

ISO 13485

Ensuring the Success of Your Medical Device Quality Management System

ISO 13485 contains requirements essential for organizations operating at any tier in the medical device supply chain. While ISO 13485 is a standard unto itself, it is largely based on the ISO 9001 model for the convenience of its users. Its primary objective is to facilitate standardized medical device regulatory requirements. The ISO 13485 standard includes requirements for process validation, installation and servicing activities, risk management, and documented procedures and records.

Organizations can register to ISO 13485 as a standalone certification or in conjunction with other standards such as ISO 9001 or AS 9100. An ISO 13485 certification from NQA USA demonstrates your organization's commitment to providing products and services that consistently meet medical industry customer and regulatory requirements.

Benefits of ISO 13485 Registration

- ▶ Creates a competitive advantage
- ▶ Ensures a consistent and effective approach to business management
- ▶ Reduces risk factors by employing risk management techniques
- ▶ Provides repeatability and consistency within the manufacturing processes
- ▶ Engages top management involvement

Why Choose NQA?

- ▶ We tailor our programs to fit your organization's specific needs
- ▶ We provide strong back office support with a Client Support Representative dedicated to your account
- ▶ We can conduct integrated audits (audits of more than one standard at a time)
- ▶ You will be assisted by accredited professional auditors who are competent and personable

Requirements

- ▶ Basic Quality System requirements with several enhancements for medical device manufacturers
- ▶ Risk Management approach throughout the quality management system
- ▶ Validation of processes
- ▶ Consideration of statutory and regulatory requirements
- ▶ Use of advisory notices as communication tools
- ▶ Recordkeeping assuring product consistency, positive product traceability, and recall

Let us help you become ISO 13485 certified!

Contact NQA USA today by calling us toll-free at 800-649-5289 or email us at info@nqa-usa.com



Contact us

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