WHITE PAPER

ISO 13485:2016

Medical Devices - Quality Management System

A gate way to be sure about medical devices.

Global Standards

Success through management excellence

ISO 13485:2016 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 and applicable regulatory requirements. Such organizations can be involved in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g. technical support). ISO 13485:2016 can also be used by suppliers or external parties that provide product, including quality management system-related services to such organizations.

Requirements of ISO 13485:2016 are applicable to organizations regardless of their size and regardless of their type except where explicitly stated. Wherever requirements are specified as applying to medical devices, the requirements apply equally to associated services as supplied by the organization.

The processes required by ISO 13485:2016 that are applicable to the organization, but are not performed by the organization, are the responsibility of the organization and are accounted for in the organization's quality management system by monitoring, maintaining, and controlling the processes.

If applicable regulatory requirements permit exclusions of design and development controls, this can be used as a justification for their exclusion from the quality management system. These regulatory requirements can provide alternative approaches that are to be addressed in the quality management system. It is the responsibility of the organization to ensure that claims of conformity to ISO 13485:2016 reflect any exclusion of design and development controls.

If any requirement in Clauses 6, 7 or 8 of ISO 13485:2016 is not applicable due to the activities undertaken by the organization or the nature of the medical device for which the quality management system is applied, the organization does not need to include such a requirement in its quality management system. For any clause that is determined to be not applicable, the organization records the justification as described in 4.2.2.

ISO 13485, Medical devices – Quality management systems – Requirements for regulatory purposes, is an internationally agreed standard that sets out the requirements for a quality management system specific to the medical devices industry.

BENEFITS OF MEDICAL DEVICES - QMS

Management system's conformity with ISO 9001, ISO 13485 or ISO14001 can help company open doors to untapped domestic and international business opportunities and the benefits.

Expanding market access

National regulatory authorities require or strongly prefer that manufacturers marketing medical products in their countries have a third-party audited and certified management system in place. Investing in such a system speeds access into those countries that require it, and expedites market entry into the others.

Reducing cost of sales

Your certification establishes your company's credibility and commitment to quality. Because the task of explaining the specifics and demonstrating the effectiveness of your quality system is more straightforward, it takes less time to earn your prospective customers' trust and confidence.

Improving performance

Based on a uniform and widely-accepted system of process control, your company's certified management system helps you improve your products and processes. This can foster improved relationships with your suppliers, business partners, and customers, and give you a real advantage in the marketplace.

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