1   Purpose

To provide minimum mandatory requirements and outline best practice for ensuring that company auditors have a common baseline of training and experience in order to carry out GMP Quality and Compliance Audits of company suppliers and internal audits of their own sites.

2   Scope and Applicability

This International Guideline is applicable to all manufacturing Operations and Research and Development sites, for staff performing GMP Quality & Compliance Audits externally of company suppliers and internally of its sites.

3   Definitions

3.1   Audit

An audit is a systematic and independent review to verify compliance, suitability and/or data integrity.

Audits may assess: systems, processes, procedures, facilities, products, records and/or data for compliance with policies, standards, procedures, guidelines, regulations or regulatory submissions.

3.2   Certified Lead Auditor

An auditor qualified by the auditor training and certification requirements in this guideline and appointed to lead an audit team for a specific internal/external audit.

3.3   Joint Audit

A supplier audit that is conducted by an audit team with auditors from two or more other sites.

3.4   Participant

A specialist / technical expert who provides specific knowledge or expertise with respect to a particular organization, process, activity or subject to be audited.

3.5   Supplier

An umbrella term that covers both Vendors and Contractors supplying API, intermediates, raw materials, packaging components, excipients, formulated products, packaged products, and/or providing services, e.g. calibration, validation, laboratory testing etc. to the company.

4   Responsibilities

It is the responsibility of local QA Management to ensure that auditors are competent

encompass theoretical and practical aspects of the job including training in procedures. All training must be documented in the individual's training record.

Participants in an audit team would be expected to study the training module

5.2.1 Auditor Training

All internal and external auditors must study and apply the training modules:

- Induction (high level).
- Worldwide Regulatory Requirements. Orientation of worldwide regulatory requirements & standards.
- Auditing Essentials for a cGMP Audit. How to audit, tools/techniques, audit process, templates etc.
- Quality Systems training modules
- Training modules relevant to the audits that they will perform New auditors should accompany company certified Lead Auditors to gain practical experience. For smaller sites this can be achieved by joint audits.
  In order to have a professionally recognized qualification it is recommended for internal and external auditors to obtain an independent auditor training qualification.

5.3 Auditor Certification

Lead Auditors must be certified by the company for the type of audit to be performed e.g. sterile manufacturing, API supplier etc. QA Management may document an auditor's equivalent training and/or experience in order to certify a Lead Auditor.

5.4 Auditor Continuous and Refresher Training

Auditors have a personal and professional duty to keep their knowledge and experience up to date with the current GMP and ongoing trends in pharmaceutical quality management, development, manufacturing and technology used within the industry.

The management must provide periodic in-house training events, presented using modern communication tools like audio- /videoconferencing. This should be organized by a nominated sub team and include topics from internal and external environment that are relevant to auditors.

Joint audits can also be used as continuous training and harmonization of audit performance when there is a clear justification and added value for the business. The needs for training must be regularly evaluated by local QA Management. Any additional training courses in specific subjects/areas and/or refresher training should be discussed between the auditor and their line manager during the annual performance and development planning sessions