

Medical Devices

Quality Management System Solutions for the Medical Device Industry



In today's business climate, good governance, corporate responsibility and effective risk management are business critical. Successful organisations, regardless of their industry, are cognisant of this environment and proactive in their response.

Medical device manufacturing and medical service companies have additional concerns; not the least of which is the need to demonstrate compliance to multiple national regulatory requirements as a prerequisite to market entry.

The global solution for more than 6000 medical device organizations in over 70 countries includes the development, implementation and certification of a management system based on ISO 13485:2003.

The Standard

With an emphasis on Risk Management, **ISO 13485:2003, Medical devices - Quality management systems - Requirements for regulatory purposes** specifies the requirements for a quality management system where an organization must demonstrate its ability to provide medical devices and related services that consistently meet customer and regulatory requirements.

A primary objective of the International standard is to provide a harmonized set of medical device regulatory requirements; facilitating entry into global markets. Consequently, ISO 13485:2003 provides a sound platform for compliance to national regulatory requirements including:

- EU CE Mark Medical Device Directives, Annex II, V and VI,
- CMDCAS (Classes II, III and IV), and
- FDA Quality System Regulation, 21 CFR 820.

Correlation to ISO 9001:2008

ISO 13485:2003 is a process approach model based on the widely accepted ISO 9001 Quality Management System Standard. Because of its inherent regulatory focus, which drives the need to maintain documents and records in accordance with national regulatory agencies, the standard's requirements relating to documentation are much more prescriptive than those in ISO 9001:2008.

Those requirements in ISO 9001 that have no regulatory significance have been excluded. This means that an organization certified to ISO 13485:2003 can not claim compliance to ISO 9001:2008 unless the excluded requirements have been adequately addressed. It also means that the Standards are compatible and the delta between them can be bridged quite successfully.

Inform...Assess

Complex business issues require customized solutions delivered by an organization that understands your industry and your needs.

Whether you need to satisfy contractual agreements, demonstrate regulatory compliance, improve internal processes, or enhance your competitive edge, SAI Global can help.

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