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# ISO 13485:2003
# Medical Devices Management System

## What is ISO 13485?

ISO 13485 is quality system standard designed specifically for medical device companies. The standard is mandatory for most Class 2a, 2b and 3 medical devices and IVDs in Europe and Canada. The ISO 13485 standard supplements ISO 9001 and has many of the same requirements. However, there are additional requirements for process control, design control, retention of records, accountability, traceability, customer satisfaction and more.

ISO 13485:2003 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.

## What is the purpose of ISO 13485?

The primary objective of ISO 13485:2003 is to facilitate harmonized medical device regulatory requirements for quality management systems. As a result, it includes some particular requirements for medical devices and excludes some of the requirements of ISO 9001 that are not appropriate as regulatory requirements. Because of these exclusions, organizations whose quality management systems conform to this International Standard cannot claim conformity to ISO 9001 unless their quality management systems conform to all the requirements of ISO 9001.

## What are the requirements of ISO 13485?

All requirements of ISO 13485:2003 are specific to organizations providing medical devices, regardless of the type or size of the organization. Some key points adopted by the ISO-13485 include: 1) focus on meeting regulatory requirements; 2) focus on meeting customer requirements; 3) use of a process approach; 4) maintenance of the effectiveness of quality management systems; and 5) maintenance of procedural documentation.

If regulatory requirements permit exclusions of design and development controls, this can be used as a justification for their exclusion from the quality management system. These regulations can provide alternative arrangements that are to be addressed in the quality management system. It is the responsibility of the organization to ensure that claims of conformity with ISO 13485:2003 reflect exclusion of design and development controls.

If any requirement(s) in Clause 7 of ISO 13485:2003 is(are) not applicable due to the nature of the medical device(s) for which the quality management system is applied, the organization does not need to include such a requirement(s) in its quality management system.

The processes required by ISO 13485:2003, which are applicable to the medical device(s), but which are not performed by the organization, are the responsibility of the organization, and are accounted for in the organization's quality system.

Special system/ process requirements of the ISO-13485 include: 1) risk management systems; 2) clinical evaluations and trials; 3) product cleanliness and contamination controls; 4) requirements for implantable devices; 5) proper communication of advisory notices; and 6) additional research and development requirements.

## Benefits of Registration to ISO 13485

- ISO 13485 promotes harmonisation of regulatory requirements for manufacturers of medical devices on an international scale.
- A number of countries have incorporated ISO 13485 into their regulatory systems. Compliance with ISO 13485 can be used in support of regulatory compliance.
- Enables your organization to become more cost-effective.
- Improves internal communications, efficiency and resilience to change.
- Improves product and process quality and provides a basis for meeting regulatory requirements.
- Requires your organization to monitor and improve key business and customer satisfaction measures.
- Certification to ISO 13485 satisfies a significant portion of the EU Directive requirements for marketing medical devices in Europe.