Global Harmonization Working Party

GHWP

Towards Medical Device Harmonization

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Title: White Paper on Overview of Quality Management System Requirements in GHWP member county or region against ISO 13485:2016

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Preface

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Introduction

The GHWP member countries or regions have different requirements on Quality Management System (QMS) for placing medical devices on the market, which can be divided into three categories:

1. No requirements
2. Implemented ISO 13485
3. Country specific Good Manufacturing Practice (GMP), Good Distribution Practice (GDP) or equivalent regulations

Purpose

This document overviews QMS requirements (status end 2024) and compares the various GMP requirements against ISO 13485: 2016 standard in GHWP member countries or regions.

This document is not intended to evaluate the advantages and disadvantages of laws and regulations of member countries or regions, but only for objective comparison for members' reference.

Scope

This document applies to applicable medical devices and in-vitro medical devices.

The overview scope of regulations used for this study is subject to both GMP for manufacturers with focus pertaining to pre-market requirements and GDP against importer, distributor, and authorised representative. The comparison scope for this study is subject to GMP regulations only.

References

- **ISO 13485**:**2016** Standard
- **China**: Good Manufacturing Practice (GMP) 2014 No.64
- **Chinese Taipei**: Guidelines for Medical Device Quality Management System
- **India**: Medical Device Rules, 2017
- **Indonesia**: Indonesia Regulation MOH No. 4 of 2014 Requirements
- **Japan**: MHLW Ministerial Ordinance No. 169 in 2004: Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and In Vitro Diagnostic Reagents
- **Jordan**: Guidelines to GMP for Medical Devices_2001
- **Kingdom of Saudi Arabia**: Requirements for Inspections and Quality Management System for Medical Devices_2011
- **South Korea**: KGMP regulation, KGMP guideline_2022

1. Overview

Quality Management System Requirements in GHWP Member Countries and Regions

Summary		
Adherence to ISO 13485:2016	Adoption of GMP based Equivalent Regulations	No mandatory QMS requirements
1 Chile	1 China	1. Brunei Darussalam
2 Kazakhstan	2 Chinese Taipei	2. Cambodia
3 Kenya	3 India	3. Hong Kong SAR
4 Kyrgyz Republic	4 Indonesia	4. Laos PDR
5 Malaysia	5 Japan	5. Mongolia
6 Pakistan	6 Jordan	6. Myanmar
7 Philippines	7 Kingdom of Saudi Arabia	7. Zimbabwe
8 Singapore	8 South Korea	8. Kingdom of Bahrain
9 South Africa		
10 State of Kuwait		
11 Sultanate of Oman		
12 Tanzania		
13 United Arab Emirates		
14 Yemen		
15 Thailand		
16 Vietnam		

Approximately 75% of the GHWP member countries or regions have implemented QMS requirements, through either adherence to ISO 13485:2016 or adopting of GMP based equivalent regulations.

2. Clause Analysis

This section compares the eight GHWP member countries and regions, who have GMP or local QMS regulations, against ISO 13485:2016. The objective is to analyse their differences, collate them, to form conclusions from the analysis results. For more details, please refer to Appendices.

China

Although there are differences in the content of China GMP comparing with ISO 13485, the coverage of the elements of the provisions is basically same respectively, for examples Quality System, Document and Records Control, Management Responsibilities, Resource Management, Design & Development and Risk Management, Production and Service Provision, Procurement,

Quality Control and Improvement. The main difference lies in the fact that China GMP and its appendices have more detailed requirements in some aspects to facilitate better implementation.

Chinese Taipei

In April 2021, Taiwan Food and Drug Administration (TFDA) released the Medical Device Quality Management System Regulation that separated the control of medical devices from the "Pharmaceutical Good Manufacturing Practice Regulations". Therefore, the requirements for the quality management system (QMS) for both domestic and foreign manufacturers shifted from ISO 13485:2003 to ISO 13485:2016.

Before a medical device can be sold in Taiwan, Quality System Documentation (QSD) registration for the manufacturing facility is required in addition to medical device registration. QSD registration is only waived for Class I (non-sterile) medical devices. A QSD license in Taiwan - received upon QSD registration approval - is similar to Good Manufacturing Practice (GMP) for medical devices.

