GMP <u>Auditors Qualification</u> e-Certificate course
(DIPLOMA in GMP AUDITING)

Self-inspection / Internal Audit should be carried out by a team of competent, capable & qualified auditors. Understanding this need of the industry, we are pleased to announce a **hundred days certificate e-learning course. This is a specially designed <u>correspondence course</u> by knowledgeable & experienced faculty of our institute. You would gain advantage in developing competency in GMP auditing, meeting the GMP requirements of auditors' qualification / certification along with role enhancement and job enrichment**. Your search for a total GMP auditors certification course ends here and this comes from a **25 year old institute** experienced in training and auditing for API, FDF, Biotech, Excipients, Packing material, Pharmaceutical Equipment, Medical Devices, Cosmetic, Food and GMP service providers.

Duration – 100 days **Mode :** Distant Learning **Admissions open now!**
Course Commences : June 15, 2020 **Contents** : Please refer the next page

This course is ideally suited for :

- Professionals engaged in all three tiers of GMP Self inspection / Quality Audits working in various departments as Research & Development (Development QA in particular) Manufacturing & Packaging, Quality Assurance (including Documentation, Validation, Audit & Compliance and PQR), Quality Control Laboratory (including Chemical & Stability Testing / Instrumentation / IPQC and Microbiology), Stores & Warehouse (across the supply & distribution chains), Engineering & Maintenance, Regulatory Affairs, Pharmacovigilance, and Clinical Operations.
- Personnel responsible for auditing vendors, suppliers and contractors
- Professionals who have two years and above of GMP experience and wish to gain expertise in GMP auditing.
- Individuals from varied pharmaceutical background intending to Qualify or Re-qualify themselves as internal GMP auditors.

Methodology

Written material on all the four modules mentioned on preceding pages shall be mailed at suitable intervals followed with written evaluation at the end of each module. There shall be an interactive training session (webinar) prior to completion of the course. The participants of this diploma programme must complete a project involving self inspection and internal audits. The details on the project to be completed shall be intimated to the delegates at appropriate time during the diploma programme. The performance including written evaluation and project shall be assessed. A certificate of competency along with statement on evaluation shall be issued to each qualifying participant.

For further details on enrollment please get in touch with :

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COURSE CONTENTS

Module-I - Internal audit / Self inspection systems: Introduction and overview

- Definitions of audits (US,EU,ICH and ISO)
- Regulatory requirements for self inspection/internal audits(WHO, EU, PICS, MHRA, IN and other regulatory agencies)
- Audit types and details ; Reasons for internal Audits ; Auditing styles
- Audit process flow management ; SOP on self inspection/ internal audit
  - Scope
  - Frequency
  - Purpose
  - Approvals
- Auditing Tools
  - Physical tools
  - Checklists(Advantages/disadvantages)
  - Audit plan preparation
  - Meeting Approach
- Self inspection: concerns and value addition

Module II - GMP auditing essentials

- Essentials of a good auditor
- Requirements for auditor's qualification
- Auditor training needs and necessities
- Auditor's roles and goals
- Auditors Do's and Don'ts
- Soft skills for Auditors
  - Questioning Skills
  - Communication skills
    - Oral
    - Written
    - Non- verbal communication/ body language
    - Emphatic listening skills for auditors
  - Interpersonal skills
  - Decision Making
  - Time Management
- Company culture and auditing ;
- Outcomes of good auditing

Module III - The breadth and depth of internal auditing

- Problems involving internal Audits ;
- Why the System of internal audit doesn't work
- Risk based approach to self inspection/ internal audits;
- Regulatory and system approach
- The PICS EU and WHO approach –
- Setting frequencies using the risk ranking and filtering QRM tool
- Application of FTA QRM tool to investigate audit failures
- Vendor and supplier audits
  - ICH Q10 approach
  - USFDA quality agreements
  - TGA supplier qualification guide
- Sensing signals during vendor Audits
- Writing meaningful audit reports
  - Difference between observations and findings
  - Accurate audit reporting
  - Audit report content and format
  - Key aspects of audit report preparation
  - The 7 C's of audits report
  - Reporting findings effectively
  - Conclusion and classification of audit reports
  - Tracking and trending of audit reports
- Reported non compliances in the system of internal audits

Module IV – Mechanics of operation of internal audits

- Grading of audit observations / deficiencies
- Understanding and differentiating isolated and systemic deficiencies
- The regulatory approach for grading observations as critical ,major minor
- A risk level classification of GMP audit findings and linkages to audit frequency
- Prioritizing - What systems should the Auditors look for during the conduct of an audit
- What documents should be generally audited during internal audits / self inspections
- Checkpoints during facility tour – the high gain observations
- Most common GMP violations and common trends of GMP audit findings
- Review of sample non compliance reports from the inspections of various Regulatory agencies
- Maintaining the GMP continuum through effective internal audit / self inspection systems