ISO 13485:2016
Medical devices

Advice from ISO/TC 210

![ISO logo] **a practical guide**

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About this handbook

All organizations face challenges when developing or updating their quality management system (QMS) and it is hoped that this handbook will be used to provide additional insight and understanding of the requirements in ISO 13485 [1], *Medical devices — Quality management systems — Requirements for regulatory purposes*. It is not expected that you will sit down and read this handbook in one sitting, but that you might use it as a reference when questions come up about specific requirements. Therefore, it is broken up into the sections outlined in the contents in line with the clause structure of ISO 13485. It is expected that you have basic practical experience with QMS and the applicable regulatory requirements within the medical devices sector to effectively understand the guidance provided. In this handbook, advice to guide understanding of ISO 13485 and its application is given by first listing the full text of ISO 13485, followed by the intent of that section and relevant guidance. Examples have been used wherever possible as an aid to understanding what the requirements mean.

This handbook has been written by a task group of technical experts from ISO's Technical Committee TC 210. A draft was circulated to all the member national standards bodies and liaison organizations of ISO/TC 210 to obtain feedback and comments; these have been considered by the task group prior to release of the final text. The requirements of ISO 13485 are general in nature and, with the exception of a few subclauses that are applicable to specific medical device types, are intended to be applicable to all medical device organizations, regardless of their type, size, or the product they provide. This handbook is intended to guide organizations that provide product, including services, that affect any part of the lifecycle or supply chain of a medical device. Such organizations can be manufacturers, importers, distributors, service providers or authorized representatives. In addition, this handbook can be useful to regulatory authorities and certification bodies concerned with conformity to ISO 13485.

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1)   In this handbook, the reference to ISO 13485 pertains to the third edition published in 2016 unless a different date is included in the reference.

The guidance given in this handbook describes concepts and methods that can be considered by your organization to assist in the development, implementation and maintenance of your QMS and this can be applicable to the design, development, production, installation, servicing and post market surveillance of medical devices. This handbook has taken into consideration requirements and guidance contained in documents as listed in the bibliography from the following organizations:

- International Medical Device Regulators Forum (IMDRF) including those documents maintained from the disbanded Global Harmonization Task Force (GHTF);
- International Organization for Standardization (ISO);
- European Committees for Standardization (CEN and CENELEC);
- National regulatory bodies.

This handbook does not define any requirements nor add to or otherwise change the requirements of ISO 13485 and is intended to assist interested parties with the application of ISO 13485. The guidance contained in this handbook is intended for educational purposes and is not intended to be used to assess or audit compliance with regulatory requirements or to be used for identifying specific deficiencies of a QMS, unless the guidance is voluntarily incorporated into the documentation describing and supporting your organization's QMS, or unless such guidance is specifically made part of the regulatory requirements relevant to your organization's operation. It should be noted that this handbook does not set out to provide specific guidance with respect to generic QMS requirements which are common to both ISO 13485 and ISO 9001.

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Foreword

Quality Management Systems (QMS) — General comments

A QMS is the way your organization directs and controls those activities that are related, either directly or indirectly, to achieving its intended results. Broadly, it consists of your organization's structure together with the planning, processes, resources and documents or records that you use to achieve your quality objectives (such as meeting your customers' and applicable regulatory requirements, establishing and maintaining your QMS, or improving your product).

Generic QMS requirements are defined in ISO 9001 and are intended to be applicable to any organization, regardless of its type or size, or the product it provides. However, the requirements of ISO 13485 are intended to be applicable to any medical device organization regardless of size and activity as a basis for demonstrating and supporting compliance with applicable regulatory requirements. User should also be aware that ISO 13485 is based on the format of its previous edition (ISO 13485:2003) and ISO 9001:2008 and not the High Level Structure for Management System Standards as defined in ISO/IEC Directive, Part 1, Annex SL used for ISO 9001:2015. Annex B of ISO 13485 contains a table cross-referencing the clauses of ISO 13485 and ISO 9001:2015.

