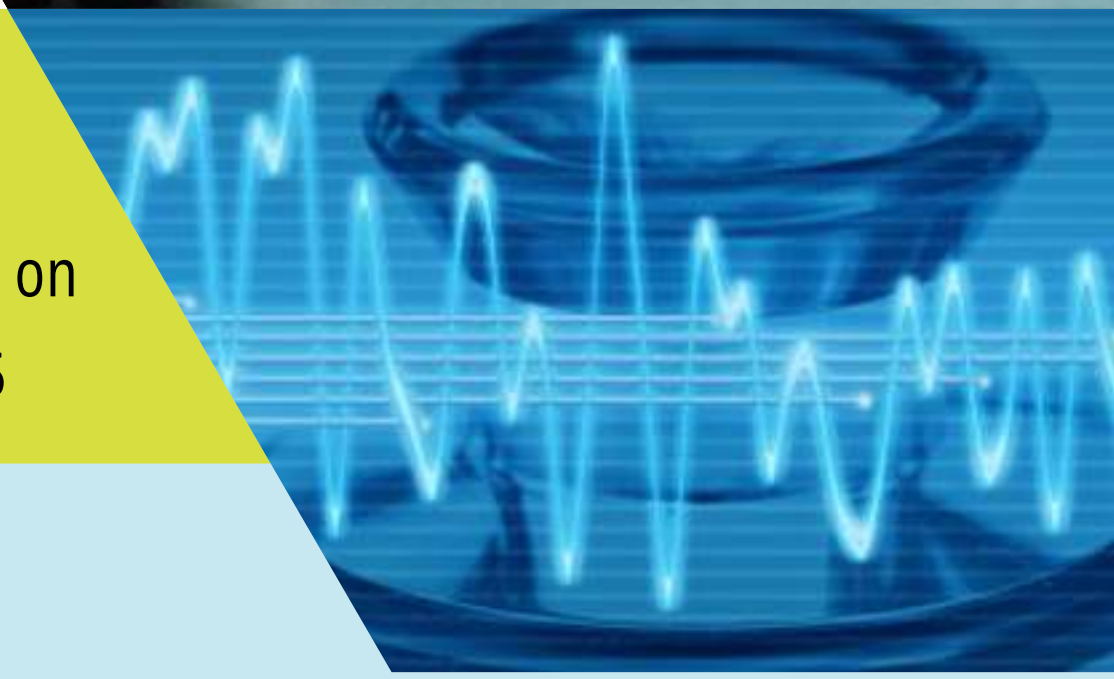
QMS – Quality Management System for Medical Devices

White Paper on

ISO 13485



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What is ISO 13485:2003?

You can't buy trust. BUILD IT through ISO 13485.

Demonstrate your ability to supply medical devices through Quality Management System for Medical Devices - ISO 13485

ISO 13485 is the quality management system standard for medical devices. This standard applies the ISO 9001:2008 process approach to quality, and replaces ISO 13485:1996 and ISO 13488:1996.

ISO 13485:2003 provides an effective base model for compliance with the EU CE marking Medical Devices Directives requirements. ISO 13485:2003 is also considered to be fully compatible with the FDAQSR.

ISO 13485 is an international standard, recognized throughout the world for establishing a business management system specific to the medical device industry. ISO 13485 is applicable to organizations that manufacture private label medical devices, in vitro diagnostic medical devices, and medical components.

The ISO 13485 standard supplements ISO 9001 and has many of the same requirements. Some of the additional requirements to ISO 9001 requirements relate to

- Design controls,
- Risk management,
- Environmental controls,
- Special processes (e.g. Software validation),
- Traceability, record retention, and
- Regulatory actions (such as vigilance),

ISO 13485: 2003 has been harmonised against the medical device directives.

- Medical Devices Directive
- Active Implantable Médical Devises Directive,
- In Vitro Diagnostic Directive

This means that compliance with this standard automatically demonstrates compliance with the specific parts of the directives that require a quality management system.

Formal certification of quality management system, specifically for medical devices, to ISO 13485:2003 proves advantageous, for medical companies which export their products to the global market.