TGMP is mandatory for all medical device manufacturers who want to sell their products in Taiwan, while 13485:2016 is voluntary and can be used as a means for medical device manufacturers to demonstrate their commitment to quality and regulatory compliance.

Some differences between TGMP and ISO 13485:2016:

TGMP demands compliance with local requirements, for instance: handling of patient records in accordance with Taiwan Personal Data Protection Act, UDI for medical devices as a traceability method, vigilance reporting, and the undertaking of corrective and preventive measures, etc.

India

1) Risk Management Approach:
   - ISO 13485: Integrates risk management throughout the quality management system, emphasizing a proactive approach to identifying, analysing, and controlling risks associated with medical devices throughout their lifecycle. It requires organizations to establish processes for risk analysis and control, ensuring potential hazards are addressed systematically.
   - India GMP: While it also addresses risk management, the approach might be more implicit through requirements such as design controls and process validation rather than a lifecycle approach as emphasized in ISO 13485.
2) Lifecycle Management:
   - ISO 13485: Provides a framework covering the entire lifecycle of medical devices, from the conceptual phase to disposal. It includes requirements for design and development, production, and post-production activities, ensuring continuous focus on quality and safety.
   - India GMP: Covers the full lifecycle with significant emphasis on pre-market approval, production controls, and quality systems, tailored to meet the regulatory environment in India.
3) Regulatory Requirements:
   - ISO 13485: Serves as a global standard and is not tied to any specific country's regulations. It is widely recognized and can facilitate international trade by meeting the quality requirements of multiple regulatory bodies.
   - India GMP: Specific to the regulatory requirements of India, including provisions unique to the Indian market, such as the need for registration and compliance with local standards and regulations.
4) Documentation and Record-Keeping:

- ISO 13485: Requires extensive documentation and record-keeping to demonstrate compliance with the standard and support the organization's quality management system, ensuring transparency and providing a basis for continuous improvement.
- India GMP: Incorporates specific requirements for documentation and record-keeping that align with Indian regulations, which may include additional or different record-keeping requirements compared to ISO 13485.

5) Post-Market Surveillance:

- ISO 13485: Underscores the importance of ongoing post-market surveillance to monitor the performance and safety of medical devices after they have been released to the market, helping to identify any unforeseen issues and take appropriate actions.
- India GMP: Includes requirements for post-market surveillance, such as the need to report adverse events and product complaints, with specific mechanisms for monitoring and reporting that align with Indian regulatory requirements.

6) Audit and Inspection:

- ISO 13485: Does not specify the audit and inspection process in detail, allowing organizations to define their approach as part of their quality management system. This provides flexibility while ensuring that internal and external audits are conducted effectively.
- India GMP: May have specific guidelines for audits and inspections that align with Indian regulatory requirements, including expectations for regulatory body interactions and compliance verification processes.

Key Points of Consideration:

- Adaptability: Organizations must adapt their quality management systems to meet both ISO 13485 standards and India GMP regulations, ensuring all local requirements are addressed.
- Compliance Verification: Manufacturers must verify compliance with both standards, as non-compliance can lead to regulatory penalties.
- Continuous Improvement: Both standards promote a culture of continuous improvement, encouraging regular reviews and updates to processes and systems.

Indonesia

1) Risk Management Approach:

- ISO 13485: This standard emphasizes the importance of risk management throughout the quality management system. Risk management is particularly crucial in the design and development phases, where potential risks to health and safety are identified and mitigated. ISO 13485 requires documentation of risk management processes and the results of risk assessments.
- Indonesia GMP: While Indonesian GMP does not explicitly mention risk management in the provided text, it is implied through the requirement of quality management systems and the need to ensure product safety and efficacy. The GMP would likely incorporate risk management principles to meet these goals, although the specifics are not in the provided excerpt.

2) Lifecycle Management:

- ISO 13485: Covers the entire lifecycle of medical devices, from design and development to production, storage, distribution, installation, and servicing. It requires organizations to demonstrate their ability to consistently meet customer and regulatory requirements throughout these stages.
- Indonesia GMP: Includes the application of quality management systems and adherence to good manufacturing practices at all stages.