Further reference can be sought from ISO 9000:2015 *Quality management systems — Fundamentals and vocabulary*, including the fundamental concepts, the quality management principles, as well as the terms and definitions for quality management. Any differences in definitions of terms between ISO 9000 and ISO 13485 are contained in Clause 3 of ISO 13485.

When putting a QMS in place, a good understanding of the detailed requirements for a QMS is necessary. There are several sources for information that you can use (see the bibliography), in addition to this handbook. The standards and other references provided in this handbook could be used by your organization to meet the applicable regulatory requirements, but that is a decision your organization should make and this handbook does not outline any requirements to adopt conformity to any standard.

One fundamental concept that your organization has to understand is the concept of quality. From ISO 9000:2015, the quality of product includes not

only their intended function as well as safety and performance, but also their perceived value and benefit to the customer. From the perspective of the medical device industry, this includes the therapeutic benefit to a patient.

In general, QMS standards should not be confused with product standards. While product standards give explicit requirements for a particular product, including service, QMS standards specify requirements for good management practices in order to have a high probability to achieve quality, but generally without referencing any particular type of product. ISO 13485 does provide requirements for identified types of product (e.g., requirements for sterile medical devices, implantable medical devices).

The use of product standards, QMS standards and quality improvement approaches are all means of improving your organization's ability to meet customer and applicable regulatory requirements or the competitiveness of your organization (recognizing that these are not exclusive of each other).

Implementation of a QMS should not result in excessive bureaucracy, paperwork, or lack of flexibility. Nor should your QMS be an unreasonable financial burden. Expenditures relating to implementing and maintaining a QMS should be considered an investment with a return on investment in the form of benefits and improvements. Every organization will already have a management structure and this should be the basis on which its QMS is built.

What is an ISO 13485 Quality Management System?

A QMS conforming with ISO 13485 requirements is a documented set of interrelated processes, including any forms or templates, that establish, implement, and maintain the provisions outlined in the requirements of the standard with the aim of meeting customer and applicable regulatory requirements for businesses operating in the medical device sector. These processes and their interactions are also subject to improvement as directed by top management to achieve quality objectives. The intent of the latest edition of ISO 13485 is not to impose new requirements on your organization, but to clarify existing requirements that were vague, confusing or implicit in nature to ensure common interpretation by all users. If your QMS already exists and is based on one of the older editions, it will need to be updated to ISO 13485. Whether

you are implementing a new QMS or updating your existing QMS, the advice given in this handbook is relevant.

ISO 13485, Annex A provides some detailed commentary on the changes between the 2003 and 2016 editions. This annex is recommended reading prior to planning for transition as it will assist in the development of transition plans. However, the whole content of the respective clauses should be considered when determining what action is required and not just the topics listed in Annex A in order to ensure full compliance with the requirements.

Furthermore, ISO 13485, Annex B provides a correlation between ISO 13485 and ISO 9001:2015. This will be of particular use and benefit to your organization if it currently holds dual certification to both ISO 9001 and ISO 13485 and you wish to continue to hold dual certification. See the guidance on Clause 0.4 for additional information.

Why have a quality management system (QMS)?

The adoption of a QMS is a strategic decision that guides your organization to improve its overall performance and to provide a sound basis for its sustainable development initiatives. Clause 0.1 of ISO 13485 lists several reasons for having a QMS.

Many organizations implement a formal QMS after finding that their customers in both the private and public sectors want assurance that the product they intend to purchase will meet their requirements for quality. Those customers are looking for the confidence that can be provided by an organization offering product produced under a suitable, adequate and effective QMS, such as one conforming to ISO 13485.

For medical device organizations, compliance with ISO 13485 can support conformity assessment options that are used in different regulatory jurisdictions.

A QMS on its own will not necessarily lead to an improvement of work processes or to improvements of your product. It won't solve all your problems. It is a means for you to take a systematic approach to fulfilling your organization's objectives, which in turn should achieve such improvements.

