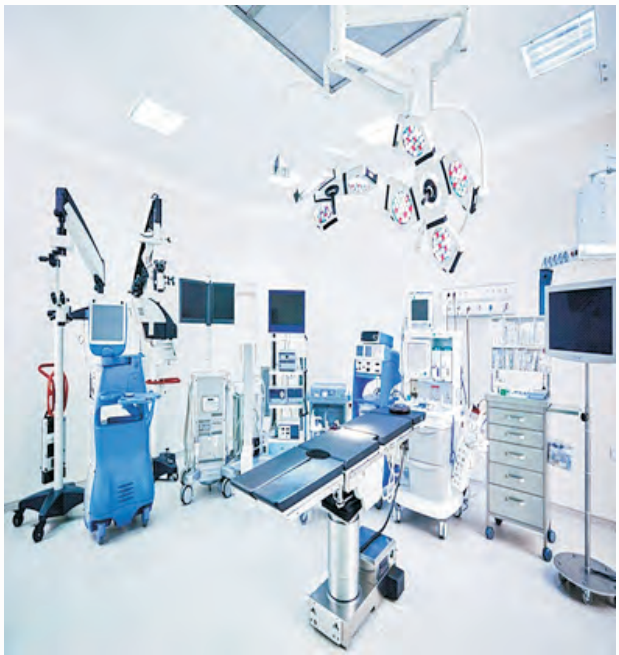
Integrated Quality Certification Private Limited

ISO 13485 – Medical Devices Quality Management System Requirements

Management System

A Management System is the framework of processes and procedures used to ensure that an organisation can fulfil all tasks required to achieve its policies and objectives. Documented information ensures that everyone is not just "doing his or her thing", that there is a defined way to complete each of the business process organization has planned effectively and efficiently utilizing available resources. Management system ensures that all personnel are aware of their roles, responsibility and authority for effective implementation of process including continual improvement.

Medical Devices –



A medical device is any device intended to be used for medical purposes in many diverse settings. Medical devices benefit patients by helping health care providers diagnose and treat patients and helping patients overcome sickness or disease, improving their quality of life.

Significant potential for hazards are inherent when using a device for medical purposes and thus medical devices must be proved safe and effective with reasonable assurance before regulating governments allow marketing of the device in their country.

As a general rule, as the associated risk of the device increases the amount of testing required to establish safety and efficacy also increases. Further, as associated risk increases the potential benefit to the patient must also increase.

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Medical devices vary in both their intended use and indications for use. Medical devices range from simple, low-risk devices such as tongue depressors, medical thermometers, dental implants & supplies, sterile medical supplies – reagent for in vitro use, laboratory machine, disposable gloves, and bedpans to complex, high-risk devices that are implanted and sustain life, such as high-risk devices those with embedded software such as pacemakers, and which assist in the conduct of medical testing, implants, and prostheses.

Design of medical devices constitutes a major segment of the field of biomedical engineering. To ensure that all medical devices comply to applicable regulations which are collectively called as MDD – Medical Device Directives, with an objective of meeting the intended functional requirements and thus safe to use.

Medical device packaging is another highly regulated aspect. Often medical devices and products are sterilized and the package sterility must be maintained throughout distribution to allow immediate use by physicians. A series of special packaging tests measure the ability of the package to maintain sterility. Package testing is part of a quality management system including verification and validation. It is important to document and ensure that packages meet regulations and end-use requirements. Manufacturing processes must be controlled and validated to ensure consistent performance.

As Medical device are highly complicated and technologically evolving (including mobile medical application), with usage of software, state – of - the art hardware technology, artificial intelligence including ensuring cyber security, considering technology driven medical devices (pace-makers, deep brain simulators) can incorporate and have the ability to transmit patients vital health information from a patient's body to medical professionals in real-time scenario.

Medical Devices Quality Management Systems -

ISO 13485 MDQMS provides a framework to achieve sustained success in a complex, demanding and ever-changing environment of medical devices technology to address the medical device directives, regulations, responsibilities and as well as demonstrating a commitment for safety and quality of medical device.

