QHSE SOLUTIONS

Advisory | Independent Assurance | Knowledge Management

ISO 13485

QUALITY MANAGEMENT SYSTEM -MEDICAL DEVICES

ISO 13485 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.

The primary objective of ISO 13485 is to facilitate harmonized medical device regulatory requirements for quality management systems. As a result, it includes some particular requirements for medical devices and excludes some of the requirements of ISO 9001 that are not appropriate as regulatory requirements.

Benefits of ISO 13485

Most companies choose to achieve ISO 13485 Certification for 'key business benefits', which include:

- Increase access to more markets worldwide with certification
- Outline how to review and improve processes across your organization
- Increase efficiency, cut costs and monitor supply chain performance
- Demonstrate that you produce safer and more effective medical devices
- Meet regulatory requirements and customer expectations

ISO 13485 Standard

This international standard is based off the ISO 9001 international standard with specific requirements to meet regulatory needs. This standard, applicable on a voluntary base, was designed in particular for medical device manufacturers;

The ISO 13485 standard, officially named EN ISO 13485:2003, can be used by organizations in the design, development and production process for medical devices but also related services. It can also be used by notification bodies to meet regulatory requirements.

Though replicating the format of ISO 9001, ISO 13485 switches the focus from customer satisfaction and continual improvement to standardization of regulatory requirements for medical devices manufacturers. ISO 13485 can be achieved by upgrading from ISO 9001 or as a standalone certification.

Certification provides many tangible benefits:

- Reduce operational costs by highlighting process deficiencies and improving efficiency
- Increase customer satisfaction by consistently delivering quality products and systematically addressing complaints
- Proven commitment to quality through an internationally recognized standard
- Adds transparency to the way complaints, surveillance or product recalls are handled

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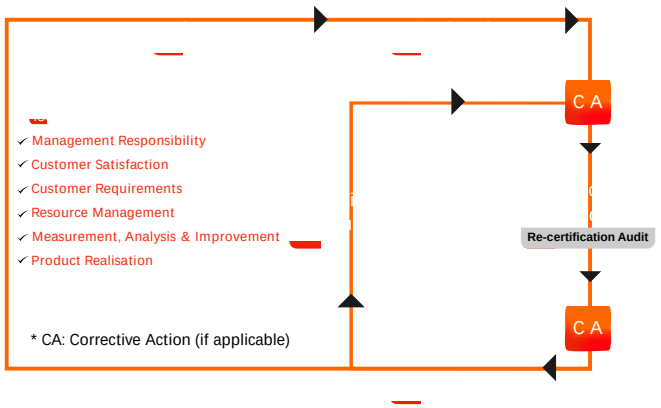
Key steps in our approach are:

- Contract signature
- Pre-audit (optional): gap analysis and diagnosis of your systems current position against requirements of the standard;
- Initial Audit: to verify the establishment and implementation of th basic structure of your system
- Certification audit (certificate issued after successful certification audit);
- Surveillance audits to follow the continual improvement;
- Re-certification after 3 years through full audit or continual assessment.

Following each step, a factual and comprehensive report is promptly delivered allowing your company to continually improve its management system performance.



ISO 13485 Standard

Recognition:

QHSE Certification is accredited by IABCI-(E) for ISO 13485 certification.

Business understanding:

Our auditors understand that the application of the standard can be quite different in small, medium and large organizations, and are trained to assess your system in a way that will be appropriate to your business. Our customers chose us because they know we're a partner they can depend on, and they continue to stay with us each year because they value the insight that their auditor gives to their business. Registration is more than a certificate; it's an opportunity to make your business better, and QHSE Certification partners with customers to ensure they receive the most from their audits.

Combined services:

QHSE Certification offers the possibility of combined certifications to the largest range of recognized standards, bringing consistency, optimization and efficiency.

QHSE Solutions

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