ISO 13485 contains requirements for improvement, using feedback from sources such as complaint handling, post market surveillance, handling of nonconformities, corrective actions and preventive actions. You use these processes to ensure that worthwhile and cost effective improvements are being achieved.

Introduction

0.1 General

This International Standard specifies requirements for a quality management system that can be used by an organization involved in one or more stages of the life-cycle of a medical device, including design and development, production, storage and distribution, installation, servicing and final decommissioning and disposal of medical devices, and design and development, or provision of associated activities (e.g. technical support). The requirements in this International Standard can also be used by suppliers or other external parties providing product (e.g. raw materials, components, subassemblies, medical devices, sterilization services, calibration services, distribution services, maintenance services) to such organizations. The supplier or external party can voluntarily choose to conform to the requirements of this International Standard or can be required by contract to conform.

Several jurisdictions have regulatory requirements for the application of quality management systems by organizations with a variety of roles in the supply chain for medical devices. Consequently, this International Standard expects that the organization:

— identifies its role(s) under applicable regulatory requirements;
— identifies the regulatory requirements that apply to its activities under these roles;
— incorporates these applicable regulatory requirements within its quality management system.

The definitions in applicable regulatory requirements differ from nation to nation and region to region. The organization needs to understand how the definitions in this International Standard will be interpreted in light of regulatory definitions in the jurisdictions in which the medical devices are made available.

This International Standard can also be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer and regulatory requirements applicable to the quality management system and the organization's own requirements. It is emphasized that the quality management system requirements specified in this International Standard are complementary to the technical requirements for product that are necessary to meet customer and applicable regulatory requirements for safety and performance.

The adoption of a quality management system is a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by the:

a) organizational environment, changes in that environment, and the influence that the organizational environment has on the conformity of the medical devices;
b) organization's varying needs;
c) organization's particular objectives;
d) product the organization provides;
e) processes the organization employs;
f) organization's size and organizational structure;
g) regulatory requirements applicable to the organization's activities.

It is not the intent of this International Standard to imply the need for uniformity in the structure of different quality management systems, uniformity of documentation or alignment of documentation to the clause structure of this International Standard.

There is a wide variety of medical devices and some of the particular requirements of this International Standard only apply to named groups of medical devices. These groups are defined in Clause 3.

Intent

This section provides understanding that ISO 13485 specifies the QMS requirements for medical devices for regulatory purposes.

Guidance

The way you run your organization is unique. ISO 13485 gives you a framework for good management practice that you can apply to your organization. The standard specifies requirements for a QMS that has been recognized as being aligned with internationally accepted good practice for running an organization with responsibilities in the lifecycle or supply chain for medical devices.

This section describes a set of points that can be addressed in your QMS, but does not say how you do them. Furthermore, this section indicates that you do not need to align your documentation with the clause structure of the standard. Hence, there is considerable freedom in meeting the requirements of the standard.

ISO 13485 specifies the QMS requirements for medical devices for regulatory purposes. Customers could make certification to ISO 13485 a requirement for you to do business with them. A QMS aims to give confidence to your customers that your organization can deliver a product or service that conforms to requirements. It requires you to prove your ability to meet both your customers' requirements and any associated regulatory requirements.

You can decide to have your QMS assessed for certification. While this is not mandatory or required by the standard, it could be a regulatory requirement in some jurisdictions. Your organization will still benefit from the implementation and maintenance of a suitable, adequate and effective QMS, regardless of whether or not assessment or certification by a third party is a regulatory requirement.

Medical device organizations included within the scope of ISO 13485 could consider the adoption of other management systems (e.g., ISO 14001 — Environmental Management System, ISO 27001 Information Security Management System or others). Since there are no requirements for your organization to conform the structure of its QMS to the structure of any management system standard and there is no direct conflict of requirements, your organization can integrate these systems without compromising conformity.

The scope of the edition explicitly covers areas of business including supply chain/distribution and other activities throughout the lifecycle of the medical device.

When judging the applicability of the guidance in this handbook, you should consider the nature of the medical device(s) to which it will apply, the risk associated with the use of these medical devices, and the applicable regulatory requirements.

