What is ISO 13485?

.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.

Maintain regulatory compliance by being ISO 13485 certified

The ISO 13485 standard is an effective solution to meet the comprehensive requirements for a QMS. Adopting ISO 13485 provides a practical foundation for manufacturers to address the Medical Device Directives, regulations and responsibilities as well as demonstrating a commitment to the safety and quality of medical devices.

What are the benefits of being certified to ISO 13485?

ISO 13485 Certification can help you improve overall performance, eliminate uncertainty, and widen market opportunities. Companies with this certification communicate a commitment to quality to both customers and regulators.

- Outline how to review and improve processes
- Increase efficiency, cut costs and monitor performance
- Demonstrate that you produce safer medical devices

- Meet regulatory requirements and customer expectations

High performing organizations expect ISO 13485 auditing to be thorough, competent, relevant and challenging of the manufacturers quality management systems; effective auditing drives significant benefits to the manufacturer. **The beneficial outputs of an effective audit include:**

• Meaningful feedback on the effectiveness of the quality management system

• Confidence in compliance with regulations

• Identification of areas requiring attention

• Confirmation that best practise is achieved

• Detection of areas of non-compliance and possible risk

• Reporting and certification that is valuable and recognized

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. Although 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. Therefore compliance with ISO 13485 provides a presumption of conformity with the basic European Union (EU) quality assurance requirements for CE marking (additional EU requirements apply). Market Now can verify medical device manufacturers selection of the most efficient conformity assessment routes to achieve CE marking. Start to plan your transition to ISO 13485:2016 Users of this key medical device standard should start planning in order to begin to develop suitable transition plans. The international working group has proposed a work plan for development of a mapping document to support users who chose to adopt new versions of both ISO 13485 and ISO 9001. There will not be an updated version of ISO 14969 - Guidance on the application of ISO 13485:2003. However, the alternative proposal is a handbook which would provide users with relevant guidance and interpretation of the requirements of ISO 13485:2016.

When an organization adopts ISO 13485, it commits to establishing, documenting, implementing, and maintaining a quality management system, which includes a commitment to an effective internal audit program. There are four steps to conducting a complete and effective internal audit.

Plan

Planning is an important component to the ISO 13485 standard. Organizations must consider product realization, ISO 13485 in its entirety, and quality management system requirements established by the organization. This is in addition to all of the activities related to the product, such as planning of the product, customer requirements, design, purchasing, production, storage, and measuring, and any additional requirements.

Do

Conducting internal audits is one of the biggest areas of nonconformity seen in support of the ongoing process over time. As costs rise and enthusiasm for an effective system fades,

organizations begin to falter. However, in order to maintain an effective quality management system, an organization must press on and conduct its internal audit plan.

Check

Once an internal audit is conducted, the results are reported, and actions to correct deficiencies must be processed immediately and any causes for nonconformities must be eliminated.

Questions to consider are:

• Have deficiencies been corrected?

• Were they corrected effectively and in a timely manner?

• Were the causes well understood and eliminated?

• Were there any trends noted in the process or in the product?

Act

The final step in conducting an effective internal audit is focusing on understanding and measuring the effectiveness of the actions taken, and understanding and measuring the effectiveness of the internal audit process.

Questions to consider here are:

• Do we need more people?

• Do we have the right people?

• Are the people trained effectively?

• Are we seeing and understanding the right areas of the organization to detect and see the corrections that will make our devices safer and prevent defects from getting on the market?

ISO 13485:2016 - The harmonized standard is here

ISO 13485:2016, the Medical Device Quality Management System standard, has been harmonized to the European Medical Devices Directives: MDD, AIMDD and IVDD. EN ISO 13485:2016 now replaces the previous version of the standard, EN ISO 13485:2012, in the EU Official Journal, with the date of 'cessation of presumption of conformity' of EN ISO 13485:2012 stated as 31 March 2019.

Standard harmonization allows manufacturers to use their compliance to the standard as evidence of conformity to the requirements of relevant legislation. The harmonization of EN ISO 13485:2016 is another step towards compliance to the recently published Medical Devices and IVD Regulations, which

will supersede the current Directives in 2020 and 2022, respectively. Find out more about MDR transition and IVDR transition.