THE GROWING DIVIDE

WHY ISO 13485:2016 IS THE ONLY CHOICE WHEN IT COMES TO PATIENT SAFETY

WHAT YOU CAN'T SEE CAN HURT YOU.

DON'T PUT YOUR PATIENTS AT RISK.

ARE YOUR VENDORS UP TO DATE?

The medical device industry has shifted to a higher standard, introducing a growing divide in quality and patient safety assurance.

General

ISO 9001:2015

A generic framework to enhance customer satisfaction in a wide range of industries; not focused on the safety and efficacy of medical devices.

- LANDSCAPING
- FLORAL
- LOGISTICS
- CONSTRUCTION
- PROFESSIONAL CLEANING

VS

Medical Devices

ISO 13485:2016

A rigorous, patient-focused and risk-based quality management system to ensure those in the high-risk medical device industry are delivering the highest level of patient safety and quality.

- MEDICAL DEVICE DESIGNERS
- MEDICAL DEVICE MANUFACTURERS
- MEDICAL DEVICE SERVICERS

One is for:
REPAIRING LAWNMOWERS

The other is for:
SERVICING VENTILATORS

THERE IS NO SUCH THING AS A HARMLESS SHORTCUT

Third-party ISO 13485:2016 certification ensures patient safety isn't compromised at any step of the medical device lifecycle.

3 KEY REQUIREMENTS

(Out of 80+) to illustrate why ISO 13485:2016 is the only acceptable standard.

RISK-BASED APPROACH

WHY IT MATTERS:

New standards require a risk-based approach at every step of a provider's Quality Management System (QMS), with consideration for the impact of medical device technology — from software to documentation.

CUSTOMER FEEDBACK

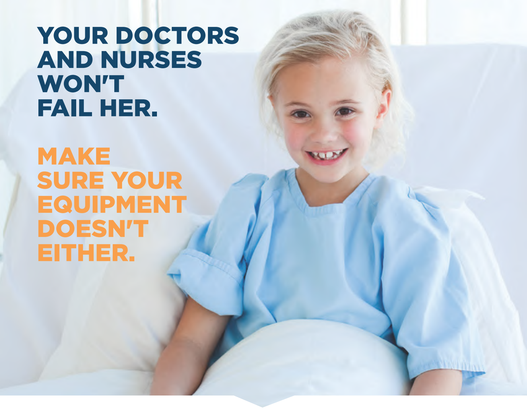
WHY IT MATTERS:

ISO 9001 focuses on customer satisfaction; ISO 13485 focuses on customer feedback on device performance. The difference? Added focus on keeping patients safe, not just happy.

RECALL MANAGEMENT

WHY IT MATTERS:

A rigorous recall management process to ensure quick customer notification of recalls — active identification of impacted devices. Minimizes both patient risk and hospital disruptions caused by recalls.



YOUR DOCTORS AND NURSES WON'T FAIL HER.

MAKE SURE YOUR EQUIPMENT DOESN'T EITHER.

THE CHOICE IS CLEAR

ISO 9001:2015 vs ISO 13485:2016

	ISO 9001	ISO 13485
Determine, monitor and review external and internal issues	✓	✓
Use risk-based thinking for planning and management	✓	✓
Provide and maintain resource monitoring	✓	✓
Monitor and analyze implementation with an internal audit program	✓	✓
Utilize risk-based approaches that consider patient safety through every step		✓
Provide early warning of quality issues through a feedback system		✓
Investigate equipment incidents reported through customer feedback		✓
Maintain the suitability and effectiveness of the quality management system		✓
Control medical devices with regard to advisory notices (product recalls, etc.)		✓
Control the work environment to prevent contamination		✓
Retain obsolete controlled documents for the life of the medical device		✓
Staff trained and supervised to work in special conditions (bloodborne pathogens, etc.)		✓
Control of customer property, including confidential health information		✓
Validation of computer software		✓
Full traceability of devices, including documents and records		✓

Align your patient safety goals with a vendor committed to the highest standards in the country.

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