0.2 Clarification of concepts

In this International Standard, the following terms or phrases are used in the context described below.

— When a requirement is qualified by the phrase "as appropriate", it is deemed to be appropriate unless the organization can justify otherwise. A requirement is considered appropriate if it is necessary for:
  — product to meet requirements;
  — compliance with applicable regulatory requirements;
  — the organization to carry out corrective action;
  — the organization to manage risks.

— When the term "risk" is used, the application of the term within the scope of this International Standard pertains to safety or performance requirements of the medical device or meeting applicable regulatory requirements.

— When a requirement is required to be "documented", it is also required to be established, implemented and maintained.

— When the term "product" is used, it can also mean "service". Product applies to output that is intended for, or required by, a customer, or any intended output resulting from a product realization process.

— When the term "regulatory requirements" is used, it encompasses requirements contained in any law applicable to the user of this International Standard (e.g. statutes, regulations, ordinances or directives). The application of the term "regulatory requirements" is limited to requirements for the quality management system and the safety or performance of the medical device.

In this International Standard, the following verbal forms are used:

— "shall" indicates a requirement;
— "should" indicates a recommendation;
— "may" indicates a permission;
— "can" indicates a possibility or a capability.

Information marked as "NOTE" is for guidance in understanding or clarifying the associated requirement.

Intent

This section provides understanding of the concepts that have been adopted throughout ISO 13485. This understanding, together with correct interpretation, helps you apply the requirements in the standard correctly.

Guidance

Risk — Throughout ISO 13485 the use of the term risk is in the context of the safety and performance of the medical device and meeting applicable regulatory requirements. It is not to be confused with financial risks or risks to business performance. The revisions in this edition incorporate the concept of risk-based approaches to establish, implement, maintain and improve the QMS. The risks to the effective and compliant operation of the QMS should be understood. In identifying risks and opportunities, your organization should focus on preventing or reducing undesired effects through risk reduction or preventive actions. This risk-based approach should apply to all processes required for your QMS.

Services — The term product can include services. This is important as the standard now explicitly allows organizations, such as distributors, authorized agents, and providers of sterilization services, to apply the requirements in a similar way as the medical device manufacturers. These organizations do not produce a product but provide services important in the life-cycle or supply chain of medical devices.

Notes — Throughout the standard and in this handbook the reader will see additional guidance in the format of a NOTE. There can be confusion that these notes provide the solution to a requirement and therefore are required to be used or met. It is important to understand that a NOTE cannot contain requirements. They are only for additional information and guidance to help the user. The notes in ISO 13485 are intended to provide clarification or information that can be helpful to understand a requirement but are not a requirement. Notes can also contain reference to the informative references given in the Bibliography to ISO 13485 that are repeated in the Bibliography to this handbook together with additional informative references referred to in this handbook. One other clarification is that the notes within the definitions (Note to entry) are different than the NOTE within the text of the standard as the note to entry is intended to modify the definition for clarity.

0.3 Process approach

This International Standard is based on a process approach to quality management. Any activity that receives input and converts it to output can be considered as a process. Often the output from one process directly forms the input to the next process.

For an organization to function effectively, it needs to identify and manage numerous linked processes. The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the "process approach."

When used within a quality management system, such an approach emphasizes the importance of:

a) understanding and meeting requirements;
b) considering processes in terms of added value;
c) obtaining results of process performance and effectiveness;
d) improving processes based on objective measurement.

Intent

This section outlines the use of the process approach within your QMS.

