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ISO 13485

Quality management for medical devices

MOTIVATION AND BENEFITS

ISO 13485 provides an international standard for enabling manufacturers of medical devices to substantiate an effective quality management system. This standard refers to all organizations that are operating within the supply chain or are involved in placing devices regulated by the relevant EU regulations for medical devices and in-vitro diagnostics on the market.

ISO 13485 is an important standard for the implementation of system requirements according to regulations in Europe (MDR, IVDR). Certification according to this standard is substantial for economic operators in the business of medical devices not only in Europe but also internationally.

The standard establishes requirements for all types of medical devices, which also include services and software. The medical devices range from sterile to non-sterile, invasive to non-invasive as well as non-active to active implants.

In the course of the conformity review procedures required in Europe for MDR and IVDR according to article 10, demonstration of a quality management system is an important prerequisite for obtaining registration and thus the right to sell medical devices in Europe or to place them on the market (CE marking). As the regulations of some system requirements don‘t include further details for the implementation, ISO 13485 still needs to be used in practice.

ISO 13485 has some features that are congruent with those of other management systems, especially ISO 9001. A focus is placed on complying with laws relevant to quality as well as the introduction of a risk management acc. to ISO 14971.

The advantages for organizations do not only include the registration aspects but also transparency of the organizations’ own performance, operations following defined processes and the fact that the organization is made aware of legal changes. Furthermore, effective actions for risk management can help to minimize and thus control risks in connection with the devices concerned.

OBJECTIVES

- assuring quality, transparency and safety and security
- identifying business and product risks
- important prerequisite for the registration of medical devices

TARGET GROUP

Any organizations developing and manufacturing medical devices and placing them on the market as well as organizations that are suppliers or service providers to such organizations.

CRITERIA

Application of ISO 13485 is particularly conceived for organizations striving for a management system that is well aimed, more conclusive and more integrated. In this respect, the organization needs to meet all the applicable and legal requirements in connection with product safety in the organization’s management systems for medical devices. In addition to the criteria for ISO 9001, requirements relating to risk management will have to be met. Moreover, special requirements placed on sterile medical products and medical products that can be implanted actively will have to be adhered to. Internal and external audits are to provide relevant support.

OTHER RELEVANT STANDARDS

ISO 9001, ISO 14971

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MEDICAL DEVICES: QUICK SCAN FOR BEGINNERS RELATING TO ISO 13485

Many organizations are thinking about starting to be active in the field of medical instrumentation. As a rule, these organizations are subcontractors and do not want to put any medical devices of their own into circulation, in this phase. Nevertheless, system certification should be striven for in connection with this project, helping organizations to stand out against their competitors.

In order to give these organizations, which have, in most cases, already established a quality management system, an overview of requirements of ISO 13485 that have already been implemented or are still open, Quality Austria offers the Quick Scan for Beginners relating to ISO 13485. This is a short audit that serves to systematically review and assess the extent to which the requirements of the Standard are met. The Quick Scan will also dedicate a speical focus on the requirements of ISO 13485.

Targets

reviewing against requirements relating to medical devices (ISO 13485)

Target group

Any organizations that would like to start to be active in the field of medical instrumentation and establish a relevant management system or adapt their existing quality management systems.

Criteria

At this short audit, the extent to which all the requirements of ISO 13485 are met will be reviewed.

QUALITY AUSTRIA – WHO WE ARE

We are the leading Austrian contact for the Integrated Management System, based on quality, environmental and OH&S (occupational health and safety) management, and the topic of business excellence. Our main focuses are system and product certification, training and personal certification. We are accredited by the Federal Ministry for Digital and Economic Affairs (BMDW) for system, product as well as personal certification and have many international registrations and accreditations. Furthermore, we present the Austrian Excellence Award together with the BMDW and award the Austria Quality Seal.

Additionally, we organize several forums and conferences and have issued numerous publications. We participate actively in standardization bodies and international networks such as EOQ, IQNet and EFQM. We cooperate with some 50 partner and member organizations worldwide and thus ensure the facilitation of global know-how.

Having more than 1.000 auditors, trainers, assessors and technical experts all over the world, we ensure the successful implementation of standards and regulations within the organizations and provide sector and product specific knowledge with a very high focus on practical relevance. More than 10.000 customers in approx. 30 countries and over 6.000 annual participants in our trainings benefit from the long-standing expertise of our organization. We adapt our offer according to our clients' needs and support them in achieving their long-term goals!

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