

Halderstone



Training module

Auditing Product & Service Development

Assess controls, validation and effectiveness in product and service design & development against ISO 9001 requirements



Do design reviews exist but delivery problems still originate in design?

Overview

Design and development activities determine whether products and services can reliably meet requirements before delivery begins. In ISO 9001, design and development controls are intended to ensure that requirements are translated into workable solutions through structured planning, review, verification, and validation.

In practice, design controls often appear complete in documentation while weaknesses surface later in delivery: unclear inputs, informal design decisions, ineffective reviews, or insufficient validation under real operating conditions.

This module develops the capability to audit whether design and development activities are sufficiently controlled and produce reliable outcomes. Participants first review how design and development functions within ISO 9001 for both products and services, then learn how auditors test planning discipline, review effectiveness, verification and validation evidence, and design change control.



Target audience

- Aspiring auditors who want to audit quality management systems against ISO 9001 following best practices
- Practising ISO 9001 auditors who want to strengthen their audit knowledge, judgement, and effectiveness

Is this module for you?

It is a good fit for you if you...

- audit product or service design and development within ISO 9001 management systems.
- want to assess whether design controls prevent predictable delivery failures.
- seek to judge design review, verification, and validation evidence.
- need to test whether design changes are controlled across the lifecycle.
- expect to strengthen audit conclusions on design and development effectiveness.

It may be less suitable for you if you...

- prefer to design products, services, or development processes yourself.
- are looking for engineering design methods or innovation techniques.
- focus primarily on product development management rather than auditing.
- do not intend to audit design and development activities.

Learning outcomes



Key outcomes

- Assess whether design and development activities are planned and controlled within the management system
- Test whether design inputs, reviews, verification, and validation provide credible assurance of performance
- Trace design decisions and outputs to delivery outcomes using defensible audit evidence

Additional capabilities

- Evaluate whether design changes are controlled across the lifecycle
- Detect common design failure patterns such as incomplete inputs or ineffective reviews
- Select meaningful sampling targets when auditing design and development activities
- Formulate defensible audit conclusions on design and development effectiveness



Agenda

Design and development in ISO 9001

How product and service design translate requirements into solutions and why weaknesses in design control frequently appear later in delivery

Effective auditing of design and development

How auditors judge whether design controls provide credible assurance rather than relying on documentation alone

Design inputs and planning

How to evaluate whether design inputs are complete, feasible, and aligned with customer, regulatory, and operational requirements

Design reviews as control points

How to test whether design reviews identify risks, assumptions, and feasibility issues before they reach delivery

Verification and validation evidence

How auditors distinguish between verification of design outputs and validation under realistic operating conditions

Design changes across the lifecycle

How to evaluate whether design changes are identified, assessed, approved, and communicated without introducing uncontrolled risk

Design-to-delivery traceability

How to follow evidence trails linking design decisions, outputs, and delivery outcomes to detect design-related failures

Case-based audit simulation

Applying the learned concepts, methods, and approaches in a realistic case setting

Included materials



Learning materials

- Slide deck
- Participant workbook

Templates & tools

- Audit interview planning tool
- Documented information checklist
- Sampling tool
- Audit analysis worksheets
- Failure pattern library
- Supporting AI prompt set

Confirmation

- Confirmation of participation

Preparation guidance

Assumed background

This module assumes participants can perform basic audit activities and apply evidence-based judgement.

Helpful background includes:

- General understanding of ISO 9001 terminology and management system structures
- Ability to follow audit trails across design documentation, technical records, and operational evidence
- Basic familiarity with product or service development activities

Preparatory modules

Foundation (depending on background)

Useful if you are new to the underlying concepts

- Audit Principles

Supporting (optional)

Helpful but not required to participate effectively

- Auditing Operational Control

Logistics



Available languages

- English
- German

Standard delivery options

- Virtual live teaching
- Blended learning (e-learning + live)

Bespoke delivery options

- On-site delivery at your place
- Content adapted to your organization



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