SA HB 13485:2020
ISO 13485:2016 HB1

SA HB 13485:2020

Handbook

AS ISO 13485:2017 — Medical devices — A practical guide

SA HB 13485:2020

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Preface

This Handbook was prepared by the Standards Australia Committee HE-028, Quality Management and Corresponding General Aspects for Medical Devices.

The objective of this document is to provide additional insight and understanding of the requirements in AS ISO 13485:2017, *Medical devices — Quality management systems — Requirements for regulatory processes* (from here on referred to as "The Standard"). It is divided into sections outlined in the Contents in line with the clause structure of the Standard. The Handbook provides advice to guide understanding of the Standard and its application by including the text of the clauses of the Standard, followed by the intent of those clauses, and with the relevant guidance. Examples have been used wherever possible as an aid to understanding the intent and interpretation of the requirements.

The requirements of the Standard are general in nature and, with the exception of a few subclauses that are applicable to specific medical device types, are intended to be applicable to all medical device organizations, regardless of their type, size, or the product they provide. This document is intended to guide organizations that provide products, including services, that affect any part of the lifecycle or supply chain of a medical device. Such organizations can be medical device manufacturers, importers, distributors, service providers or authorized representatives, including Australian sponsors of medical devices. In addition, this handbook can be useful to regulatory authorities and certification bodies around the world, including in Australia.

This document does not define any requirements nor add to or otherwise change the requirements of the Standard but is intended to assist interested parties with the application of the Standard. The guidance contained in this Handbook is intended for educational purposes and is not intended to be used to assess or audit compliance with regulatory requirements or to be used for identifying specific deficiencies of a QMS, unless the guidance is voluntarily incorporated into the documentation describing and supporting an organization's QMS, or unless such guidance is specifically made part of the regulatory requirements relevant to an organization's operation. It should be noted that this document does not set out to provide specific guidance with respect to generic QMS requirements which are common to both AS ISO 13485 and AS/NZS ISO 9001.

This document is identical with, and has been reproduced from, *ISO 13485:2016 — Medical devices — A practical guide*.

As this document has been reproduced from an International Handbook, a full point substitutes for a comma when referring to a decimal marker.

Australian or Australian/New Zealand Standards that are identical adoptions of international normative references may be used interchangeably. Refer to the online catalogue for information on specific Standards.

The terms "normative" and "informative" are used in Standards to define the application of the appendices or annexes to which they apply. A "normative" appendix or annex is an integral part of a Standard, whereas an "informative" appendix or annex is only for information and guidance.

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