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 سواءً 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 جودة الأجهزة الطبية" بتبني المواصـــــــفة الدولية رقم (IEC/TR 80002-1:2009) "برمجيات الأجهزة الطبية – الجزء 1 : الدليل الإرشادي لتطبيق (ISO 14971) في برمجيات الأجهزة الطبية"، 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. (IEC/TR 80002-1:2009) "Medical device software -- Part 1: Guidance on the application of ISO 14971 to medical device software” 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 (../../14..AH), agreed with (../../20.. G).

Scope

This technical report provides guidance for the application of the requirements contained in ISO 14971:2007, Medical devices— Application of risk management to medical devices to MEDICAL DEVICE SOFTWARE with reference to IEC 62304:2006, Medical device software— Software life cycle processes. It does not add to, or otherwise change, the requirements of ISO 14971:2007 or IEC 62304:2006.

This technical report is aimed at RISK MANAGEMENT practitioners who need to perform RISK MANAGEMENT when software is included in the MEDICAL DEVICE/SYSTEM, and at software engineers who need to understand how to fulfil the requirements for RISK MANAGEMENT addressed in ISO 14971.

ISO 14971, recognized worldwide by regulators, is widely acknowledged as the principal standard to use when performing MEDICAL DEVICE RISK MANAGEMENT. IEC 62304:2006, makes a normative reference to ISO 14971 requiring its use. The content of these two standards provides the foundation for this technical report.

It should be noted that even though ISO 14971 and this technical report focus on MEDICAL DEVICES, this technical report may be used to implement a SAFETY RISK MANAGEMENT PROCESS for all software in the healthcare environment independent of whether it is classified as a MEDICAL DEVICE.

This technical report does not address:

– areas already covered by existing or planned standards, e.g. alarms, usability engineering, networking, etc.;
– production or quality management system software; or
– software development tools.

This technical report is not intended to be used as the basis of regulatory inspection or certification assessment activities.

For the purposes of this technical report, “should” is used to indicate that amongst several possibilities to meet a requirement, one is recommended as being particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required. This term is not to be interpreted as indicating requirements.