

Internal Auditor Training

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Internal Auditor Training



The Internal Auditor training module is **ideal** for any organization looking for assistance with compliance with ISO 9001 section 6.2 and 8.2.2 or FDA's Quality System Regulation (QSR) 21 CFR Part 820.22 and 820.25. The module is also applicable to any company interested in evaluating supplier performance/compliance through supplier audits.

Audits are performed to determine whether activities/practices and related results comply with requirements, whether the requirements themselves are adequate, and/or whether a system is effective. Audits are a critical and necessary input to management review.

An organization should establish an audit program to assess the strengths and weaknesses of their and/or their supplier's quality management system. The audit process should include the planning, implementation, and reporting activities associated with conducting an audit. The Internal Auditor Training module is designed to provide participants with a knowledge and understanding of the basic concepts associated with conducting effective audits. The module presents the information in simple, easy to understand language. Auditing terminology, audit application, reasons for auditing, audit objectives, attributes essential to an auditor, audit questioning techniques, audit preparation and planning, understanding and documenting audit nonconformances and audit reporting are presented. Additionally, the module highlights where mock exercises are suggested to assist participants with comprehension of the material. Sample audit report forms are included as part of the presentation.

For more information, contact us today!

Phone: (813) 784-8457

Fax: (530) 690-8393

Email: info@qaracc.com

Audit Terminology

Assessment vs. Audit

The **audit** is the activity of examining and inquiring into the Quality System.

The **assessment** is the process of determining the results of the audit based on evidence collected during the audit.

As a result:

The **auditor** is an "observer of fact" whereas the **assessor** is an "appraiser, measurer, judge of".

Course Objectives

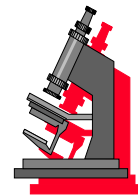
Teach potential auditors:

- ✓ Auditing Terminology
- ✓ Reasons for Auditing
- ✓ Audit Objectives
- ✓ Attributes Required of an Auditor
- ✓ How to Prepare an Audit Plan
- ✓ Auditing Techniques
- ✓ Understanding and Documenting Audit Nonconformances
- ✓ Audit Reporting

Audit Focus

The focus of an audit is on the need for evidence.

"Quality must be seen to be achieved"



Course Outline

- Auditing Terminology
- Quality Auditing Applications
- Reasons & Objectives of Auditing
- Auditor Profile
- Audit Preparation & Planning
- Performing the Audit
- Audit Reporting

Questioning Techniques

Much of the auditors time will be spent asking questions, but even more time should be spent listening and observing. As a result, to obtain the response you require, your skill in asking questions is critical.

Five basic types of questions:

- Open
- Closed
- Clarifying
- Leading
- Antagonistic