PRA CONSULTANCY

SOP Consultancy Center
State Of Practices Consultancy Center

Advanced GMP Pharmaceutical Quality Systems (GMP PQS) Auditor/ Lead Auditor Training

Amman - Jordan

24th - 28th February 2024

THEORETICAL & PRACTICAL TRAINING

Course overview:

Auditing is a critical function within a pharmaceutical company.

It provides management with information about how effectively the company controls the quality of their processes and products. Auditors must perform their jobs competently to ensure their company's compliance with relevant pharmaceutical regulations and other quality standards like (e.g., ICH).

It's crucial to understand the requirements of a Pharmaceutical Quality Management System, and the importance of this in maintaining control and facilitating continual improvement throughout the product lifecycle.

This Auditing GMP training is specifically designed to address the challenges of GMP auditing for the pharmaceutical industry and present the basic competencies required to effectively perform the auditor's assigned responsibilities, whether for internal and/or external audits.

GMP audits help ensure products are made and controlled in accordance with appropriate quality standards, and current industry best practices, and that they comply with applicable health authority regulatory requirements and guidance documents.

This interactive and intensive five-day training "Advanced GMP Pharmaceutical Quality Systems (GMP PQS) Auditor/Lead Auditor" is designed for individuals wishing to develop the essential skills necessary to perform effective departmental and system audits, and the knowledge to apply what they have theoretically learned in auditing a pharmaceutical manufacturing facility, followed by writing an audit report finding.

Why to Join:

- Learn the different types of audits, and when to perform each.
- Learn the knowledge, understanding, skills, confidence, and techniques to audit a pharmaceutical manufacturing company.
- Learn how to effectively perform department audit or self-inspection, audit pharmaceutical quality systems, site audits, external audits, etc.
- Identify key elements of the audit process and learn what is involved in each.
- Learn to conduct audits of any element of the pharmaceutical quality system while building on and improving your abilities to eventually conduct full facility audits.
- Developing your auditing skills.

Outcome of this training:

- Understand the GMP context for pharmaceutical quality system auditor / lead auditor.
- Have knowledge about audit planning, conducting, report writing, categorization of deficiencies found, and follow-up.
- Know the key skills and techniques for managing an audit.
- Have developed the essential soft skills of a good auditor.
- Classify audit findings into three categories: Critical, major, and minor.
- Provide guidance for auditing of suppliers, contractors, Contract Manufacturing Organizations “CMO” service providers, outsourced activities, and self-inspections.

Course Methodology:

Principles and Audit 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

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
- Assessing the auditor
- Managing auditors

Preparation for the audit and Audit Initiation

- Learn which documents should be reviewed from past audits, how to select personnel from every department as key people for the forthcoming audit, and how to prepare the audit plan.

Conducting the Audit

- Auditing including:

- Materials management
- Documentation system
- Pharmaceutical quality systems
- Sterile products
- Oral solid dose
- Packaging
- Other

- Wrap-up Meeting

Audit Report & Follow-up

- Audit Report and categorization of findings
- Follow-up

Audit Closure

- Learn how to close an audit in a professional and controlled manner, and how an overview of the whole audit is given. Where, audit findings are summarized, recommendations are given, discussions are initiated, and timelines for any preventive / correction action are set.

Who should attend:

Pharmaceutical auditors assessing:

- suppliers of starting materials including API and packing components
- Contract manufacturing organizations
- contract service providers
- manufacturing operations
- packing operations
- testing laboratories
- warehouse and distribution operations

Individuals who works with Authorities, Notified Bodies & International guidelines provider such as (e.g., USFDA, PIC/S GMP GCC, SFDA, JFDA, etc.)

Individuals who want to work as auditors.

Individual who works with entities that are audited with QA & QC Departments.

Internal auditors who conduct full or partial GMP and pharmaceutical quality management system audits within their own organization.

Pharmaceutical quality practitioners – consultants, audit programme managers and other related personnel

Pharmaceutical auditors working for third-party certification bodies/registrars who complete full GMP and pharmaceutical quality management system audits of suppliers, including:

- audits of raw material and component suppliers
- audits of different phases of the product lifecycle

Types of companies hiring

- Pharmaceutical Manufacturing Companies
- API /Excipients manufacturing Companies
- Drug Store distribution companies
- Packaging Companies
- Service Provider Companies
- Food & Beverage Companies

Modules

1. General

- Why to audit: Purpose of the audit
- Audit Duration
- Types of audits
- How to perform an audit in six steps
- Prepare the audit Plan “Audit Agenda.”
- Be prepared (Review documents: SMF, Quality Manual, list of SOPs, MVP)
- When not to audit a second party
- Risk Based approach for auditing
- How to avoid pitfalls during a GMP audit/inspection

2. What to include in a Pharmaceutical Audit Checklist

2.1 General Controls

- Organizational & Management Responsibilities
- Employee Orientation, Quality Awareness, and Job Training
- Plant Safety and Security
- Internal Quality/GMP Audit Program

2.2 Facility Control

- Facility Design and Layout
- Environmental Control Program
- Facility Maintenance and Good Housekeeping Program
- Outside Contractor Control Program

2.3 Equipment control

- Equipment Design and Placement
- Equipment Identification
- Equipment Maintenance and cleaning
- Measurement Equipment Calibration Program
- Equipment Qualification Program

2.4 Material/Component Control

- Material/Component Specification and Purchasing Control
- Material Component Storage and Handling
- Inventory Control Program
- Vendor/Supplier Control Program

2.5 Operational Control

- Material/Component/Label Verification, Storage and Handling
- Equipment/Line/Area Cleaning, Preparation, and Clearance
- Operational Process Validation and Production Change Order Control
- In-Process Inspection, Sampling, and Labratory Control

2.6 Reprocessing/Disposition of Materials

2.7 Finished Product Control

- Finished Product Verification, Storage, and Handling
- Finished Product Inspection, Sampling, Testing, and Release

2.8 Distribution Controls

2.9 Marketing Controls

2.10 Complaint Handling and Customer Satisfaction Program

Modules

3. Wrap-up meeting

Learn why a wrap-up meeting is important to every audit, where non-conformities found are listed, and critical findings are highlighted.

4. Audit Report findings, categorization, and classification

Learn how to report the audit findings, categorize and classify findings into minor, major, and critical. Where, audit findings are specified, recommendations are given, discussions are initiated., and timelines for any preventive / correction action are set.

5. Audit Follow-up

Learn how to follow-up the implementation of Corrective & Preventive Actions (CAPA), and how to review CAPA response, monitor the progress and verify the results.

6. Audit Closure

Learn how to close an audit in a professional and controlled manner, and how an overview of the whole audit is given.

7. Common Audit Findings/Trends

- US-FDA 483's audit findings
- US-FDA Warning Letters
- PIC/s
- MHRA

8. References

2 Days Practical in one GMP-certified Pharmaceutical Manufacturing Site in Jordan.

Certification

- Training Certificate issued by PRA & SOPCC, mentioning practical part with specifying the name of the manufacturing site.
- You will be certified as GMP Pharmaceutical Quality Systems (GMP PQS) Auditor/Lead Auditor issued by Global Assessment Academy/Global Assessment KFT – Hungary, approved by European Accreditation (EUAC 106) – London, (three years validity).

Timeline

24th - 28th February 2024

8 hrs/day
(9 am – 5 pm)

5 days
Practical & Theoretical

PRA CONSULTANCY

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@PRACONSULTANCY

www.pra-me.com

Tel: +971 4 299 9398 Mob: +971 562988438

Email: traninig@pra-me.com