



investtrend

Medical Devices Quality Management

Protecting the Integrity of the Medical Device Industry!

ISO 13485 is an international standard that specifies requirements for regulatory purposes for medical device manufacturers. It provides a framework for companies to meet their customer and regulatory requirements. It is becoming widely accepted as the international standard to address medical device requirements around the world.

The main goal is to provide a harmonized model for quality management system requirements in the international market since different countries might have different standards. While it remains a standalone document, ISO 13485 is generally harmonized with ISO 9001. It includes some particular requirements for medical devices with emphasis on;

- The promotion and awareness of regulatory requirements as a management responsibility.
- Controls in the work environment to ensure product safety.
- Focus on risk management activities and design transfer activities during product development.
- Specific requirements for inspection and traceability for implantable devices.
- Specific requirements for documentation and validation of processes for sterile medical devices.
- Specific requirements for verification of the effectiveness of corrective and preventive actions.

Compliance with ISO 13485 is often seen as the first step in achieving compliance with European Union regulatory requirements.

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.

All requirements of ISO 13485:2003 are specific to organizations providing medical devices, regardless of the type or size of the organization.

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.

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 management system.