

## Practical solutions

Our Qualified Assessors will:

- examine your company's key activities in relation to medical standards
- help you to establish a program to deal with any areas that do not comply
- produce Policy and Procedures Manuals based on your business systems
- help your staff understand and implement an effective Management System
- conduct a training program with your staff
- conduct an audit of your management systems to monitor conformance.

Once confirmed that your Management Systems are in place and assessed we will advise you regarding suitable registration.



**Don't take a chance  
find out more!**

**Contact us Now:**

**Business Manager**



**Email: [enquiries@imsm.com](mailto:enquiries@imsm.com)  
Web: [www.imsm.com](http://www.imsm.com)**



## What is ISO 13485

ISO13485:2003 is the technical specification applicable to the management systems for the design, development, installation, production and servicing of medical devices.

The European Medical Directive describes a Medical Device as:

“.....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 principle 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 .....

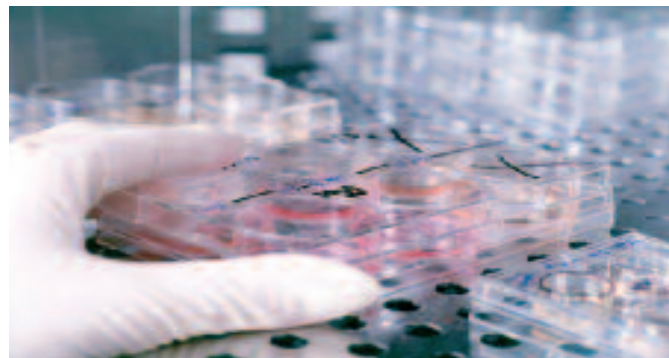
ISO 13485:2003 is not a product standard. It's a process standard. Therefore, it's not enough to establish a management system that complies with the ISO 13485:2003 standard, you also need to comply with all relevant product and service oriented technical standards and regulations.

## Why do I need ISO 13485?

- To establish a management system that is oriented towards the design, development, production, and installation of medical devices and related services.
- To demonstrate your ability to supply medical devices and related services that meets customer expectations and complies with regulatory requirements.
- To evaluate how well your organisation is able to meet customer expectations and comply with regulatory requirements.

Effective management systems are recognised as a key regulatory consideration for allowing medical device manufacturers to market their products around the world. The level of management system will vary from market to market and depend on the risks and hazards associated with the devices.

Whatever devices they produce, medical device manufacturers have the responsibility to constantly deliver devices that are safe and efficient.



## International Standards are our business

For more than 10 years, and with thousands of satisfied clients around the world, IMSM has worked with many companies to achieve ISO standards. IMSM adds value by attracting new clients and improving efficiency, through quality (ISO 9001), information security (ISO 27001), environmental (ISO 14001), health & safety (BS OHSAS 18001), and other management systems, providing a fixed fee, fixed timescale, integrated solution.

You are guaranteed:

- IRCA qualified and experienced assessors
- Fixed fee for better budgeting
- Smooth integration of own systems
- No red tape or bureaucracy
- Potential savings through better working practices
- Consultancy help with documentation and manuals

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**[www.imsm.com](http://www.imsm.com)**