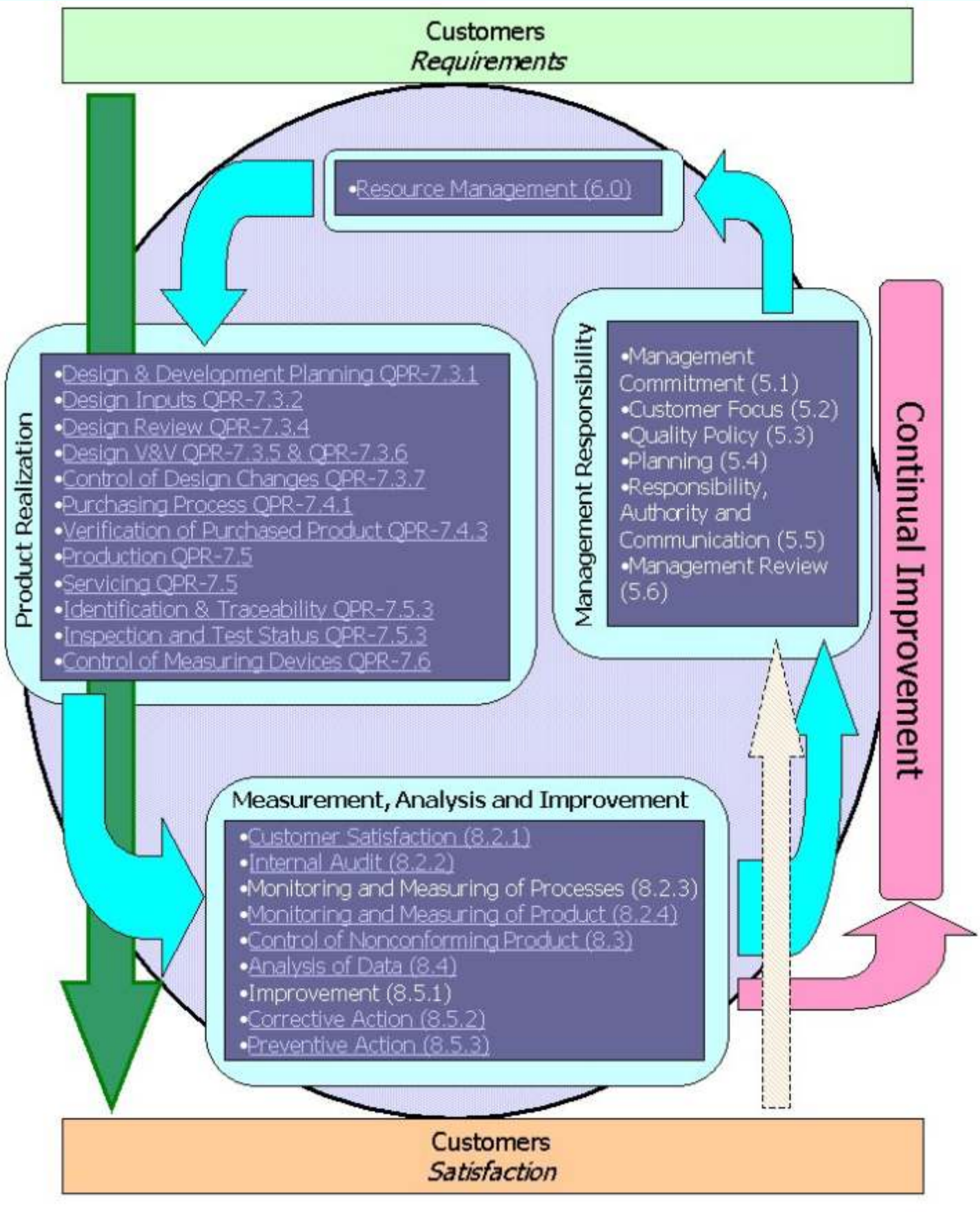
- In the European Union, the fulfillment of EU Directives (e.g. Active Implantable Medical Devices Directive, Medical Devices Directive and In Vitro Diagnostic Directive) allows the free trade of medical devices.
- Canada requires that medical device manufacturers marketing their products in Canada must have a quality system certified to ISO 13485 by an accredited certification body.

