

QA ✓ **RA Compliance Connection, Inc.**
presents

Internal Auditor Training

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A Two-Day Comprehensive Training Program

Why are audits so important?

Both the FDA QSR and ISO 9001 require that internal quality system audits be performed. The ability of an organization to conduct effective audits of its quality management system is critical in our competitive marketplace. This course is designed to provide participants with the necessary skills to develop and implement an effective internal quality system audit program which meets ISO 9001 and FDA QSR requirements. Interactive activities help participants develop a hands-on understanding of the audit cycle and facilitate the implementation of a good audit program.

This course is for you if:

- You are responsible for implementing an internal audit program that meets FDA QSR or ISO 9001 requirements.
- You would like to gain the skills necessary to conduct effective internal quality system audits.
- You are responsible for leading supplier quality system audits and second party audits.
- You would like to become an active member of the internal audit team.

You'll learn:

- How to plan and manage an effective audit.
- How to collect and document objective evidence and techniques for effective questioning and listening.
- How to write-up an audit report that can be used as a tool for improvement.

COURSE OUTLINE

Introduction

Audit Terms and Definitions

Auditing Applications

Reasons for Auditing

Auditor Objectives

Auditor Profile

Audit Preparation & Planning

Questioning Techniques

The Audit Plan

Performing the Audit

Documenting Observations

Audit Reporting

Presenting the Report

†Familiarity with FDA QSR and/or ISO 9001 requirements recommended.

COST

\$700 per person (5 person min)

\$495 each additional over 5