



GHWP

Global Harmonization Working Party

Towards Medical Device Harmonization

PROPOSED DOCUMENT

Title: Comparison study of new ISO13485 vs. QMS requirements in GHWP member economies

Authoring Group: Working Group 7 – Quality Management System: Operation and Implementation

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- **Preface**

The document herein was produced by the Global Harmonization Working Party (GHWP, known as AHWP), a voluntary group of medical device regulators and industry from GHWP members in Asia, Africa, America and beyond. The document has been subject to consultation throughout its development.

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- **Introduction**

There are 33 member economies of GHWP, and these economies have different requirements for QMS. According to the purpose of regulatory coordination, GHWP Technical Committee Working Group 7 needs to investigate the management of QMS in members. The 33 member economies can be divided into three categories: No any requirements to QMS, those who use ISO13485 directly, and those who use GMP and equivalent regulations.

- **Purpose**

This document is intended to show the requirements of GHWP member economies for QMS before 2023 and does not guide members on how to define the meaning of QMS.

- **Scope**

This document applies to applicable medical devices and IVD medical devices **intended to be imported into regulated countries or manufactured in regulated countries.**

This document only considers from quality and regulatory perspectives, not from the business or operation during manufacturing and importation.

- **References**

ISO13485 Standard and member economies' GMP

1 Definitions

1.1 GMP

GOOD MANUFACTURING PRACTICES

1.2 ISO 13485

Medical Devices-Quality management systems-Requirements for regulatory purposes

- **2. Overview**

2.1 Use ISO 13485

14 member economies

Chile, India, Kazakhstan, Kingdom of Saudi Arabia, Kyrgyz Republic, Pakistan, State of Kuwait, Sultanate of Oman, Tanzania, United Arab Emirates, Yemen, Singapore, Malaysia, Indonesia

2.2 Use GMP and equivalent regulations

11 member economies

USA, China, Chinese Taipei, Japan, Korea, Philippines, Thailand, Vietnam, Jordan, Kenya, South Africa

2.3 No QMS

8 member economies

Brunei Darussalam, Cambodia, Hong Kong SAR, Laos PDR, Mongolia, Myanmar, Zimbabwe, Kingdom of Bahrain

Around 80% coverage of ISO 13485 and GMP or local equivalent regulations in Manufacturer QMS.
The ISO 13485 and GMP applications among GHWP Members are comparable.

- **3. Clause by Clause Analysis**

Compared with the 14 member economies with local laws and regulations, there are some differences between them and ISO13485 as a whole, but the style and management philosophy tend to be the same.

For details, please see Annex I: GHWP WG7 QMS Comparison table

- **4. Conclusion**

This document is not intended to evaluate the advantages and disadvantages of laws and regulations of member economies, but only for objective comparison for your reference.

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