Management System Certification for Medical Device Manufacturers

ISO 13485:2003

The History of ISO 13485:2003

Introduced by the International Organization for Standardization in July 2003, ISO 13485:2003 is recognized throughout the world as a quality management system standard **designed specifically for medical device manufacturers.**

Based on the **same basic principles as ISO 9001:2008**, ISO 13485:2003 is often seen as a crucial first step in ensuring manufacturing and design processes consistently **produce quality products that meet regulatory requirements**. ISO 13485:2003 is used to assist in the synchronization of quality management systems and medical device regulatory requirements. Because of this, the standard includes various requirements for medical devices and excludes various requirements of ISO 9001. As a result , those companies that are registered to ISO 13485:2003 cannot necessarily claim compliance with ISO 9001.

Manufacturers who assemble a combination of non-medical as well as medical products should also consider working to and meeting the requirements of ISO 9001:2008 with the possibility of registering to the standard.

Important Aspects of the Standard

1. ISO 13485:2003 was written as a model to meet the quality system requirements of various global regulations.
2. ISO 13485:2003 is **compatible with other "non-quality" management systems such as ISO 14001, or OHSAS 18001**.
3. If a company meets ISO 13485:2003 requirements, it should **easily be able to meet the FDA QSR requirements**. Although ISO 13485:2003 has not been adopted by the FDA, the FDA participated in writing ISO 13485:2003 to ensure the requirements are aligned.
4. **Risk management is a key element** of ISO 13485:2003. ISO 14971 serves as a guide for risk management.
5. **TR 14969 is a guidance document** for the use and implementation of ISO 13485:2003.
6. Since ISO 13485 was written as a model for regulatory requirements, it has additional procedures requirements to the procedural requirements of ISO 9001
7. There is no significant relationship between ISO 13485:2003 and ISO 9001:2008.

Special Points and System/Process Requirements

The ISO 13485:2003 standard has eight sections. Three sections are general information for manufacturers about the standard and are not auditable. Certification focuses on the five key auditable sections:

- **Quality Management System**
- **Management Responsibility**
- **Resource Management**
- **Product Realization**
- **Measurement, Analysis, and Improvement**

Additional special points and system/process requirements of ISO 13485 include:

- Focus on meeting **regulatory requirements**
- **Risk management** systems
- Clinical evaluations and/or evaluation of medical device performance as required by national or regional regulations is necessary for design and development validation
- Product **cleanliness and contamination** controls
- Requirements for **implantable devices**
- Proper communication of **advisory notices**
- Additional **research and development** requirements

Advantages of Registration to ISO 13485:2003

With ISO 13485:2003 registration, manufacturers are provided with a **process-based model** and approach to developing and improving effectiveness of a quality management system.

ISO 13485:2003 registration also assists in meeting customer and global regulatory requirements by:

- **Maintaining global recognition** as the best quality practices from companies within the medical device industry
- **Enabling companies to work within various countries** and organizations, meeting necessary regulations and obligations
- **Helping to create an organized framework** in which companies can maintain and evaluate their processes and customer response
- **Providing a framework** to ensure maintenance and improvement of the effectiveness of those processes with applicable requirements

- **Enabling improved performance,** such as increased sales, increased timeliness in getting products to the global marketplace, reduced costs, fewer errors, less waste, better use of time and resources and a lower product failure rate
- **Demonstrating compliance with European Union Directives** through establishment and independent assessment of the quality management system

Who Should Register?

- Companies who manufacture **private label** medical devices and hope to eventually place them in the EU market
- Organizations that **design and assemble** medical devices
- Medical **component manufacturers**
- Manufacturers that want to prepare for future **IVD regulatory obligations** to enter the EU

Steps to Registration

No matter what a manufacturer's QMS situation, the following steps will help prepare for ISO 13485:2003 registration:

1. **Purchase and read the standard** — Reading the standard is the only way to get a good understanding of the requirements. Once you have bought it, familiarize yourself with the basic concepts and process model, and review all the specific requirements.
2. **Consider training** — In order to gain more knowledge about ISO:13485:2003, manufacturers should consider attending a training course on the standard. Training in ISO 9001:2008 should also be considered.
3. **Develop a transition plan** — A well thought out transition plan, including a gap analysis and responsibility allocation, is key to the success of the transition.
4. **Implement the standard** — Begin using ISO 13485:2003, keeping in mind to use process mapping, flow charting, and electronic systems to remain in control of the QMS.
5. **Change procedures and communicate to organization** — As the users of the new QMS, company employees need to have a full understanding of what changes are being made.
6. **Consider a pre-assessment** — A pre-assessment can be a great way to ensure an organization is prepared to pass the registration audit the first time.
7. **Schedule a registration audit** — Schedule a date for registration assessment, and be ready enjoy the benefits of being ISO 13485:2003 registered.

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SRI Quality System Registrar

Quality • Environmental • Security
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Pittsburgh Headquarters
300 Northpointe Circle
Suite 304
Seven Fields, PA 16046

TEL 724.934.9000
FAX 724.935.6825