13485 Academy
ISO 13485 Online Consultation Center

How can ISO 13485 help your business grow?

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Introduction

If you're in the business of developing and manufacturing medical devices, then "risk" and "risk management" have become terms synonymous with your daily operations. Your most important and critical responsibility is to bring a medical device to market that provides a needed function to a patient or consumer and is also proven to be safe and effective to use.

To stay ahead of the game, you must demonstrate compliance with regulatory requirements, manage risks, and ensure best practices throughout every step of a product's lifecycle, including service and delivery.

How can ISO 13485 help you in achieving this? ISO 13485 provides an international approach to meeting the wide-ranging requirements of medical device production and related services for the global market. This white paper will help you understand how your business can grow through implementing the ISO 13485 standard.

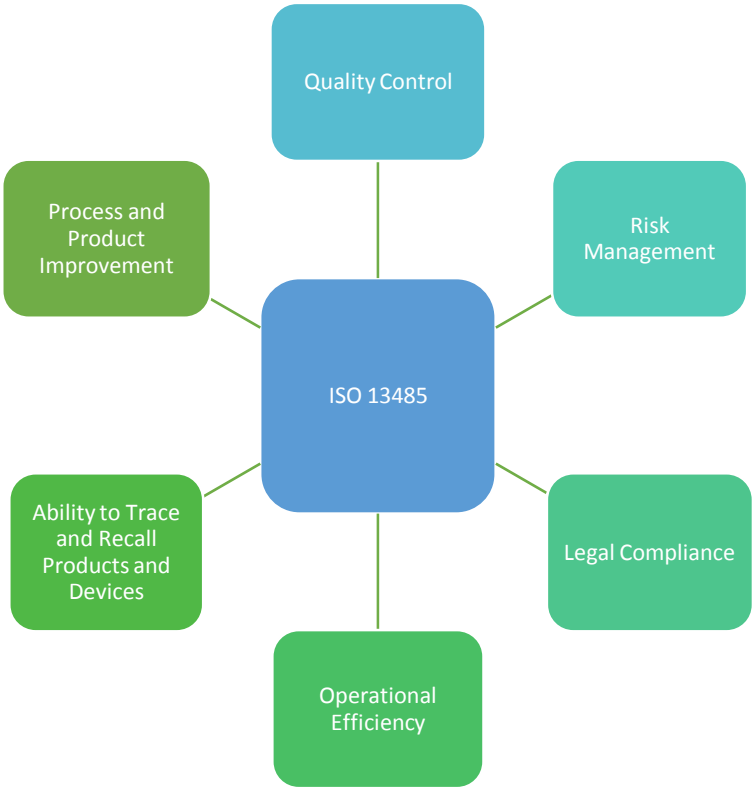
A brief overview of ISO 13485

ISO 13485 is one of the medical device industry's most widely used international standards for quality management. It is a standalone Quality Management System (QMS) standard, derived from the internationally recognized and accepted ISO 9000 Quality Management Standard series.

The primary objective of the ISO 13485 standard is to provide a harmonized model for creating and maintaining an effective QMS for the design and manufacture of medical devices in order to meet customer requirements.

