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Medical Devices-QUALITY MANAGEMENT SYSTEM (QMS)

What is a Medical Device ?

A medical device is an instrument, apparatus, implement, machine, implant, in vitro reagent, or other similar article, that is intended for use in the diagnosis, prevention and treatment of disease or other medical conditions.

What is a MD-Quality management system?

A quality management system (QMS) is a set of policies, processes and procedures that help an organization meet the requirements expected by its stakeholders.

In the medical devices industry, a QMS is required by regulators in most countries.

ISO 13485 enables an organization to consistently provide safe and effective medical devices and fulfil customer and regulatory requirements.

It is also flexible enough to meet the individual needs of different types of medical devices organizations.

13485 – An Overview ?

- ISO 13485 is a Management Systems Standard specifically developed for the manufacture of Medical Devices.
- Its primary objective is to facilitate harmonized medical device regulatory requirements.
- 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 standard contains specific requirements for manufacture, installation and servicing and calls for:
  - Implementation of a Quality Management System with several enhancements
  - Risk Management approach to product development and product realisation
  - Validation of processes
  - Compliance with statutory and regulatory requirements
  - Effective product traceability and recall systems

Why Implement an ISO 13485 ?

ISO 13485 can help organizations involved in any part of a medical device's life cycle:

- Demonstrate compliance with regulatory and legal requirements
- Ensure the establishment of QMS practices that consistently yield safe and effective medical devices
- Manage risk effectively
- Improve processes and efficiency as necessary
- Gain a competitive advantage

MEDICAL DEVICES QUALITY MANAGEMENT SYSTEM

BENEFITS OF MEDICAL DEVICES - 13485

- Implementing a Quality Management System, in general, helps to motivate staff and provide a better definition of roles and key responsibilities.

- Helps the organization to demonstrate its ability to systematically provide medical devices and services that consistently meet customer requirements, meet applicable regulatory requirements (compliance) and safety standards.

- Cost savings can be made through improved efficiency and productivity, as product or service deficiencies will be highlighted and corrected.

- Improvements can be developed on
  - a systematic and monitored base
  - resulting in less wasteless inappropriate or rejected work
  - fewer complaints

- Provides a systematic approach to risk management.

- Systematic, smoother, transparent and documented handling of activities required by regulation such as post-marketing follow-up and surveillance, complaints handling, CAPA implementation, field actions or product recall handling, vigilance and competent authorities reporting, and clinical experience enrichment.

- Systematic incorporation, at an early stage and within the design and development process, of the regulatory requirements impacting on the product itself and its technical features.

- Help creating a systematic vision embracing the medical device lifecycle, medical device packaging, its labeling, its installation, its servicing, and its usability. This includes the information provided together with the medical devices, the commercial claims, the unspoken user expectations, the feedback from users or patients, the risks associated with use, the benefits brought to the single patient and to the Community, the costs and the disposal of the medical device.

How to go about ISO 13485 ?

- Define the scope of QMS - Medical device implementation, which may cover part or all of core functions of the organization.
- Identify organization processes & controls over them.
- Prepare Quality Manual & procedures outlining the organization Profile.
- Define Quality Policy & Objective.
- Get Approval from management ensuring statutory Regulatory compliances.
- Implementation of measuring & monitoring thru Internal audits & Management Review.

Are you looking for ISO 13485 ?

Call the further information at;

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