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ISO 13485:2016 Revision Factsheet

A quick guide to the revised
ISO 13485:2016 standard.

What is ISO 13485?

ISO 13485, Medical devices – Quality management systems – Requirements for regulatory purposes, addresses the development, implementation and maintenance of a quality management system intended for use by medical device manufacturers and suppliers. The standard details requirements for a quality management system that meets customer requirements and allows the incorporation of applicable regulatory requirements within an organisation's quality management system.

In the EU, the requirements of EN ISO 13485 have been harmonised with the Conformity Assessment Procedures of the EU's Medical Device Directive (93/42/EEC), the Directive for In Vitro Diagnostic Medical Devices (98/79/EC) and the Directive for Active Implantable Medical Devices (90/385/EEC). Conformity Assessment Procedures in conjunction with a certification to EN ISO 13485 by a Notified Body provides a presumption of compliance with relevant EU legislation. Health

Canada also requires medical device manufacturers marketing their products in Canada to have their quality management system certified to ISO 13485.

Although ISO 13485 is similar in scope and intent to ISO 9001, it also includes additional quality management system requirements that can be used by an organisation involved in one or more stages of the medical device life-cycle. As a result, ISO 9001 certification is generally not an acceptable substitute for certification to the requirements of ISO 13485.

The ISO 13485 revision

Work to revise ISO 13485 began in April 2012. Because the revision of ISO 13485 was the first since the standard's last revision in 2003, the ISO working group responsible for the revision faced the significant task of addressing nearly a decade of changes in technology and regulatory requirements.



In addition, during the years since the publication of ISO 13485:2003, existing management standards continued to evolve and new management systems standards were introduced. The ISO working group was also challenged with finding ways of integrating ISO 13485 requirements more closely with those of other management systems standards to ease the implementation and maintenance process for device manufacturers with multiple management systems in place.

Activity related to the current revision of ISO 13485 was accelerated in 2015 with the publication of a second version of the Draft International Standard (DIS)/ISO 13485 in February 2015, and the release of a Final Draft International Standard (FDIS)/ISO 13485 on 29th of October 2015 for balloting by ISO member countries. The revised standard ISO 13485:2016 was published on 1st March 2016.

Summary of the key changes

The ISO 13485 revision includes significant changes in a number of important areas. The following sections offer a summary of these changes.

Quality management system (Clause 4)

All processes that are part of a manufacturer's quality management system will now need to be developed using a risk-based approach. This represents a significant expansion of the risk management approach in ISO 13485:2003, in which only product design controls and product realisation processes were subject to risk management requirements. In addition to this important change, processes that are outsourced must also apply a risk-based thinking approach.

This section of the standard also requires that any software used as part of the quality system be validated and documented. In addition, the revised standard requires the maintenance of a comprehensive technical file for each manufactured device that includes a description of the device along with all relevant specifications and records.

Management responsibility (Clause 5)

Changes to this section of ISO 13485 primarily involve clarifications of existing requirements regarding quality management system planning, responsibility and authority, management representation and management review.

Resource management (Clause 6)

The standard will now require device manufacturers to define the specific skills and experience required for personnel involved in the maintenance of the quality management system. Further, ISO 13485 certified organisations will be required to maintain systems for ensuring that personnel maintain the requisite knowledge through ongoing training, as well as a mechanism for assessing the effectiveness of such training.

A new clause in this section also addresses contamination control issues for sterile medical devices, and includes requirements related to the validation of processes intended to ensure the integrity and effectiveness of sterile device manufacturing requirements.



Product realisation (Clause 7)

Clause 7 addresses specific requirements within each of the areas defined within this enlarged scope of product realisation. Further, as previously noted, medical device manufacturers will be expected to incorporate risk management principles in determining the application of these requirements. New sub-clauses have been added in design and development for transfer of design and development outputs to manufacturing and maintaining a design and development file.

Measurement, analysis and improvement (Clause 8)

Under this section of the revised standard, device manufacturers will be expected to formalise their processes for obtaining feedback from both production and post-production activities, and to develop sound methods for incorporating that feedback into its risk management programme. The revised standard also strengthens requirements regarding the investigation and control of nonconforming products, as well as those related to corrective and preventative actions. New sub-clauses have been created in monitoring and measurement for complaint handling and reporting to regulatory authorities.

Other considerations

It is important to note that the revision of ISO 13485 does not adopt the so-called high-level structure for management system standards detailed in Annex SL of the ISO Directive. As a result, there are important structural differences between the revised ISO 13485 and the recently published ISO 9001:2015. These differences are likely to complicate the compliance and auditing process for medical device manufacturers who are currently certified to both ISO 13485 and ISO 9001.

How can you prepare?

The published version of ISO 13485 will provide a three year transition period for device manufacturers and other organisations certified to ISO 13485:2003. However, given the extent of the anticipated changes, as well as the structural differences between the revised ISO 13485 and ISO 9001:2015, transitioning to the new requirements is likely to require a considerable investment of time and resources. Therefore, medical device manufacturers and other ISO 13485 certified organisations are advised to promptly begin the process of evaluating the application of the standard's new requirements to their existing quality management system, in order to determine the scope of required changes and the time required to implement them.

How can we help you?

TÜV SÜD Product Service is the largest Notified Body for medical devices in the world, and a leading certification body for quality management systems applicable to the manufacture and component supply of medical devices. Our audit teams include experts with the skills and expertise needed to accurately assess the compliance of your quality management system. Even though we do not provide specific advice, instructions or solutions towards the development and implementation of a management system, we can provide you with generic information needed to understand your exposure to non-compliance issues. This unique combination of experience makes TÜV SÜD ideally suited to address the needs of medical device manufacturers and their suppliers seeking to achieve or maintain ISO 13485 certification.



Why choose TÜV SÜD?

TÜV SÜD offers a complete range of testing, certification and auditing services to manufacturers of medical devices and its suppliers, helping them to manage risks and to protect and promote the health and safety of patients, users and, where appropriate, other persons. Our global network of more than 500 dedicated medical health and services professionals include noted scientists and physicians recognised as authorities in their respective fields. These capabilities make TÜV SÜD the preferred single source for worldwide compliance with medical device regulations.

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TÜV SÜD is a premium quality, safety, and sustainability solutions provider specialising in testing, inspection, auditing, certification, training, and knowledge services. Represented by more than 22,000 employees across 800 locations worldwide, TÜV SÜD's service portfolio adds value to businesses, consumers and the environment.