Guidance

The ISO 13485 QMS is process based. The processes described in the standard should not be treated as stand-alone processes. The processes interact and overlap. Together they define a system that ensures product is in conformity and that any deficiencies are addressed in an adequate manner. For this reason, it is essential that any quality considerations are made bearing in mind the various contributions of the relevant processes. A checklist approach to assessing the adequacy, suitability and effectiveness of your QMS should be avoided as this often introduces a bias towards a given process and leads to overlooking of the process interactions and other related processes. For example, some (but not all) of the expectations of the QMS are for:

- the requirements (organization, customer, QMS, regulatory) to be implemented into controlled documents,
- personnel to be assigned to carry out tasks as defined by these documents,
- competent personnel to be trained to follow these documents,
- personnel to follow these documents and to maintain records demonstrating compliance with the documented requirements,
- personnel to use appropriate equipment (calibrated, maintained, approved) and materials (identified, verified, of known status),
- processes and product to be appropriately monitored/measured or validated, and
- any nonconformities (whether identified through customer complaint, production, internal/external audit or other processes) to be appropriately investigated and handled through application of corrective actions.

A process can be seen as a set of related activities carried out step-by-step following a logical sequence that allows you or your organization to achieve a desired result. The desired result is good/high quality product that conforms to the customer's specified requirements. The model of a process based QMS is presented in ISO 13485, Clauses 4 to 8. Customers and regulatory authorities play a significant role in defining requirements as inputs. Monitoring of

customer feedback requires the evaluation of information relating to whether your organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of ISO 13485, but does not show processes at a detailed level.

ISO 13485 promotes the adoption of a process approach to identify and manage linked processes when developing, implementing and improving the suitability, adequacy and effectiveness of a QMS with the objective of providing medical devices that meet customer and regulatory requirements.

An effective organization has to identify and manage numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next (see Figure 1).
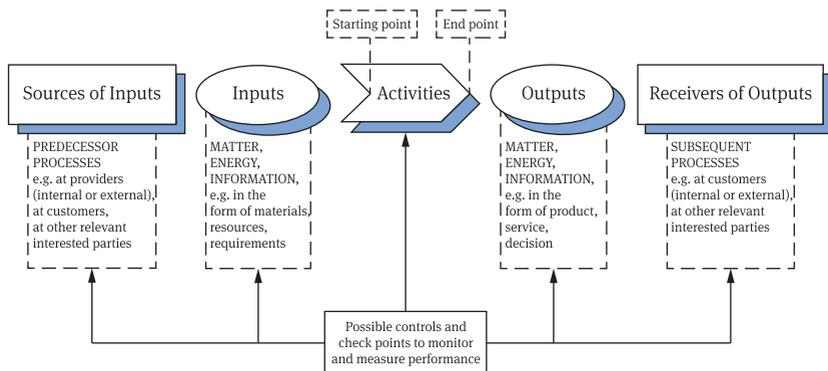

Figure 1 — Schematic representation of the elements of a single process (This figure is taken from ISO 9001:2015)

ISO 13485 employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based approach. The process approach enables your organization to plan its processes and their interactions. The PDCA cycle enables your organization to ensure that its processes are adequately resourced and managed, and that opportunity for improvement is determined and acted on. A risk-based approach enables your organization to determine

the factors that could cause its processes and its QMS to deviate from the planned results and to put in place preventive measures to minimize negative effects.

The PDCA cycle can be applied to all processes and to the QMS as a whole. The PDCA cycle can be briefly described as follows:
- **Plan**: establish the objectives of the system and its processes; the resources needed to deliver results in accordance with customers' requirements; your organization's policies; and identify and address risks and opportunities.
- **Do**: implement what was planned.
- **Check**: monitor and (where applicable) measure processes and the resulting product against policies, objectives, requirements and planned activities, and report the results.
- **Act**: take actions to maintain and improve performance, as necessary.

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

As used within a QMS, the process approach emphasizes the importance of:
- understanding and meeting requirements,
- considering processes in terms of added value,
- obtaining results of process performance and effectiveness, and
- improving processes based on objective measurement.

To conform to the requirements of ISO 13485, your organization needs to plan and implement actions to address risks. Addressing risks establishes a basis for increasing the suitability, adequacy and effectiveness of the QMS, achieving improved results and preventing negative effects. A risk-based approach is essential for achieving a suitable, adequate and effective QMS. The concept of a risk-based approach has been implicit in previous editions of ISO 13485 including, for example, carrying out preventive action to eliminate potential nonconformities, analyzing any nonconformities that do occur, and taking action that is appropriate for the effects of the nonconformity to prevent recurrence.

