ISO 13485 MEDICAL DEVICES QUALITY MANAGEMENT SYSTEMS

In today's global marketplace, many organizations are utilizing ISO 13485 as a platform to build their business management system. Certification to ISO 13485 is key to securing and maintaining global business. ISO 13485 sets regulatory requirements for a management system for medical devices or services, and can also be used to meet customer requirements.

The primary objective of the standard is to harmonize medical device regulatory requirements for quality management systems and is specific to organizations providing medical devices or services, regardless of the type or size of the organization. Based on the ISO 9001 process approach to quality management, ISO 13485 focuses on what manufacturers must do to provide safe and effective medical devices.

BENEFITS OF CERTIFICATION TO ISO 13485

Registration allows organizations to demonstrate regulatory compliance and commitment to risk management. Third-party certification is preferred in many international markets, and is the accepted basis and starting point to achieve the medical device CE mark for products manufactured or sold in Europe. It can also be used as a benchmark to meet Good Manufacturing Practice (GMP) compliance in the United States. An ISO 13485 certified quality management system can aid access to U.S. and international markets. It also:

- Enables your organization to prepare for product-to-market regulatory requirements for the medical device markets of Europe, Australia, Asia and all major developed and emerging markets
- Provides confidence of quality risk management and Good Manufacturing Practices within the medical device supply chain throughout the medical device product lifecycle
- Demonstrates that appropriate regulatory requirements are implemented within your organizational processes
- Offers confidence that best practice validation and GMP have been implemented and evaluated
- Satisfies a significant portion of the EU Directive requirements for marketing medical devices in Europe



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NSF-ISR Qualifications

> NSF-ISR was one of the first U.S. registrar to obtain ANAB accreditation for ISO 13485.

> Our auditors are professionals, experienced in business management systems and the medical device industry.

> Audits focus on customer satisfaction, business goals and objectives.

NSF-ISR Advantages

> We bring real-world knowledge and practical experience to our auditing program.

> We offer value-added auditing. Our approach ensures audits focus on important business areas.

> NSF-ISR's lead auditors are assigned to your organization on a long-term basis.

> Our stringent auditor training and ongoing evaluations ensure consistency of your audits.

> Additional services including expert training and education in medical device design, testing and manufacture are available through NSF Health Sciences.

Whether your goal is to enhance operations, expand locally or operate internationally, ISO 13485 certification demonstrates your organizations commitment to quality.

OTHER SERVICES

NSF-ISR offers comprehensive management systems registrations to internationally accepted standards for many industries, including ISO 9001 Business/Quality Management, ISO 14001 Environmental, AS91XX and FAA Advisory Circular (AC) 00-56B Aerospace, IATF 16949 Automotive, OHSAS 18001/ ISO 45001 Occupational Health and Safety, ISO/IEC 20000 Information Technology, and ISO 27001 Information Security.

Additional NSF International services include audits, certification, testing, and training for the food, water and health science industries as well as a full range of sustainability solutions for your company.

For more information, visit **www.nsf-isr.org** or contact: **information@nsf-isr.org**

NSF INTERNATIONAL STRATEGIC REGISTRATIONS (NSF-ISR)

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