

QUALITY AUDIT

A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements, and whether these arrangements are implemented effectively and are suitable to achieve objectives.

It is the process by which an independent body assures itself and the stakeholders that an educational institution has adequate and appropriate mechanisms set up to ensure quality of educational provisions.

Institutional Accreditation is another term used to denote more or less the same thing as an academic audit or quality audit.

Types of Audits:

- Internal Audit
- External Audit

Purpose of internal Audit:

Internal audits ensure that an organization is meeting its own quality standards or contractually required standards. This is also called a first party audit.

Internal audits may be done by auditors who work for the company being reviewed. They may also be hired by the company to audit its own functions. However, auditors must be independent of the function they are auditing.

- Determine the level of compliance
- Build confidence (hopefully) in GMP and the QA system
- Build interdepartmental trust, understanding, and communication (if the audit is done properly and tactfully)
- Determine measures necessary to improve
- Premises, equipment, environment
- Operations, actions, procedures.
- Personnel/training
- Provide a stimulus for improvement
- Recommend corrective action
- Monitor improvement

Purpose of External Audit:

External auditors are separate from the company they are auditing because they are independent. They may be hired by a supplier or customer to ensure that the audited company meets their quality standards. They may be audited by the government to verify that they meet specifications. External audits can be done by quality consultants specializing in the quality standards for those organizations. In all of these cases, the audit is called an external audit.

- Establish and monitor capability of supplier or contractor to deliver
- Goods and services that are fit for purpose (and on time, and in the quantity required)
- Build mutual confidence
- Promote understanding and communication between the parties involved

Second Party Audits:

External audits done by a company that has a contract with the audited firm is called a second party audit. The second party quality audit is done by the company holding the audit.

Third Party Audits:

External quality audits done by an organization that has no contract with the company it is auditing is called a third-party audit. A third-party external audit can be done to attain or maintain certification in a quality standard. A third-party audit by an independent auditor can also be mandated by law to qualify for government contracts. A third-party audit of a company can also be done at the request of a supplier or customer who would be considered a second party audit if they performed the quality audit themselves.

Process Audits:

A process audit verifies that a documented process meets quality standards. This process could be a manufacturing process or service process.

Product Audits:

A product quality audit verifies that a physical product meets design specifications and other quality measurements. Product audits may require measuring physical dimensions, product testing, or destructive testing. A

product audit can involve checking the calibration and test equipment used to verify that the product meets quality standards.

System Audits:

A system audit is a review of the quality system used by a company. It is a review of how quality standards are measured and met by the company. It verifies the procedures used to measure the quality of the product, how defects are recorded, and how the company ensures that failed product is not passed.

There are the 4 steps to successfully conduct quality audits:

1. Planning:

The actions taken prior to the audit are decisive for the success of the activities. Planning begins with the preparation of a plan, which will guide the execution of the audit. This plan should present all the activities in a timeline, as well as the scope, detailing the processes, departments or products to be audited. At this stage, it is also important that the auditor identifies all related documentation, such as quality policies or procedures. Also at this stage, a preliminary list of the people to be interviewed can be drawn up.

2. Preparation:

This is the moment when the auditors can learn more about the company's QMS, taking a closer look at the system documentation. It is important that each member of the audit team be prepared for the activity, with access to the verification checklist. The checklist is essential to guide the auditor so that no details to be assessed are overlooked, as well as for recording the findings and observations.

3. Execution:

The execution of audits takes place with the collection of information, which determines if the department in question is following established standards and quality control procedures. At this stage, the auditor interviews people, asking questions and taking note of the findings. Depending on the findings, audit plans and checklists may have their scope widened, and may be subject to further evaluation. It is at this time that non-conformities will be registered, that is, situations that have occurred which are in conflict with standardized processes and procedures.

4. Conclusion and Follow-up:

Once the audit is completed, the “real” work begins. The audit team meets to review problem areas and to determine recommendations for correcting quality problems. This information will be included in the Audit Results report. This report is an important input for strategic meetings held by leaders. It helps to evaluate the results and define how to implement the improvement actions suggested by the audit team.