ISO 13485: 2003 represents the requirements that medical device manufacturers must incorporate into their management systems. The current document supersedes its 1996 incarnation as well as EN 46001, EN 46002 and ISO 13488.

Though based on ISO 9001, 13485 removes 9001's emphasis on continual improvement and customer satisfaction. In its place is an emphasis on meeting regulatory as well as customer requirements, risk management and maintaining effective processes, namely the processes specific to the safe design, manufacture and distribution of medical devices.

13485 is in part designed to produce a management system that facilitates compliance to the requirements of customers and—preeminently—various global regulators. While being certified to 13485 does not fulfill the requirements of either the FDA or foreign regulators, the certification aligns an organization's management system to the requirements of the FDA's Quality System Regulation (QSR) requirements as well as many other regulatory requirements found throughout the world. Therefore, 13485 certification serves to create a management system that can be thought of as a framework on which to build compliance to various regulatory and customer requirements.

13485 dictates that risk management must be thoroughly documented and conducted throughout a product's entire lifecycle, from initial concept to delivery and post-delivery. However, the standard leaves the specifics to a related standard, ISO 14971: 2001, Application of Risk Management for Medical Devices. While 13485 states that a manufacturer's management team is charged with the management of device-related risks and the development of risk management plans, 14971 defines a list of steps to be taken by management in order to fulfill risk-related requirements. While it is not mandatory that a manufacturer be 14971 certified in order to attain 13485 certification, being certified to the former standard can ease the attainment of certification to the latter.


Customers
Requirements
•Resource Management (6.0)
Product Realization
•Design & Development Planning QPR-7.3.1
•Design Inputs QPR-7.3.2
•Design Review QPR-7.3.4
•Design V&V QPR-7.3.5 & QPR-7.3.6
•Control of Design Changes QPR-7.3.7
•Purchasing Process QPR-7.4.1
•Verification of Purchased Product QPR-7.4.3
•Production QPR-7.5
•Servicing QPR-7.5
•Identification & Traceability QPR-7.5.3
•Inspection and Test Status QPR-7.5.3
•Control of Measuring Devices QPR-7.6
Management Responsibility
•Management Commitment (5.1)
•Customer Focus (5.2)
•Quality Policy (5.3)
•Planning (5.4)
•Responsibility, Authority and Communication (5.5)
•Management Review (5.6)
Continual Improvement
Measurement, Analysis and Improvement
•Customer Satisfaction (8.2.1)
•Internal Audit (8.2.2)
•Monitoring and Measuring of Processes (8.2.3)
•Monitoring and Measuring of Product (8.2.4)
•Control of Nonconforming Product (8.3)
•Analysis of Data (8.4)
•Improvement (8.5.1)
•Corrective Action (8.5.2)
•Preventive Action (8.5.3)
Customers
Satisfaction

BENEFITS OF ISO 13485 CERTIFICATION

ISO 13485 implementation improves / leads to :-

- POLICIES & OBJECTIVES set by 'top management'
- Conformance to Legal and Regulatory Requirements
- Recognition by regulators around the world of ISO 13485:2003 as a good basis for addressing medical device design and manufacturing regulatory requirements
- Controlled consistency of manufactured products
- Managed productivity and efficiency, controlling costs
- Competitive advantage and increased marketing and sales opportunities.
- Improved customer perception of the organization's image, culture and performance.
- improved internal and external Communications
- greater understanding of the organization's processes
- clear responsibilities and authorities agreed for all staff
- improved use of time and resources
- reduced wastage
- greater consistency and traceability of products and services
- Customer Confidence, Satisfaction and TRUST
- Level of Assurance in Organisational QUALITY
- Organisational PROFITABILITY
- Ability to Differentiate Organisation for Competitive Advantage
- Organisational Credibility & Reputation

THE CERTIFICATION PROCESS

It also is important to keep the target market in mind. For instance, if a medical device manufacturer wants to sell in North America, it should seek certification through a registrar accredited by a North American accreditation body to ensure they will meet country-specific or customer requirements.

