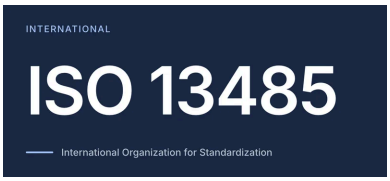
SmartSuite

Framework / Quality & Safety / ISO Industry Standards

ISO 13485:2016

ISO 13485:2016 specifies quality management system requirements for organizations in the medical device life-cycle and is the basis of the FDA's QMSR and the EU harmonized standard.



What it is

ISO 13485:2016 is the international standard for quality management systems of organizations involved in one or more life-cycle stages of a medical device, from design and development to servicing. ISO's technical committee ISO/TC 210 published it as the third edition on March 1, 2016, replacing ISO 13485:2003 and ISO/TR 14969:2004.

It specifies requirements for regulatory purposes: the organization identifies its role or roles under applicable regulatory requirements, identifies the requirements that apply to those roles and builds them into its quality management system (introduction, 0.1). Suppliers and other external parties can use it too (clause 1). It is a stand-alone standard based on ISO 9001:2008, and conformity to it does not by itself claim conformity to ISO 9001 (0.4).

At a glance

PUBLISHER
International Organization for Standardization (ISO)

TYPE
Standard

VERSION
ISO 13485:2016

EFFECTIVE
March 1, 2016 (third edition published; ISO sets no separate effective date)

DOMAIN
Quality & Safety

FAMILY
ISO Industry Standards

REGION
International

INDUSTRY
Healthcare & Life Sciences

ADOPTION MODEL
Certification

IMPLEMENTATION COMPLEXITY
High

Source: iso.org/standard/59752.html

Why it matters

- **A regulatory basis** The FDA's QMSR incorporates ISO 13485:2016 into 21 CFR Part 820 from February 2, 2026, and EN ISO 13485:2016 is listed as a harmonized standard for Regulation (EU) 2017/745.
- **A medical device file for each device** One or more files per device type or family contain or reference the documents that show conformity to the standard and to regulatory requirements (clause 4.2.3).
- **Design records that stay current** A design and development file per device type or family includes or references conformity records and records of design changes (clause 7.3.10).
- **Regulator-facing processes** Complaint handling (8.2.2), reporting to regulatory authorities (8.2.3) and control of nonconforming product detected after delivery (8.3.3) are written into the system.

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How SmartSuite supports ISO 13485:2016

Quality Manual and Document Control

Hold the quality policy, procedures and the justification recorded for any clause not applicable (clauses 1 and 4.2.2).

Medical Device Files

Keep one record per device type or family that links to the documents in its medical device file (clause 4.2.3).

Design and Development Records

Track design stages, reviews, verification, validation, transfer and changes against each device (clauses 7.3.2 to 7.3.10).

Supplier and Purchasing Controls

Record supplier evaluation, purchasing information and verification of purchased product (clause 7.4).

Complaints and Regulatory Reporting

Log complaints and reports made to regulatory authorities with dates and owners (clauses 8.2.2 and 8.2.3).

Nonconformities, Audit and Review Actions

Track nonconforming product, corrective and preventive actions, internal audit findings and management review actions to closure (clauses 5.6, 8.2.4, 8.3 and 8.5).

Common framework mappings

IEC 62304

ISO 14971:2019

Official resources

ISO 13485:2016 Standard

Defines requirements for a quality management system specific to medical devices for regulatory compliance.

iso.org/standard/59752.html

ISO 13485 Implementation Guidance

Provides official guidance on implementing ISO 13485 requirements in medical device organizations.

iso.org/publication/PUB100234.html

ISO 13485:2016 Application Information

Outlines application of ISO 13485 for quality management in medical devices, ensuring safety and effectiveness.

iso.org/publication/PUB100398.html

Frequently asked questions

What is ISO 13485:2016 and who uses it?

ISO 13485:2016 is the third edition of the ISO quality management system standard for organizations involved in one or more life-cycle stages of a medical device, and for suppliers that provide product or services to them (clause 1). Manufacturers, importers, distributors and others identify their role under the regulations that apply and build those requirements into the system (0.1).

Is ISO 13485 certification mandatory?

The standard itself does not require certification; it says certification bodies and other parties can use it to assess an organization's system (0.1). Whether a certificate is needed depends on the market. In the United States, the FDA's QMSR incorporates ISO 13485:2016 into 21 CFR Part 820 instead, and MDSAP gives one audit that serves several regulators.

How does ISO 13485 relate to the FDA's QMSR?

The Quality Management System Regulation took effect on February 2, 2026 and amends 21 CFR Part 820 to incorporate ISO 13485:2016 and clause 3 of ISO 9000:2015 by reference. The FDA states that the rule now specifically requires risk management. Where an ISO 13485 clause conflicts with the Federal Food, Drug, and Cosmetic Act or its regulations, those control.

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What are the medical device file and the design and development file?

For each device type or family, clause 4.2.3 requires one or more files that contain or reference documents showing conformity to the standard and compliance with regulatory requirements. Clause 7.3.10 requires a design and development file that includes or references conformity records and records of design changes.

Can an organization exclude requirements?

Yes, within limits. A requirement in clause 6, 7 or 8 that does not apply because of the organization's activities or the device can be left out, and the justification is recorded as described in 4.2.2. Design and development controls can be excluded only where regulatory requirements permit, and conformity claims must reflect it (clause 1).

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Full framework page and mappings: smartsuite.com/frameworks/iso-13485-medical-device-quality-management-systems-2016