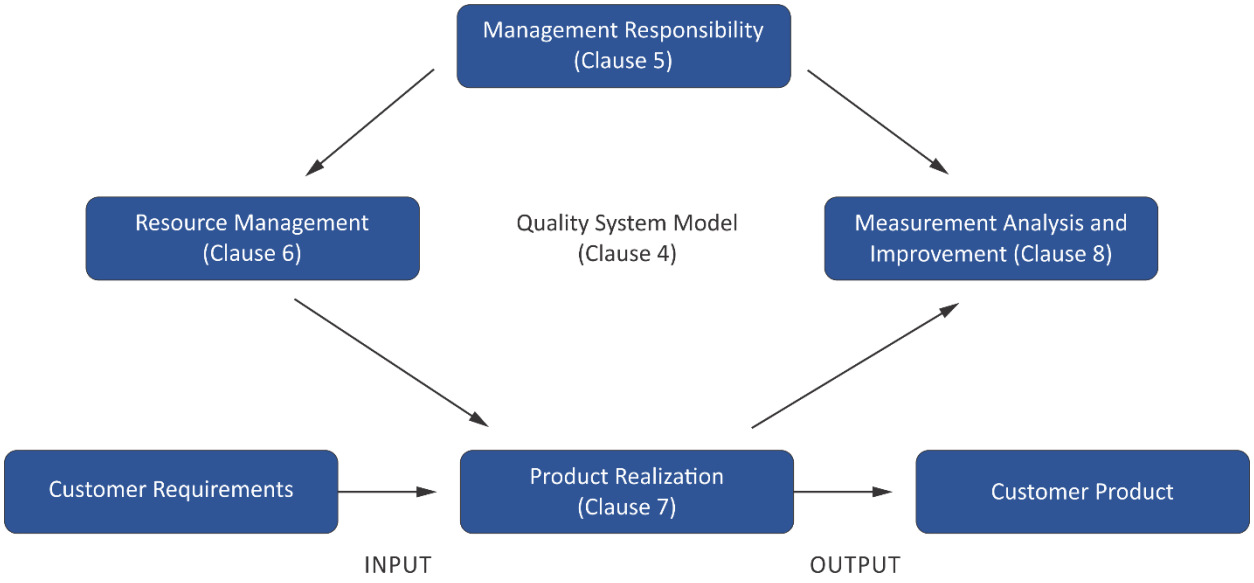
The standard contains specific requirements for a QMS for the design and manufacture of medical devices and can be used by an organization for the design, development, production, and installation and servicing of medical devices as well as for the design, development, and provision of related services in order to make the medical devices safe for their intended purpose.

The key areas addressed by ISO 13485 include:



The ISO 13485 structure is split into eight sections. The first three sections are introductory sections that describe the objective and standard application, and sections 4 to 8 contain specific standard compliance requirements. Learn more about the structure of this standard in the article ISO 13485 structure and requirements.

Figure 2 below indicates how the ISO 13485 standard is organized.



ISO 13485 benefits medical devices and related service organizations. It ensures an organizational commitment to product or service quality and also increases the efficiency and control within the organization.

An organization that is ISO 13485 certified has all of its processes in control and in compliance with an internationally recognized standard. This can help companies gain credibility with customers around the globe, no matter where they are in the supply chain.

Learn more about ISO 13485 in the article What is ISO 13485?

Who is ISO 13485 made for?

ISO 13485 applies to companies in the medical device industry involved in various stages of the medical device lifecycle, including medical device design and development, production stage, storage and dispatch, installation, and maintenance and provision of technical support services. ISO 13485 can also be used by suppliers or external agencies that provide QMS-related services or products to medical device organizations.

Organizations involved in one or more stages of the medical device lifecycle	Suppliers or external parties who provide products to such organizations
• Manufacturers of medical devices • Quality management consultants who provide consultancy services to medical device organizations • Manufacturers of sterile medical devices • Manufacturers of surgical medical devices	• Raw materials • Components • Sub-assemblies • Medical devices • Sterilization services • Calibration services • Distribution services • Maintenance services

The requirements of ISO 13485 are applicable to organizations regardless of their size and the product types, except where explicitly stated. Requirements that are specified to be applied to the medical devices should be equally applicable to the associated services supplied by the organization. The requirements may differ based upon the class of medical device – from the smallest medical device like a needle, to large devices like pacemakers used in hospitals.

If any clause(s) of ISO 13485 is not applicable due to the nature of the medical device or the activities undertaken by the organization, the organization is not required to include such requirement in its Quality Management System with a written justification.

