Information Guide

PQSmitra
Simple & Practical

ISO 13485:2016
QMS for Medical Devices

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What is ISO 13485?

ISO 13485 Medical devices - Quality management systems - QMS. It represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices.

ISO 13485 requirements include compliance to ISO 9001 and Other sector specific requirements. These include:

- The promotion and awareness of regulatory requirements as a management responsibility.
- Controls in the work environment to ensure product safety
- Focus on risk management activities and design control activities during product development
- Specific requirements for inspection and traceability for implantable devices
- Specific requirements for documentation and validation of processes for sterile medical devices

Specific requirements for verification of the effectiveness of corrective and preventive actions

While it remains a stand-alone document, ISO 13485 is generally harmonized with ISO 9001. A principal difference, however, is that ISO 9001 requires the organization to demonstrate continual improvement, whereas ISO 13485 Certification requires only that the certified organization demonstrate the quality system is effectively implemented and maintained. Additionally, the ISO 9001 requirements regarding customer satisfaction are absent from the medical device standard.

Which Organizations are eligible for ISO 13485 Certification?

- The certification is availed primarily by the companies which are into design and manufacture of medical devices. This ISO 13485 standard can also be used in other industry sectors when a quality management system with additional requirements over an ISO 9001:2015 system is needed.

What are the focus points of ISO 13485 Certification?

- Integration of customer requirements specific to design and manufacture of medical devices
- Standardization of the manufacturing processes and other business processes
- Risk management and Contingency planning
- Formulating Quality Policy and Objectives
- Setting up system for documentation and records.
- Management information system
- Business performance and sustainability

What are the document requirements for ISO 13485 Certification?

The organization shall demonstrate continual improvement in the field of quality management system for medical devices by maintaining, establishing, implementing and providing documented information.

- The documented information required for ISO registration
- The organizations scope for Medical Devices
- The organizations Quality policy and Quality Objectives
- A Quality Manual (Medical Devices)
- Standard operating Procedures
- Records at individual process / department. E.g. Sales, Purchase, Production, Quality Assurance, Maintenance, Customer Service.

How will ISO 13485 Certification Benefit your Organization?

- Opportunity to supply ISO 13485 medical devices and/or supply to medical devices OEM.
- Recognition and opportunity to cater to the export market
- Recognition of the certificate and the system by other industry sectors
- Improved product safety and traceability management
- Manufacturing process controls enhancing Quality and Productivity
- Business process streamlining and efficiency improvement
- Better business performance and Enhanced sustainability.

How did ISO 13485 evolve throughout the year?

- ISO 9000:2015 - Quality management system (QMS)
- ISO 10012, Measurement management systems — Requirements for measurement processes and measuring equipment.

What happens to my existing Certificate when any standard is revised?

- Generally, whenever there is a revision, the previous standard is kept valid for 2 to 3 years. It is also called as transition period. Earlier the organization certified as per previous standards is expected to upgrade and get certified in accordance with revised new standard.

How long will it take me to get ISO Certified?

- This dependence on a number of factors, like the size of your firm, the complexity of your processes, the procedures you already have in place, and so on. Implementation can take 2-3 months for a smaller company (less than 100 people) and 5- 6months for a larger organization (more than 100 employees). The procedure is also influenced by the amount of time and resources your firm has to devote to implementation. That time should be factored into your overall schedule ahead of time, especially if you have a registration deadline to meet.

How much does QMS ISO Certification Cost?

- The ISO certification cost is determined by a variety of criteria, including internal resourcing capabilities, pre-existing management system documentation, as well as the size and scope of products and services offered by the organization. The cost of the Certification Body and the cost of the ISO Consultant are two of the most important charges involved.

Is QMS ISO 13485 Certification (ISO Registration) difficult?

- An ISO certification will need time, effort, and improvement from a variety of departments inside a company. The steps that must be done, however, are well worth it for any organization. Owners, staff, and customers will all gain from it.

How PQSmitra help you with a Hassle – Free Implementation Process for ISO 13485:2016?

ISO 13485 Certification being a specific standard for design and manufacture of medical devices, the requirements are very stringent as it directly associated with the human health and safety. The manufacturing and administrative controls expected to be implemented are at shop floor and office processes as well. In such scenario, the practical, easy and effective implementation of the system is very essential. PQSmitra team with an expertise more than 20 years has supported many clients implement ISO 13485 and get the successful certification.

The ISO 13485:2016 implementation process is described below:

- Review of the existing QMS - Quality Management System. This review is carried out through discussions and verifications of records during visits to the client organization. Product safety related requirements are assessed right from the designing and manufacturing operations.
- 100% documentation support is offered by PQSmitra. This includes shop floor controls as well as control on documentation and records.
- Training and hand holding for better understanding of the requirements and effective implementation.
- Routine assistance and system verification to ensure compliance to the requirements.
- Internal audit and Management review
- ISO 13485 Certification audit – Stage 1 and Stage 2
- Submission of action plan on audit observations
- Review of report by the certification authority and awarding the certificate to the organization.

PQSmitraService Features appreciated by clients

Simple & Practical Approach

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