ISO 13485 : 2016
Medical Devices

WHAT IS ISO 13485?

ISO 13485 is a type of Quality Management System (QMS) for companies that provide medical devices. Anyone in the medical device industry knows that products need to consistently meet client and regulatory requirements. ISO 13485 is an internationally trusted standard that ensures such vital technology as yours is safe, effective and delivered to a high quality. Not only does the certification help you become compliant with national and international legal requirements, but it will help to open your business to a global market.

The ISO 13485 standard applies to any quality management system involved in the design, development, installation, production and servicing of medical devices. For this standard, a medical device - as described in the European Medical Directive - is:

"… any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the necessary software for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment, or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of or compensation for injury or handicap
- Investigation, replacement or modification of the anatomy or of a physiological process
- Control of conception

And which does not achieve its principal intended action in or on the human body by pharmacological, immunology or metabolic means, but which may be assisted in its function by such means ..."

"Mark and Richard have been superb; working with IMSM is a pleasure. We could not have implemented ISO 13485 without the assessors help. Partnering with IMSM has been critical to our success".

Dawn S.

WHO NEEDS ISO 13485?

Whatever product your business produces, medical device manufacturers are responsible for consistently delivering safe and efficient devices, which can be achieved through an effective ISO 13485 QMS.

Regulatory authorities in most major markets (including the European Union, United Kingdom, United States, Canada, Japan, and Taiwan) require, or strongly prefer, that manufacturers' who market medical products in their countries have a third-party audited and certified Quality Management System. An ISO 13485 compliant system expedites access into those countries that require it.

BENEFITS OF ISO 13485

- Competitive advantage through improved customer satisfaction and stakeholder relationships.
- Increase business growth - win more contracts and attract larger customers.
- Full ISO 13485 compliance - a prerequisite for regulatory authorities everywhere.
- Reduced operating costs through continual improvement and optimized efficiencies.
- ISO 13485 will also help you to monitor your supply chain so that you are always in control.
- Legal compliance - be confident that your company has a quality system that meets legislation demands in every corner of the global market.
- ISO 13485 will establish robust development, manufacture, distribution and control processes.
- Improved risk management - greater consistency and traceability.

RELATED SERVICES AND PRODUCTS

Beyond ISO 13485, IMSM can also introduce your business to a range of management system standards designed to be compatible and integrated to help develop and grow a profitable company by delivering audit efficiency, consistency and continual improvement.

IMSM also offers one-day and two-day Internal Auditor Training Courses and a range of services and additional products.

To explore the ways ISO standards can help to improve your business, **contact IMSM today** for an informal discussion with your local IMSM Area Manager.

Take the next step: request your no-obligation, fixed fee, custom quote today.