Organizations top management to set out the organizations strategy and policies clearly in order to get the mission, vision and values accepted and supported by its all stake holders – customers, regulators (FDA, CDSCO etc).

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Processes are specific to an organization and vary depending on the type, size and level of maturity of the organization, wherein these processes including out-sourced activity, if any, need to be managed proactively, to ensure that they are effective and efficient, and managed as a process approach, which comprises a system of network of processes including its sequence and interaction.

Thus, a planned Medical Device Quality Management System (MDQMS) provides comprehensive requirements for an organization to implement and improve medical device safety, reliability, efficacy and compliance with the contractual, statutory and regulatory requirements applicable for the product and /or service been provided. Even though ISO 13485 is designed on process model concepts of P-D-C-A, it can be used for regulatory compliance and .It ensures and can be used by organizations involved in one or more stages of the life-cycle of the medical device, including the design, development, production, production, storage and distribution, installation servicing, final decommissioning and disposal of medical devices and design / development of associated activities (technical support) devices that are safe for their intended purpose.

ISO 13485 is the quality management system standard accepted as the basis for CE marking medical devices under European Directives. Increasingly, ISO 13485 is being required, or is at least beneficial, in supporting regulations around the world. .

Even though ISO 13485 certification is not a direct requirement for CE marking medical devices under the European Medical Device Directives, it is recognized as a harmonized standard by the European Commission.

The Implementation of Medical Device Quality Management Systems is assessed, certified and monitored by independent organizations through the process of Certification.

ISO 13485 quality management system for Medical Device is prepared by Technical Committee (TC) 210. Requirements serve as method and have earned a global recognition for establishing and maintaining Medical Devices Quality Management System wherein it provides confidence to all the stake holders by putting more emphasis on the safety and efficacy of medical devices, but requiring organizations only to demonstrate effective implementation and maintenance of the quality system.

Risk-based thinking was an implied requirement enabling an organization to determine the factors that could cause its processes and its quality management system to deviate from the planned results, and to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise.

Risk being the effect of uncertainty, thus (any uncertainty) results in having positive or negative effects. A positive deviation arising from a risk can provide an opportunity, but not all positive effects of risks results in opportunities.

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SEVEN Quality Management Principles:

- Customer focus
- Leadership
- Engagement of people
- Process approach
- Improvement
- Evidence based decision making
- Relationship Management

Above SEVEN principles manifest themselves through the four main clauses:

Context of the Organization, Leadership & Planning – defining requirements

Support – determine and establish necessary resources

Operation – establish and implement processes (including verification & validation)

Performance Evaluation and Improvement – of results

Benefits of ISO 13485 Certification:

- Continual improvement process: Plan – Do – Check – Act
- Improved response to interested parties needs and expectations
- Improved acceptance of product manufactured under controlled conditions
- Opportunity for improved productivity because of implementation of validated processes, utilization of competent work force equipment, tools

ISO 13485 provides an opportunity for adoption of RBT in all their processes and improve product safety and efficacy and compliance to applicable directives. ISO 13485 Medical Devices Quality Management Systems is a valuable tool and framework to improve internal control and seek marketplace recognition of product.

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IQC's global network of auditors allows organisations to work with experienced audit resources; to add value and mitigate the MD QMS risks and have an authenticated and credible IAF recognized Medical Devices Quality Management System certification.

IQC has the edge and thus provides advantage of using the wide-pool of resources and contacts for delivering cost effective and competent certification services through IQC which is an independent entity for providing accredited, value added, independent and impartial management system certification services.

IQC's group companies include the following,

- IQC Global Engineering LLC (IQC GE), registered in AbuDhabi and accredited under EIAC for 17020, for offering Third party independent inspection, expedition and project services to oil & gas, power, engineering and industrial projects.

- IQC Global Engineering Private Ltd, registered in Bengaluru, Karnataka – INDIA, for Third party independent inspection, expedition and project QA-QC services to oil & gas, power, engineering and industrial projects.

- Neutrality for Inspection and Testing FAHHS with registered office in Amman, Jordan for offering Inspection, expediting and auditing services.