INTEGRATED QUALITY CERTIFICATION PVT. LTD.

ISO 13485 – Medical Devices, Quality Management Systems

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 responsibility and authority for effective implementation of process including continual improvement.

Planned ISO 13485 - Medical Devices, Quality Management Systems is an effective solution in providing manufacturers to address the Medical Device Directives, regulations and responsibilities as well as demonstrating a commitment to the safety and quality of medical devices.ISO 13485 is a stand-alone QMS standard, derived from the internationally recognized and accepted ISO 9000 quality management standard series. ISO 13485 adapts the ISO 9000 process-based model for a regulated medical device manufacturing environment. Even though it is based on the ISO 9001 process model concepts of P-D-C-A, it is designed for regulatory compliance. It is more prescriptive in nature and requires a more thoroughly documented quality management system.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, 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.

Organisations that claim to have adopted ISO 13485, Medical Devices – Quality Management system can therefore be formally audited and certified compliant with the standard.

Benefits of ISO 13485 – Medical Devices, Quality Management Systems

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

ISO 13485 is the best internationally-accepted model a medical device organization can implement to help demonstrate compliance to laws and regulations of the medical device industry. 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.

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