



GUIDE TO ISO 13485



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WHAT IS ISO 13485?

The ISO 13485 standard governs quality management for medical devices and related services. It's published by the International Organization for Standardization. ISO 13485 addresses:

- **Quality control**
- **Risk management**
- **Legal compliance**
- **Operational efficiency**
- **Ability to trace and recall products and devices**
- **Process and product improvement**

The most recent update to the standard was published in February of 2016, overriding previously published versions from 2003 and 1996. ISO 13485 derived from ISO 9001, a quality management certification that's available to businesses in a wide variety of industries.

However, medical device and pharmaceutical companies have specialized requirements that made some of the requirements of ISO 9001 difficult to apply. ISO 13485 was developed to address these needs.

ISO 13485 provides a great advantage for organizations producing medical devices and related services. It assures a commitment to quality and increases efficiencies within the organization. Becoming ISO 13485 certified can increase client base and reduce barriers to entry of foreign markets, product liabilities, and production down-time.

The auditing process can appear overwhelming, but it does not have to be. For those seeking their first ISO 13485 certification the following information can serve as a starting place for implementation.



THE BENEFITS OF IMPLEMENTING ISO 13485:2016

Businesses that have implemented ISO 13485 cite numerous benefits; many companies seek certification because of the financial benefits to their business. Certification demonstrates their commitment to building high-quality medical devices; that allows them to attract more clients than ever before.

1. Ability to Contract with Larger Companies

Many large medical device businesses prefer to work with vendors who are ISO 13485 certified. The 2016 update to this standard may make this even more desirable. The revisions mean that large companies are responsible for ensuring that any subcontractors conform to ISO 13485 standards. That means subcontractors who already have the certification are likely to be prioritized.

2. Demonstrate Commitment to High Quality

Both ISO 13485 and ISO 9001 are seen as indicators of an organization's commitment to quality. Achieving a quality management certification demonstrates to customers and regulators that your company values quality.

3. Expand Potential Market

Standards like ISO 13485 are created to ensure that medical devices in different places demonstrate the same reliability and quality. If you're considering exporting products, ISO 13485 certification can lend an advantage. Not only is it the first step to regulatory approval in major markets like the European Union and Canada, but it also demonstrates the quality of the product to potential buyers.

4. Help Personnel Access Relevant Information

The documentation requirements in this standard are designed to ensure that all members of a development team have access to the information they need, when they need it. Having access to the right information can reduce the time and expense associated with product development.

5. Expand and Consolidate Business Knowledge

We also hear from clients that documenting the processes associated with their medical device helps the business develop a consolidated knowledge base. This knowledge can help to identify problems, improve the product, and streamline the manufacturing process. It also makes the process of on-boarding new employees easier.

6. Make Achieving ISO 9001 Certification Easier

Many businesses hold both ISO 13485 and ISO 9001 certifications. If your business is ISO 13485 certified, achieving ISO 9001 certification is significantly easier. The requirements of these two standards are generally harmonised. ISO 9001 does contain a few requirements related to business clauses that ISO 13485 doesn't cover.



GETTING CERTIFIED FOR ISO 13485

Getting certified for an ISO standard can be a difficult process. Preparation and good organization can make it less stressful.

Understanding the requirements of ISO 13485 is a good place to start. Your auditor will be referring to these standards as they evaluate your organization. Documenting and organising your quality management procedures is another important step.

Next, make sure employees as well as management know the organization's quality management processes. Keeping everybody on the same page will help the audit process go smoothly.

It is often required to conduct an internal audit before conducting the external audit for certification. An internal audit can help you determine whether any changes need to be made to your quality management system before certification.

It's also important to choose the right auditor to conduct the audit. Since an audit is fundamentally an on-site verification of your quality management processes, look for an auditor with a local presence. This can speed up the auditing process and reduce problems that arise from language or cultural barriers.

Your auditor should also be experienced. For instance, NQA has conducted more than 50,000 certifications in 90 different countries. This means that, when questions about logistics or the audit process arise, our experienced auditors can help you find the answer.

When NQA audits a business, we work with your processes and procedures. That means you won't be required to add processes that don't work for your business. Dedicated Customer Service representatives will ensure that you have feedback throughout the registration process so that you can address questions that arise during the auditing process quickly, and get back to work sooner.

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