

Medical

Ensuring the Success of your Medical Device Quality Management System

ISO 13485:2003 contains requirements essential for organizations operating at any tier in the medical device and pharmaceutical supply chain. While ISO 13485 is a standard unto itself, it is largely based on ISO 9001 and follows that format for the convenience of its users. The primary objective of the standard is to facilitate harmonized medical device regulatory requirements and as a result, it includes some particular requirements for manufacture, installation and servicing, such as added requirements on record-control, sterilization and risk management.

Organizations can register to ISO 13485 as a standalone or in conjunction with an ISO 9001 or other registration. An ISO 13485 certification from NQA, USA demonstrates your organization's commitment to provide products and related services that consistently meet customer and regulatory requirements applicable to the medical industry.

Benefits

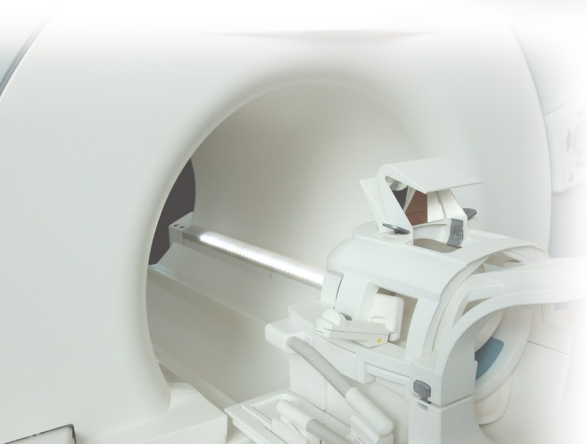
- Creates a competitive advantage.
- Ensures a consistent and effective approach to business management.
- Reduces risk factors via the use of risk management techniques.
- Engages top management involvement.
- Provides a robust framework for assuring product consistency.

Requirements

- Basic Quality System requirements with several enhancements.
- Risk Management approach to product development and product realization.
- Validation of processes.
- Consideration of statutory and regulatory requirements.
- Tracking and record keeping assuring positive product traceability and recall.

Why Choose NQA?

- Client-tailored programs designed to fit your needs.
- Strong back office support with a Client Support Representative dedicated to your account.
- "Interactive Audit" process.
- Professional, competent and personable auditors.
- Straightforward approach; no hidden fees or requirements.



R E G I S T R A T I O N S E R V I C E S

For more information on how we can help with your ISO 13485 registration, call the North American Headquarters at 800-649-5289 or visit our web site at www.nqa-usa.com.