An ISO 13485 management system can be thought of as a framework on which to build compliance to various regulatory and customer requirements. Source: Fresenius AG

If a consultant is required, the organization needs to be sure that the prospect has expertise in 13485, and requesting referrals from an accredited registrar also can aid in finding the right match. It is important that the consultant understands the organization's business that the consultant has dealt with organizations of a similar size before and has had experience with similar product lines.

Also, an organization should be wary of consultants that endeavor to radically change a management system that is already performing well. Steve Upton, medical device business unit manager for NQA, states, “The consultant should come in and align their knowledge with your requirements and the customer requirements, and that will work time after time.”

The steps to attaining 13485 certification are similar to those of 9001, with some type of off-site document review followed by a preassessment and then assessment. After certification, an organization will be subject to on-going surveillance by its certification body. The duration of the assessment is contingent on an

organization's scope—its size, number of personnel, and type and complexity of products manufactured. Taking these elements into consideration, an organization can expect an assessment to last anywhere from a couple of days to more than a month.

The frequency of surveillance assessments will be determined by an organization's scope as well as its performance, though they will usually be conducted annually or semi- annually. However, organizations should expect a complete reassessment three years after initial certification. A surveillance assessment takes into account concerns such as the fulfillment of management responsibilities, the execution of internal audits and how an organization is performing in relation to the state of the industry and customer expectations.

WHO CAN GO FOR ISO 13485 CERTIFICATION?

- Companiesthat design, manufacture, distribute, install and service medical devices for the European and World markets.
- Companies who manufacture OEM products which are sold under other company names.
- Companies who design and/or manufacture medical device components or raw materials for the medical device market.
- Companies selling, installing or servicing medical devices.
- Consultants providing design services to the medical device market.
- Companies providing services to the medical device market such as sterilisation, cleaning, testing, etc.

WHAT WE DO

Sterling International Consulting. provides proven, proprietary implementation and training support to assure that your organization meets applicable ISO 13485 requirements promptly and effectively. A certified ISO 13485 Quality Management System will

- Assure you meet all customer quality requirements
- Improve your organization's competitiveness
- Eliminate waste
- Reduce risk
- Control process variation

Sterling International Consulting. ISO 13485 QMS Implementation Support is loaded with advantages for your organization.

We offer choices... you decide just how much support you need.

- Basic Support provides a process-based, documented, implemented, audited Quality Management System (QMS), acknowledging all ISO 13485 quality requirements, ready for certification.
- Full Support provides everything in Basic Support, plus we will train and mentor an Internal Quality Audit team for your organization.

Sterling International Consulting. will witness your certification audit, if you choose. Everything we provide meets one or more ISO 13485 requirements, including

