ISO 13485:2016 - Medical devices - A practical guide

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a practical guide

ISO 13485:2016
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Advice from ISO/TC 210

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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.