQS
- Provide guidance for auditors of suppliers, contractors, CMO service providers, outsourced activities and self-inspectors

Organized by:

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