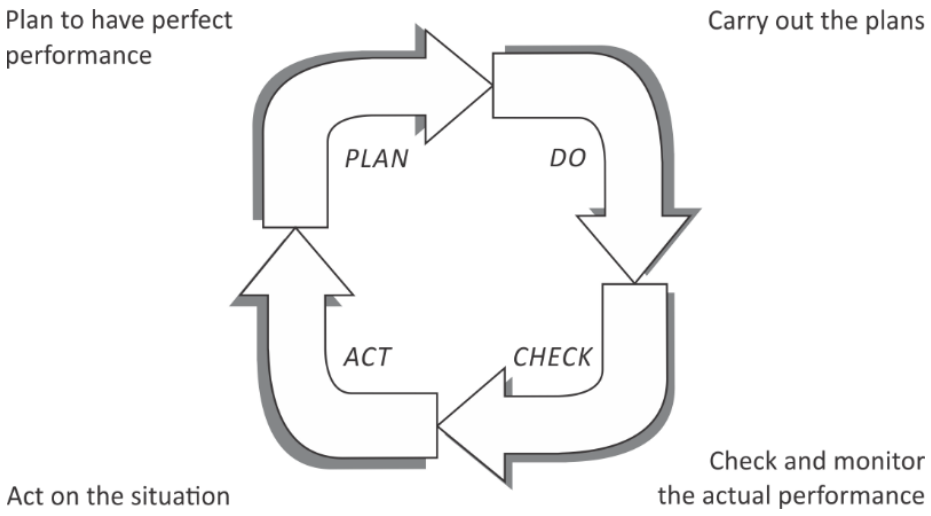
ISO 13485 is much more harmonized with international quality system regulations, e.g., the United States Food and Drug Administration (FDA) 21 CFR (Code of Federal Regulations) part 820. Also, the Medical Device Single Audit Program (MDSAP) uses ISO 13485 to reduce redundant audits of medical device manufacturers.

What is a Medical Device Quality Management System?

A Medical Device Quality Management System is a structured system of procedures and processes covering all aspects of:

- design
- manufacturing
- supplier management
- risk management
- complaint handling
- clinical data
- storage
- distribution
- product labeling, etc.

It is based on the Plan-Do-Check-Act cycle (also known as the PDCA cycle), a four-step management method used for control and continual improvement of processes and products.



Medical device manufacturing organizations require different levels of QMS. The level of the QMS is based on the device classification. For example, a Class II (medium-risk) or Class III (high-risk) device requires a more detailed and comprehensive QMS implementation than Class I (low-risk) devices.

For more about the PDCA cycle, read the article Plan-Do-Check-Act in the ISO 13485 standard.

Suggested key procedures for setting up the QMS

A few suggested key procedures for setting up the QMS include:

Overview of the requirements of a QMS

There are different requirements when implementing ISO 13485 in our system:

General requirements. In the evaluation of any ISO standard, there are a few requirements that are the driving force for the establishment and implementation of a QMS. The requirements that are specific to ISO 13485 include the following:

- adhering to the standard
- maintaining proper documentation
- ensuring the effectiveness of the implemented system
- analyzing risk factors
- minimizing risk
- identifying and following standard processes
- determining ways to track your activities, correcting any process failures or oversights, and generating records to show all the activities are being done
- determining legal requirements and following them
- maintaining responsibility for the work, even when outsourcing
- ensuring that the processes work as intended and don't negatively affect other processes

Documentation requirements. ISO 13485 has an extensive list of documentation requirements. This includes mandatory documents as well as other non-mandatory documents specified by applicable regulatory requirements. ISO requires you to document elements like:

- quality policy and objectives
- quality manual
- quality procedures and records
- medical device file
- management participation documentation
- employee training records
- documentation of infrastructure requirements needed to ensure quality
- contamination control documentation
- product realization documentation
- supplier documentation
- measurement and monitoring documentation

For more information, see this helpful article: List of mandatory documents required by ISO 13485:2016.

The benefits ISO 13485 brings to your company

The benefits of ISO 13485 cannot be overstated. Companies of all sizes have realized significant savings in cost and time, plus other improvements that an efficient Quality Management System naturally brings about. The following is a list of six top reasons to implement ISO 13485 in your company:

Improve your company's credibility and image. ISO 13485 is the internally recognized gold standard for quality in the medical device industry. Certification to this standard shows clients and customers that your company takes quality very seriously, and that you have a system in place to ensure it. Your QMS can be a powerful marketing tool, and it has become a requirement in many countries for suppliers to show compliance. This translates to more opportunity.

Improve customer satisfaction. The ISO 13485 standard is built on a set of quality management principles, one of which is ensuring customer satisfaction. This can be achieved by assessing customer needs and expectations, and striving to meet them. Customers know what they want, and what they need, and many of them will not even entertain a supplier that isn't certified. Beyond that, ensuring the satisfaction of your existing customers keeps them coming back, and helps you sell your services to new customers. This translates directly to increased revenue.

