BROCHURE 1

# Diploma in Quality Auditing (GMP Auditors Qualification Course)

For brochure 2, Refer Page 5 & 6

# 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 correspondence course 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, Excepients, Packing material, Pharmaceutical Equipment, Medical Devices, Cosmetic, Food and GMP service providers.

**Duration** – 100 days **Mode :** Distant Learning **Admissions Open Now**

**Course commences :** July15,2021 **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 participants at an 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**


**Insight's Professional Management Academy,**
SADHANA', Plot No 13, Managaldham Society, Survey No. 52,
Near Ekalavya Polytechnic, Kothrud, Pune – 411038
Hand Phone – 09822208197/9822033002 (office Time : 10 am to 6 pm)
E Mail – Insight.shirgaonkar@gmail.com ; URL – www.insightcgmp.com

# COURSE CONTENTS

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

- Definitions of audits ( US,EU,ICH and IS0)
- 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

BROCHURE 2

# Diploma in Good Manufacturing Practice ( GMP )

**DIPLOMA IN GMP e-Certificate course**
**( DIPLOMA in GMP New 'Improved 23rd Batch )**

This is a unique correspondence course ( DISTANT LEARNING ) which shall add value to your professional endeavours and shall prove to be a right choice for growth and progress in your career. This exhaustive course provides detailed inputs on current aspects of Good Manufacturing Practice.

**Duration** – 180 days **Mode :** Distant Learning

**Admission Starts :** June15, 2021 **Course Starts :** July15,2021

**Contents** : Please refer the next page.

**This course is ideally suited for :**

B.Pharm, M Pharm, BSc., MSc., B Chem., M Chem., Doctorates in science disciplines, BE, DE and Professionals working in the pharma industry as chemical engineers, commerce graduates working in stores, purchase and other personnel with relevant experience from various disciplines and departments.

**Methodology**

Written material, covering everything mentioned on the preceding page shall be mailed at suitable intervals followed with evaluation link on the material mailed. There shall be an interactive training session ( **webinar** ) prior to completion of the course. The participants of this diploma programme must complete a response sheet involving all the aspects of GMP. The details on the response sheet to be completed shall be intimated to the delegates at appropriate time during the diploma programme. The performance including submitted evaluation and response sheet shall be assessed. A certificate of competency along with statement of marks upon evaluation shall be issued to each qualifying participant.

**For further details on enrollment please get in touch with :**

Mrinmayee Shirgaonkar
Officiating Course Director

**Insight's Professional Management Academy,**
SADHANA', Plot No 13, Managaldham Society,
Survey No. 52, Near Ekalavya Polytechnic, Kothrud,
Pune – 411038
Hand Phone – 9822208197/9822033002 ( office Time : 10 am to 6 pm )
E Mail – DGMPIPMA2000@gmail.com ;
URL – www.insightcgmp.com

## COURSE CONTENTS

- Introduction to Pharmaceuticals ( API / FDF ) and various timelines from molecule to market place.
- Quality : definition, evolution, attributes, concepts, current trends and specific aspects to include modern Pharmaceutical Quality Systems ( PQS )
- GMP and its relationship with quality; from basics to specific requirements
- History of GMP and its evolution & progress and trends till date across the globe,
- Progress of GMP with current status regulatory status and trends of various regulatory agencies with important milestones and requisite updates
- Interpretations and applications of GMP in line with National and International GMP regulations and standards as essential for Pharmaceuticals

- Requirements, scope, objective and principles and practices of GMP with emphasis on GMP requirements of:
  - WHO;
  - TGA;
  - MHRA;
  - MCC;
  - HPFBI;
  - PICS;
  - EU;
  - ICH;
  - HSA
  - USFDA and
  - The revised Schedule M *and*
- Specific references to other regulatory requirements different from those mentioned above.

- Obtaining International GMP Certification and requisite renewals maintaining the GMP standards through design and implementation of effective pharmaceutical quality systems ( PQS – Q10 ) with drivers as :
  - Pharmaceutical development
  - Technology transfer,
  - Deviation management
  - Change management,
  - Knowledge management
  - Corrective And Preventive Actions (CAPA) and
  - Quality Risk Management (QRM ).
- GMP requirements for pharmaceutical manufacturing from material procurement to distribution of products and its post marketing aspects.
- Principles of Quality Assurance and Quality Management Systems from development to discontinuation (Pharmaceutical life-cycle ) for monitoring of GMP
- Principles and Practices of Good Quality Control Laboratory Practices( GQCLP ) as applicable to pharmaceuticals,

- Extensive Validation Studies & Techniques ( including qualification studies for:
  - Equipment & instrument, design, installation, operation, performance ( 4Q approach from DQ-PQ ),
  - Good Engineering Practices ( GEP ), GAMP V & ASTM model,
  - Cleaning validation,
  - analytical methods validation, computer systems validation & revalidation )
  - with particular emphasis on HVAC & water systems validation with a Risk based approach to manufacturing of pharmaceuticals.
- Good Documentation Practices and data integrity requirements
- GQCLP and Stability studies, Good Distribution Practices
- Advances in GMP requirements, Training and Auditing in GMP, Handling international GMP inspections effectively and successfully, references to relevant pharmacoepial requirements as they interface with GMP
- Implementing GMPs in your organization through quality risk management, and getting the most out of quality by maintaining the GMP continuum.