

تقديم

الهيئة العامة للغذاء والدواء جهة مستقلة الغرض الأساسي لها هو القيام بتنظيم ومراقبة الغذاء والدواء والأجهزة والمنتجات الطبية والتشخيصية، ومن مهامها وضع اللوائح الفنية والمواصفات في مجالات الغذاء والدواء والأجهزة والمنتجات الطبية سواء كانت مستوردة أو مصنعة محلياً بواسطة لجان فنية متخصصة، وقد قام قطاع الأجهزة والمنتجات الطبية بالهيئة ضمن برنامج عمل الفريق رقم (SFDA/MDS/TC 210) " فريق عمل مواصفات إدارة الجودة للأجهزة والمنتجات الطبية " بتبني المواصفة الدولية رقم (ISO 13485:2016) " الأجهزة الطبية - نظم إدارة الجودة - متطلبات الاهداف التنظيمية " ، والتي أصدرتها " المنظمة الدولية للتقييس " وذلك بلغتها الأصلية. وقد اعتمدت هذه المواصفة كمواصفة سعودية متبناة بالمطابقة بلغتها الأصلية وذلك في اجتماع مجلس الإدارة رقم () والذي عقد بتاريخ (/ / 14.. هـ) الموافق (/ / 20.. م).

Foreword

Saudi Food and Drug Authority (SFDA) is an independent organization with main purpose of regulating and monitoring of foods, drugs and medical devices. One of SFDA functions is to issue national Standards /Technical Regulation in the fields of foods, drugs and medical devices, whether imported or manufactured locally, through specialized technical committees (TCs).SFDA medical devices sector through the work program of technical committee (SFDA/MDS/TC 210) "Quality management and corresponding general aspects for medical devices " has adopted the International Standard No.(ISO 13485:2016) " ISO 13485:2016: Medical devices -- Quality management systems -- Requirements for regulatory purposes " , issued by " International Organization for Standardization " in its original language. This standard is identically adopted in its original language and has been approved as national standard by SFDA board of directors in its meeting No () Held on (/ / AH), agreed with (/ / G).

**Medical devices — Quality
management systems —
Requirements for regulatory purposes**

*Dispositifs médicaux — Systèmes de management de la qualité —
Exigences à des fins réglementaires*



Scope

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.

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