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Good distribution practice for medical devices – Requirements

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The Working Group on Good Distribution Practice of Medical Devices (GDPMDS), appointed by the Biomedical Standards Committee to assist in the preparation of this standard, comprises the following experts who contribute in their *individual capacity*:

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The organisations in which the experts of the Working Group are involved are:

Association of Medical Device Industries
Boston Scientific Asia Pacific Pte Ltd
Health Sciences Authority
Johnson & Johnson Pte Ltd
Pall Corporation Pte Ltd
Philips Electronics Pte Ltd
Singapore Manufacturing Federation – Medical Technology Industry Group
TÜV SÜD PSB Pte Ltd

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Foreword

This Singapore Standard was prepared by the Working Group on Good Distribution Practice for Medical Devices (GDPMDS) under the direction of the Biomedical Standards Committee.

In preparing this standard, reference was made to the following publications:

1. TS-01 Revision 2.1 Good distribution practice for medical devices – Requirements
2. ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes.

Acknowledgement is made for the use of information from the above publications.

Attention is drawn to the possibility that some of the elements of this Singapore Standard may be the subject of patent rights. Enterprise Singapore shall not be held responsible for identifying any or all of such patent rights.

NOTE

1. *Singapore Standards (SSs) and Technical References (TRs) are reviewed periodically to keep abreast of technical changes, technological developments and industry practices. The changes are documented through the issue of either amendments or revisions.*
2. *An SS or TR is voluntary in nature except when it is made mandatory by a regulatory authority. It can also be cited in contracts making its application a business necessity. Users are advised to assess and determine whether the SS or TR is suitable for their intended use or purpose. If required, they should refer to the relevant professionals or experts for advice on the use of the document. Enterprise Singapore shall not be liable for any damages whether directly or indirectly suffered by anyone or any organisation as a result of the use of any SS or TR.*
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Good distribution practice for medical devices – Requirements

0 Introduction

The storage, trade and distribution of medical devices can be carried out by various organisations. The nature of the risks involved (e.g. mix-ups and contamination) may be similar to those in manufacturing. The quality of medical devices can also be adversely affected by a lack of adequate control over the activities that occur during storage and distribution. Hence, factors such as storage, transportation, documentation and record-keeping practices are important in the distribution of medical devices.

The International Medical Products Anti-Counterfeiting Taskforce (IMPACT) of the World Health Organization (WHO) has also recommended that operators of the distribution chains comply with an official Good Practice Guideline (e.g. Good Distribution Practice) as part of the global effort to combat counterfeit medical products.[1]

The objective of this standard is to ensure the quality and integrity of the medical devices throughout the distribution process, thus, enhancing the confidence level and safeguarding the welfare of consumers.

1 Scope

1.1 General

This standard serves as a guide on the quality management system for the handling, storage, delivery, installation, servicing, secondary assembly and other related activities (e.g. warehousing, logistics and freight forwarding services) of medical devices including in-vitro diagnostic devices. It establishes the fundamental requirements that are to be met in order to ensure the quality and integrity of medical devices that are being imported and distributed in Singapore. The core elements of this standard focus mainly on the medical device import and distribution related activities.

The design and implementation of this standard by an organisation are influenced by the size and structure of the organisation, the processes employed and the type of medical devices it deals with. It is not the intent of this standard to imply uniformity in the structure of the quality systems or uniformity of documentation.

1.2 Application

This standard is applicable to all organisations that import and supply by wholesale medical devices in Singapore, as illustrated in Figure 1.

When the term “where appropriate” is used to qualify a requirement in this standard, it is deemed “appropriate” unless the organisation can document a justification otherwise.

If any requirement in Clause 7 and Clause 8 is deemed not applicable based on the characteristics of the medical device(s), the organisation does not need to implement such a requirement. If an organisation identifies any requirement in Clause 7 and Clause 8 that does not apply to the range of medical devices they deal in, a justification has to be provided for their exclusion from the fulfilment of that particular requirement.

Clause 8 is only applicable to organisations that perform secondary assembly and Clause 12 may be excluded for suppliers of storage, warehousing, secondary assembly and distribution services.

[1] WHO IMPACT Draft Principles and Elements for National Legislation against Counterfeit Medical Products, endorsed by IMPACT General Meeting in Lisbon, 12 December 2007.

This standard is used by both internal and external parties, including certification bodies, to audit an organisation's ability to meet the requirements specified within.

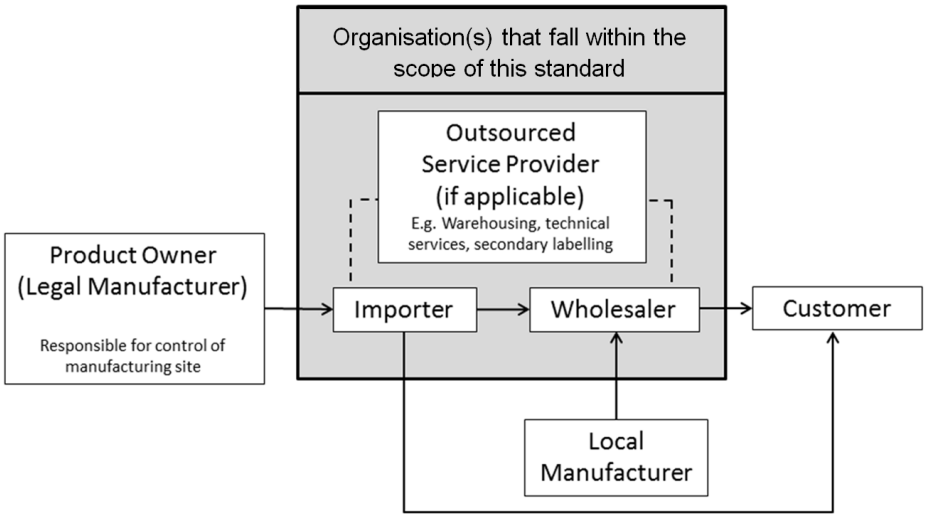

Figure 1 – Organisations involved in medical device distribution

2 Normative references

There are no normative references cited in this standard.