

Halderstone



Training module

Product Design & Development Control

Control product design and development, produce the required evidence, and manage design changes effectively



Does your product design process lack clarity and traceability, leading to repeated errors?

Overview

Unclear inputs, inadequate reviews and weak traceability make product development inefficient and risk-prone.

This training module explains how design controls help teams plan design activities, define and validate inputs and outputs, and distinguish verification from validation. Participants see how to keep the development process agile while creating the evidence needed for conformity and market confidence. The module does not cover detailed technical methods; it concentrates on governance and control.



Target audience

- People involved in designing, building, operating, or improving a QMS aligned with ISO 9001
- Executives and department heads accountable for the effectiveness and performance of a QMS
- Those responsible for processes, policies, IT systems, risks, and controls related to quality management
- Auditors of ISO 9001 who want to deepen their understanding of management-side best practices (not audit technique)

Is this module for you?

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

- implement or maintain design and development controls.
- support product or engineering teams with governance, evidence, and traceability.
- struggle to show consistent control over design inputs, reviews, and changes.
- need clearer separation between design work and production handover.
- want design control that supports development speed rather than slowing it down.

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

- already operate a clear, consistently applied design control process.
- are not involved in governing or evidencing design and development activities.
- focus primarily on service design , customer experience, or service delivery models.
- are looking for engineering methods, innovation techniques, or product strategy.

Learning outcomes



Key outcomes

- Apply design and development controls to plan activities with clear inputs and outputs
- Run design reviews that gather the right stakeholders and evidence decisions
- Differentiate verification from validation and integrate both into the development cycle

Additional capabilities

- Produce design outputs that support manufacturing, service and support teams
- Control design changes through structured evaluation and approval
- Link design and development controls to other quality processes without creating bureaucracy

Agenda

What ISO 9001 expects from product design and development control

How ISO 9001 defines when design and development controls apply, when they do not, and what auditors typically expect to see as evidence, including common gaps observed in real implementations

Planning design and development as a controlled process

How to structure design and development as a controlled process by defining stages, responsibilities, interfaces, and decision points, while aligning planning with real project execution rather than creating parallel management systems

Design inputs and design outputs

How to define usable design inputs, including requirements, constraints, standards, and prior lessons learned, and produce design outputs that are production-ready through clear acceptance criteria, specifications, and instructions

Design reviews

How to design effective design reviews that go beyond meetings and minutes, clarify the roles of reviewers and approvers, and ensure cross-functional interfaces are explicitly addressed

Verification and validation

How to distinguish verification from validation in practical product contexts and demonstrate each proportionately, using records that provide sufficient assurance without overengineering

Design and development changes

How to manage design and development changes through defined triggers, impact evaluation, and decision traceability, while protecting downstream stability through controlled handover, re-verification, and release

Case-based workshop

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

Included materials

Learning materials

- Slide deck
- Participant workbook

Templates & tools

- Extendable design and development process template
- Design input and output checklist
- Design review record template
- Verification & validation matrix template
- Design change request and impact evaluation template

Confirmation

- Confirmation of participation

Preparation guidance

Assumed background

Participants should be comfortable discussing elements of operational control at a practical level. Helpful background includes basic understanding of:

- Process thinking including the importance of clearly defined roles and responsibilities
- The importance of documented information
- Operational objectives and controls
- Controlled change handling

Preparatory modules

Foundation (depending on background)

Useful if you are new to the underlying concepts

- Operational Control

Supporting (optional)

Helpful but not required to participate effectively

- Customer Requirements & Communication

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



Halderstone

Halderstone by Langer & Co

Zürcherstrasse 2

CH-8852 Altendorf

Switzerland

info@halderstone.com

www.halderstone.com