A deviation from the expected results can be the consequence of changes in the operational environment, lack of information, unknown information or

a variety of aspects. The identification of these aspects and their effects on the performance of your organization, and the actions that can be identified to avoid or reduce the effect or the likelihood of occurrence, is important for being able to plan properly.

> ### 0.4   Relationship with ISO 9001
>
> While this is a stand-alone standard, it is based on ISO 9001:2008, which has been superseded by ISO 9001:2015. For the convenience of users, Annex B shows the correspondence between this International Standard and ISO 9001:2015.
>
> This International Standard is intended to facilitate global alignment of appropriate regulatory requirements for quality management systems applicable to organizations involved in one or more stages of the life-cycle of a medical device. This International Standard includes some particular requirements for organizations involved in the life-cycle of medical devices and excludes some of the requirements of ISO 9001 that are not appropriate as regulatory requirements. Because of these exclusions, organizations whose quality management systems conform to this International Standard cannot claim conformity to ISO 9001 unless their quality management system meets all the requirements of ISO 9001.

Intent

This section provides guidance on the compatibility of ISO 13485 with ISO 9001.

Guidance

ISO 9001 is the generic QMS standard upon which all other management system standards are based and incorporates modern quality management principles and practices. It does not provide specific requirements needed for regulatory purposes in the medical device sector. Guidance on ISO 9001 can be found, for example, in the ISO brochures, *ISO 9001 for Small Businesses —*

What to do, and in *ISO 9000 Introduction and Package module* and on the ISO/TC 176/SC 2 public website: http://isotc.iso.org/livelink/livelink/open/tc176SC2public.

ISO 13485 has been written specifically to support regulatory requirements related to QMS relevant to industries involved in the provision of medical devices.

Both ISO 13485 and ISO 9001 have been written to be complimentary and not in conflict. However, the requirements of ISO 13485 are focused to support regulatory compliance in the medical devices sector and therefore contain specific requirements that cannot be met by ISO 9001 compliance alone. On the other hand, ISO 9001 includes some explicit requirements, such as those for continual improvement and for customer satisfaction, that were deemed not to be required for medical device regulatory purposes and that are, therefore, not included in ISO 13485.

To help you to correlate the requirements of the two standards, Annex B in ISO 13485 provides a correspondence of ISO 13485 and ISO 9001 and vice versa. This can help you integrate your ISO 13485 QMS with ISO 9001 or other management systems. This approach could be particularly relevant if you seek to operate under dual certification (i.e. ISO 13485 and ISO 9001).

0.5 Compatibility with other management systems

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, or financial management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

Intent

This section provides an outline of the relationship to other management system standards to outline the ability to meet the requirements of each in a common system.

Guidance

The relationship to ISO 9001 is outlined in the previous section. There are other sector-specific management system standards based on the requirements of the ISO 9000 series developed for a number of industries or sectors. Some of these standards specify QMS requirements, while others are limited to providing guidance to the application of the International Standard within the particular sector.

ISO 13485 was designed and written to be compatible with other management system standards. Examples of other management system standards are ISO/IEC 27001— Information Security Management and ISO 14001 — Environmental Management, where:

- ISO/IEC 27001:2013 specifies the requirements for establishing, implementing, maintaining and continually improving an information security management system within the context of an organization. It also includes requirements for the assessment and treatment of information security risks tailored to the needs of that organization. The requirements set out in ISO/IEC 27001:2013 are generic and are intended to be applicable to all organizations, regardless of type, size or nature.
- ISO 14001 and its supporting standards such as ISO 14006 focus on environmental management systems. The other standards in this family focus on specific approaches such as audits, communications, labelling and life-cycle analysis, as well as environmental challenges such as climate change.

This handbook only provides guidance on the application of ISO 13485 and your organization will need to ensure you follow the requirements outlined in other management system standards if you choose to conform with them.