Improve your processes. Using the process approach outlined in ISO 13485, it's much easier to discover opportunities for improvements. You'll be able to identify and eliminate waste within and between processes, reduce errors, and avoid rework - facilitating greater efficiency and cost savings.

Improve decision-making. Another quality management principle of ISO 13485 regards the use of evidence-based decision making. When you use facts and data to drive your decisions, those decisions tend to be better aligned with the strategic goals of your company. While "gut feelings" may be appropriate in some social situations, they can spell trouble in business. An added bonus is the increased insight into the health of your processes, and any improvements that are made, once you keep track of the data.

Create a culture of continual improvement. A third quality management principle making up the foundation of ISO 13485 is the concept of continual improvement. When adopted as the culture in your organization, management and staff will always be on the lookout for ways to improve on how things are done. By establishing systematic processes for reducing problems and mitigating their effects, everyone will spend less time cleaning up mistakes, and more time delivering quality products and services.

Better employee engagement. When employees are asked to help look for ways to improve their own processes, not only will they often provide the best insight – they will also be much happier and more invested in the success of the company. The more your employees understand their roles in delivering quality products and services, the more engaged they are, which leads to increased efficiency and productivity.

Learn more about the consequences of noncompliance in the article What are the consequences of noncompliance with ISO 13485 for manufacturers of medical devices?

Learn more about ISO 13485 advantages related to purchasing in the article How can ISO 13485 clause 7.4, Purchasing, enhance procurement?

How does ISO 13485 fit to small and medium-sized enterprises (SMEs)?

With the use of quality standards, access to the market is much easier, especially for SMEs. They can give their brand more recognition and, for the customers, the assurance that the technology they are using is safe and reliable. They can meet the regulation requirements at a lower cost. Cost is reduced in all aspects of their business.

For SMEs, ISO 13485 provides a competitive advantage and helps improve their business performance and manage their business operations. Having these standards introduced into the business, SMEs can attract investors and enhance their reputation. It also encourages better internal communication and can help build the morale of small businesses.

To implement ISO 13485 in the business, SMEs should have a clear objective and adequate resources to monitor performance and metrics. Proper planning should be done, and management should have clear expectations.

ISO 13485 implementation and certification

Each medical device manufacturer has its own issues to address in order to implement ISO 13485, but a common approach that any organization can take to manage its implementation project should include the steps outlined below:

1. Get management support.
2. Identify the legal and regulatory requirements, customer requirements, and other requirements that you need to satisfy with your QMS.
3. Define your QMS scope to have a better idea of what needs to be done, and the boundaries of your implementation.
4. Define processes and procedures that must be part of your QMS.
5. Implement processes and procedures.
6. Deploy training and awareness programs to help the employees in your organization understand the basics of ISO 13485 and the purpose of implementation.
7. Choose a certification body.
8. Operate the QMS and measure the system.

9. After you have operated the QMS for the prescribed length of time and before the certification body conducts their audit, perform an internal audit of each process. Take corrective action to resolve any issues you find.
10. Conduct management review at planned intervals to ensure the continuing suitability, adequacy, and effectiveness of the QMS.
11. Look for the root cause of the problems discovered during internal audits, measurements, and management review, and then take the necessary action to correct the problems at the source.
12. Perform the stage 1 certification audit.
13. Perform the stage 2 certification audit.

For more information, see these helpful materials:

- Checklist of ISO 13485 implementation and certification steps
- Five main steps in the ISO 13485:2016 internal audit
- How to perform management review according to ISO 13485
- Project proposal for ISO 13485:2016 implementation

Conclusion

At the most basic level, ISO standards simply apply the best organizational practices to a company business. Adopting the ISO 13485 standard is beneficial to medical device companies, as it encourages them to focus on the product or services delivered, the business processes followed, and the way the business is managed. It gives accurate feedback on the products and whether they have met the expectations in terms of quality, safety, and efficiency. Whether we want to set up our business domestically or internationally, we need to regulate the business. It is becoming a pre-requisite for many customers, so if we have this standard implemented in our system, we can win new business and increase our market prospects.

Sample of documentation templates

- ISO 13485:2016 Documentation Toolkit

Free downloads

- Checklist of Mandatory Documentation Required by ISO 13485:2016
- Diagram of ISO 13485:2016 Implementation Process

References

- 13485Academy
- ISO 13485

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