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PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

ICS 11.040.01

CCS C 30

YY/T 1437-2023 / ISO/TR 24971:2020

Replacing YY/T 1437-2016

Medical devices - Guidance on the application of GB/T 42062

医疗器械 GB/T 42062 应用指南

(ISO/TR 24971:2020, Medical devices - Guidance on the application of ISO 14971, IDT)

Issued on: June 20, 2023 **Implemented on: July 01, 2024**

Issued by: National Medical Products Administration

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Foreword

This document was drafted in accordance with the rules provided in GB/T 1.1-2020 *Directives for standardization - Part 1: Rules for the structure and drafting of standardizing documents*.

This document replaces YY/T 1437-2016, *Medical devices - Guidance on the application of YY/T 0316*. Compared with YY/T 1437-2016, in addition to structural adjustments and editorial changes, the main technical changes are as follows:

-- Change the scope of the document (see Clause 1; Clause 1 of the 2016 edition);

-- Add the clause “Terms and definitions” (see Clause 3);

-- Add the clause “General requirements for risk management system” (see Clause 4);

-- Add the clause “Risk analysis” (see Clause 5);

-- Add the clause “Risk evaluation” (see Clause 6);

-- Add the clause “Risk control” (see Clause 7);

-- Change “General considerations” to “General”, and include the relevant contents of the 2016 edition changed (see 8.1; 6.1 of the 2016 edition); change “inputs and other considerations of evaluation of overall residual risk” to “inputs and other considerations”, and include the relevant contents of the 2016 edition (see 8.2; 6.2 of the 2016 edition); add “possible approaches” (see 8.3);

-- Add the clause “Risk management review” (see Clause 9);

-- Change “production and post-production feedback loop” to “Production and post-production activities”, and add relevant contents (see Clause 10; Clause 4 of the 2016 edition);

-- Add “Identification of hazards and characteristics related to safety” (see Annex A);

-- Add “Techniques that support risk analysis” (see Annex B);

-- Add “Relation between the policy, criteria for risk acceptability, risk control and risk evaluation”, and include the relevant contents of the 2016 edition (see Annex C; Clause 3 of the 2016 edition);

-- Add “Information for safety and information on residual risk”, and include the relevant contents of the 2016 edition (see Annex D; Clause 5 of the 2016 edition);

-- Add “Role of standards in risk management”, and include the relevant contents of the 2016 edition (see Annex E; Clause 2 of the 2016 edition);

Medical devices - Guidance on the application of GB/T 42062-2022

1 Scope

This document provides guidance on the development, implementation and maintenance of a risk management system for medical devices according to GB/T 42062-2022.

The risk management process can be part of a quality management system (for example one that is based on GB/T 42061-2022 [15]) but this is not required by GB/T 42062-2022. Some requirements in GB/T 42062-2022 (Clause 7 on product realization and 8.2.1 on feedback during monitoring and measurement) are related to risk management and can be fulfilled by applying GB/T 42062-2022. See also YY/T 0595-2020 [17].

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB/T 42062-2022, Medical devices - Application of risk management to medical devices (ISO 14971:2019, IDT)

3 Terms and definitions

For the purposes of this document, the terms and definitions given in GB/T 42062-2022 apply.

4 General requirements for risk management system

4.1 Risk management process

GB/T 42062-2022 requires that the manufacturer establishes, implements, documents and maintains an ongoing risk management process throughout the life cycle of the medical device. The required elements in this process and the responsibilities of top management are given in GB/T 42062-2022 and explained in further detail in this document.

management plan for the particular medical device under development. Some inputs for and considerations on the evaluation of overall residual risk are listed in Clause 8.

4.4.7 Verification activities

The risk management plan specifies how the two verification activities required per 7.2 of GB/T 42062-2022 are carried out. The risk management plan can detail the verification activities explicitly or by reference to other plans.

Verification of implementation of risk control measures can be part of design review, approval of specifications, design and development verification in a quality management system, or other verification activities in a quality management system.

Verification of the effectiveness of risk control measures can be part of design and development verification in a quality management system. It can require the collection of clinical data, usability studies, etc., as part of design and development validation in a quality management system.

4.4.8 Activities related to collection and review of production and post-production information

GB/T 42062-2022 requires the manufacturer to establish a system to actively collect and review information about the medical device in the production and post-production phases and to review this information for relevance to safety. Thus, it is important that the risk management plan includes the activities necessary to establish this system. Manufacturers should understand that the information to be collected can be voluminous and comes from many disparate sources. Consequently, robust processes should be used to analyze the information and to identify trends that could otherwise go undiscovered, so that appropriate conclusions and actions can be taken. Statistical techniques should be considered to assist in the processing of the collected data.

The system to actively collect and review information includes monitoring and receiving feedback such as complaints and adverse event reports. In addition, the system should include active solicitation of feedback from users and collection of other relevant information. The manufacturer should consider the extent of these activities and determine which activities are appropriate for the particular medical device.

For example, limited monitoring might be sufficient for medical devices with a long history of use and well understood risks. Form medical devices involving novel treatments (for example new intended uses) or innovative technologies and possibly with less understood risks, more elaborate monitoring including post-market clinical follow-up (PMCF) studies could be warranted to understand the issues that can arise in the actual use of the medical device. Further guidance is provided in Clause 10.

The method for collecting production and post-production information can be part of established quality management system processes (see for example 8.2 of GB/T 42061 [15]). While a reference to an existing procedure can be sufficient in some cases, any

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