



Your Risk Management
Advantage

WHY ISO 13485 IS IMPORTANT TO MEDICAL DEVICE MANUFACTURERS

LRQA.COM



RECOGNIZED INDUSTRY REQUIREMENT

Many medical device manufacturers now require their suppliers and service providers to be ISO 13485 certified as a prerequisite for doing business.

ENHANCED MARKETABILITY

Certification helps organizations differentiate themselves from competitors by demonstrating commitment to quality and regulatory compliance.

SUPPORTS COMPLIANCE WITH GLOBAL REGULATORY REQUIREMENTS

ISO 13485 provides a harmonized quality management framework that aligns with regulatory expectations across major jurisdictions (e.g., U.S., Canada, Europe, Japan, Australia, Brazil).

FOCUS ON PATIENT SAFETY

The standard emphasizes consistent control of processes to ensure safe, reliable, and effective medical products.

REDUCES RISK THROUGHOUT THE PRODUCT LIFECYCLE

ISO 13485:2016 integrates risk management and risk based decision making into every phase, from design to post market activities.

STRENGTHENS TOP MANAGEMENT ACCOUNTABILITY

Increased requirements for leadership responsibility ensure regulatory compliance is supported at the highest level.

GREATER CONTROL OVER SUPPLIERS AND OUTSOURCED PROCESSES

Ensures quality and compliance are maintained throughout the supply chain.

HELPS PREVENT INCIDENTS AND REPUTATIONAL HARM

A well functioning QMS reduces the likelihood of quality failures that could compromise patient safety or damage brand reputation.

SERVES AS A FOUNDATION FOR MDSAP AUDITS

ISO 13485:2016 certification supports and integrates well with the Medical Device Single Audit Program, streamlining compliance across multiple markets.



RISK MANAGEMENT IN ISO 13485

ISO 13485 places **significant emphasis on risk management** as a foundational element of a medical device manufacturer's quality management system (QMS). Risk management is not viewed as a single activity but as an **ongoing, lifecycle wide process** integrated into all stages of design, production, and post market processes.

1. A RISK BASED APPROACH TO THE ENTIRE QMS

ISO 13485:2016 explicitly requires organizations to adopt a risk based approach across the entire QMS, ensuring that decisions, controls, and processes are proportionate to the risks associated with the medical device.

This means:

- Risk is considered when defining and implementing all QMS processes.
- Risk controls must be designed to reduce the probability of harm throughout operations.

2. RISK MANAGEMENT THROUGHOUT THE PRODUCT LIFE CYCLE

The standard reinforces the expectation that manufacturers manage risk from initial design through manufacturing, installation, servicing, and post market activities.

Key lifecycle stages include:

- **Design & development** – identifying hazards and implementing risk controls early.
- **Supplier management** – ensuring purchased components and outsourced processes meet risk related requirements.
- **Production & process controls** – maintaining consistency to prevent defects.

3. INTEGRATION WITH REGULATORY REQUIREMENTS

ISO 13485 helps establish a risk management framework aligned with regulatory expectations across major jurisdictions (FDA, Health Canada, EU MDR, etc.). The standard's focus on risk supports compliance with these requirements by ensuring that hazard identification, control measures, and verification steps are documented and traceable.

RISK MANAGEMENT IN ISO 13485

4. EMPHASIS ON PREVENTING INCIDENTS THAT COULD AFFECT PATIENT SAFETY

Because medical devices directly impact patient health, risk management functions as a preventive mechanism to avoid failures, adverse events, and potential hazards that could harm patients. The factsheet emphasizes that patient safety depends on quality and consistency, and effective risk management reduces the likelihood of incidents or reputational damage.

5. INCREASED CONTROLS OVER SUPPLIERS AND OUTSOURCED PROCESSES

Manufacturers must also apply risk based controls to:

- Supplier selection
- Evaluation
- Monitoring
- Qualification

This ensures that external partners do not introduce uncontrolled risks into the device or

- Post market surveillance – monitoring complaints, incidents, and feedback to detect emerging risks.

6. ROLE OF TOP MANAGEMENT IN RISK MANAGEMENT

ISO 13485:2016 enhances requirements for leadership accountability, mandating that top management ensure:

- Regulatory compliance
- Adequate risk controls
- Appropriate allocation of resources to mitigate risk

This underscores that risk management is not just a technical function, it is a strategic and organizational responsibility.

ABOUT LRQA

LRQA is a leading global risk management partner.

Through our connected risk management solutions, we help you navigate an evolving global landscape to keep you one step ahead.

From certification and cybersecurity, to safety, sustainability and supply chain resilience, we work with you to identify risks across your business. We then create smart, scalable solutions, tailored to help you prepare, prevent and protect against risk.

Through relentless client focus, backed by decades of sector-specific expertise, data-driven insight and on-the-ground specialists across assurance, certification, inspection, advisory and training, we support over 61,000 organisations in more than 150 countries.

LRQA – Your risk management advantage.

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