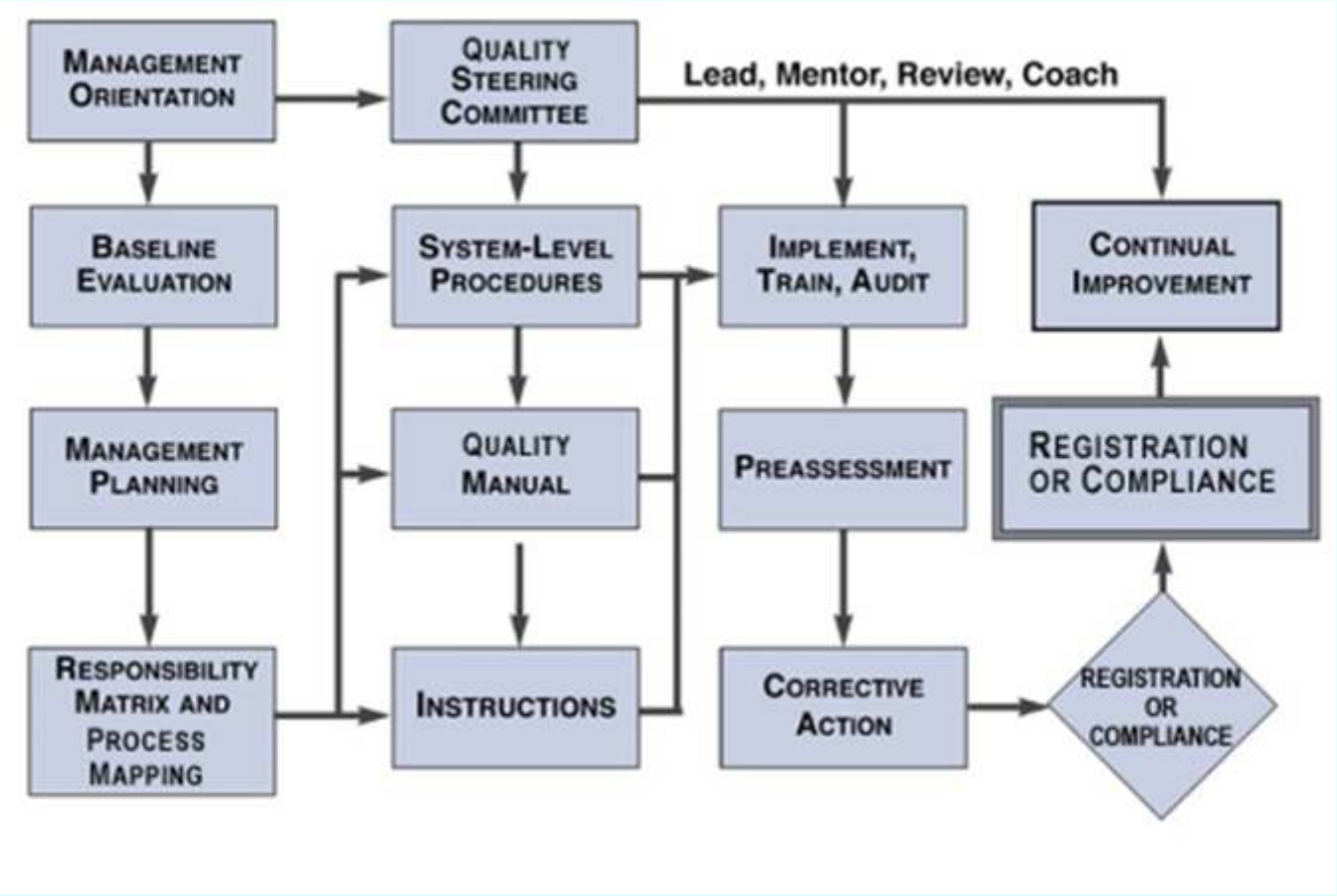
- a quality manual unique to your organization, acknowledging all ISO 13485 requirements (no "gap assessment" required)

- documentation and implementation support for your value
- added quality management system
- development of a simple, effective document and record control system
- training of an Internal Quality Audit Team, if you choose
- a mentored, full system audit of the new quality management system (no registrar "preliminary assessment" required)
- corrective/preventive action support from the full system audit
- recommendation for an economical, effective registrar, if you choose
- our witness of your registration audit, if you choose

We take the time necessary to custom fit all applicable ISO 13485 requirements to your organization. No "consultant" is as willing and able as Sterling International Consulting. to take the time to build a QMS to both reduce your costs, improve efficiency, enhance effectiveness, mitigate risks and "pass the certification audit," guaranteed!

At Sterling International Consulting., we always offer No-Nonsense Pricing, all expenses included. We welcome comparison! Sterling International Consulting.'s proven, proprietary implementation and training methods assure your organization meets all ISO 13485 requirements in minimal time and at lowest cost.

Your organization is very busy... everyone wears more than one hat. Time to implement a quality management system is often limited. We take less time to get you certified. Quality system implementation is a "team sport..." however, if your organization does not have the time, we can deliver a turn-key system, guaranteed to get you certified.



Our methods never include one-size-fits-all, "cookie-cutter" approaches. ISO 13485 quality systems requires process approaches, customer focus, and continual improvement. You cannot get that from a cookie cutter. Most importantly, our quality management systems improve your bottom line. "Cookie cutter" approaches do not work, and only add cost.

When we leave, the quality management system is yours, not ours. We provide all the knowledge and experience your organization needs to effectively manage and improve your certified QMS in the future. When we are finished, your organization owns your ISO 13485 quality management system.

Sterling International Consulting. – a team of experienced, creative, enthusiastic quality professionals committed to building and improving quality systems while permanently reducing quality costs.

We would welcome the opportunity to work with you!

For more information & customized assistance, please send us an email at info@uaeiso.com

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