



Course Overview

This course explores the full audit and inspection process from understanding the purpose and scope to preparing effectively, managing the process, and following up. It emphasises the need to be audit-ready every day, not just when an audit is announced. Updated in 2025 it reflects the latest ICH E6(R3) guidance, ensuring learners gain both current regulatory insight and practical strategies for audit success.

Learning Objectives

By the end of this course, participants will be able to

- Understand the purpose of audits and inspections and what regulators expect.
- Prepare effectively for audits, including key documents and checklists.
- Manage the audit or inspection process with confidence.
- Take the right follow-up actions to stay inspection-ready every day.

Module One

- What are audits and inspections?
- Understanding standards and guidelines
- Types of audit and inspections
- Remote audits
- Audit process
- Internal audits
- Preparing for audits and inspections
- Record keeping

Module Two

- During the audit
- Tips for a successful audit
- Following the audit
- Audit findings
- Data collection and management
- Audit reports
- Re-audit and continuous management

Duration: Approx. 2-3 hours

You are able to take this in your own time, on any device and are able to pause and restart from the place you left off. Time taken will vary depending on your experience and how many of the many optional links and activities you choose to view.



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