approved training body and have earned a reputation of integrity for contributing value and best practice. IMSM guarantees that your ISO Specialist will be highly qualified and trained to assist and audit your organisation to ISO certification.

- **Full service:** IMSM offers full implementation; we will produce the manuals and make the process as simple as possible by improving the systems already in place.
- **Training:** IMSM offers training to supplement your ISO. Training with IMSM is flexible and delivered by experienced IMSM Trainers.

What is involved?

- Our Consultant will perform a Gap Analysis which acts as the initial step in the review of your company's internal processes and practices or management systems, where applicable, to determine where your company is today in relation to achieving the standard.
- The Consultant will produce the necessary ISO documentation, which will include processes, policies, and procedures required by the Standard.
- If required, IMSM will develop and deliver tailored training programmes for your staff to supplement your ISO implementation, to ensure a full understanding and implementation of the quality controls being put in place, by way of employee development.
- The external audit is the monitoring of the company's conformance to the ISO standard. IMSM will continually support your business through the aforementioned stages as well as leading up to the audit, offering support and guidance to conformity.
- Once your organisation is confirmed as being ISO compliant, your organisation will be submitted to the certifying body deemed suitable. Upon successful completion of the audit your organisation will then be awarded certification.

Related services

Beyond ISO 13485, IMSM can also introduce your business to a range of management system standards to help develop and grow a profitable business, including:

- ISO 9001 Quality Management
- ISO 14001 Environmental Management
- ISO 27001 Information and Data Security
- ISO 45001 Health and Safety Management

These standards are all designed to be compatible and can be integrated to deliver audit efficiency, consistency and optimisation. 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.

Email: enquiries@imsm.com
Web: www.imsm.com

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Medical Devices

ISO 13485

ims
TM
iso specialists

Business challenge

Regulatory authorities in most major markets (including the European Union, United States, Canada, Japan, and Taiwan) require, or strongly prefer, that manufacturers marketing medical products in their countries have a third-party audited and certified Quality Management System in place. An ISO 13485 compliant system expedites access into those countries that require it. Whatever devices they produce, medical device manufacturers have the responsibility to consistently deliver devices that are safe and efficient.

Business solution

Based on ISO 9001's process approach to quality management, ISO 13485 focuses on the design, development, installation, production and servicing of medical devices. Its primary objective is to facilitate harmonised medical device regulatory requirements.

What is ISO 13485?

ISO 13485 allows you to evaluate and demonstrate your ability to supply medical devices and related services that meet customer expectations and complies with regulatory requirements.

The standard calls for:

- Implementation of a Quality Management System with several enhancements.
- Risk management approach to product development and product realisation.
- Validation of processes.
- Compliance with statutory and regulatory requirements.
- Effective product traceability and recall systems.

What are the key benefits to your organisation?

ISO 13485 is the most accepted global standard of its kind and will bring your business a host of benefits, including:

- 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 optimised 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 the demands of legislation 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.

Why choose IMSM?

The IMSM approach is based on a key set of principles in order to create balanced and sustained results for our clients:

- **Fixed fee:** IMSM ISO implementation is priced at a fixed rate from day one. No hidden charges, no unexpected invoices.
- **Flexible implementation:** Designed to fit around your organisation requirement and schedule.
- **Expertise:** All IMSM ISO Specialists and Consultants are successfully trained to the highest standard by an IRCA or equivalent

ISO 13485 - Prove that your company is providing safe and effective medical devices