3) Regulatory Requirements:

- ISO 13485: Is designed to be compatible with regulatory requirements in various countries. It does not specify national regulations but ensures that the quality management system can accommodate them.
- Indonesia GMP: Explicitly mentions compliance with Indonesian regulatory requirements, such as those outlined in Minister of Health Regulation No. 20 of 2017. This includes specific guidelines for the manufacture and distribution of medical devices within Indonesia.

4) Documentation and Record-Keeping:

- ISO 13485: Requires extensive documentation and record-keeping to demonstrate conformity to the standard and regulatory requirements. This includes quality manuals, procedures, risk management records, and records of product realization processes.
- Indonesia GMP: It details specific documents that must be maintained, such as quality guidelines, production records, and audit results.

5) Post-Market Surveillance:

- ISO 13485: Includes post-market surveillance as part of the quality management system. Organizations must have processes for gathering and analysing feedback after the product has been released to identify any issues that may arise.
- Indonesia GMP: Post-market surveillance is not explicitly mentioned in the provided text. However, the regulation would likely include post-market surveillance activities to ensure the ongoing safety and efficacy of medical devices.

6) Audit and Inspection:

- ISO 13485: Requires regular internal audits to verify the effectiveness of the quality management system and compliance with the standard and regulatory requirements. It also outlines the requirements for conducting these audits.
- Indonesian GMP: The GMP regulation also requires internal audits as part of the quality management system. Additionally, it may be subject to regulatory audits and inspections by the Indonesian health authorities to ensure compliance with the regulations.

Japan

Japan GMP for medical devices, also known as the Ordinance on Standards for Manufacturing Control of Medical Devices (MHLW Ordinance No. 169, or MO169).

1) Risk Management Approach:
   - ISO 13485: Integrates risk management as a fundamental pillar of its quality management system. It mandates that organizations systematically identify, analyse, evaluate, and mitigate risks associated with medical devices throughout their entire lifecycle—spanning from product conception to disposal.
   - Japan GMP: Adopts a highly prescriptive approach, outlining specific requirements for risk assessment and control measures. It ensures that manufacturers have a structured process for risk analysis and mitigation, which is in line with the Japanese regulatory framework.

2) Lifecycle Management:

- ISO 13485: Provides a framework for the entire lifecycle of medical devices, from concept to disposal. It includes requirements for design and development, production, and post-production activities, such as servicing and product surveillance.
- Japan GMP: Similarly covers the full lifecycle with additional emphasis on compliance with Japanese regulations, including specific guidelines for pre-market approval, post-marketing surveillance, and reporting mechanisms that are tailored to the Japanese market.

3) Regulatory Requirements:

- ISO 13485: Serves as a global standard and is not tied to any specific country's regulations. It facilitates international trade by meeting the quality requirements of various regulatory bodies, including those outside of Japan.
- Japan GMP: Is specifically designed to meet the regulatory requirements of the Japanese Ministry of Health, Labour and Welfare (MHLW). It includes unique provisions such as the need for Japanese language documentation and adherence to Japanese pharmacopeia standards.

4) Documentation and Record-Keeping:

- ISO 13485: Mandates thorough documentation and record-keeping to demonstrate compliance with the standard and support the organization's quality management system. It requires that records are maintained in a manner that is accessible, legible, and traceable.
- Japan GMP: Incorporates specific requirements for documentation and record-keeping that align with Japanese regulations, including the need for records to be kept in Japanese and adherence to specific formats for regulatory submissions and reports.

5) Post-Market Surveillance:

- ISO 13485: Highlights the significance of continuous post-market surveillance to monitor the performance and safety of medical devices once they are in the market.
- Japan GMP: Includes requirements for post-market surveillance, mandating that manufacturers actively collect and analyse data on the safety and performance of their devices post-launch. It also requires timely reporting of adverse events and implementation of corrective actions.

6) Audit and Inspection:

- ISO 13485: Does not detail the audit and inspection process, allowing organizations to define their approach as part of their quality management system. It does, however, require that internal audits are conducted regularly.
- Japan GMP: Provides a framework for the audit and inspection process, outlining the responsibilities of manufacturers and the regulatory authority during audits. It is designed to ensure that manufacturers comply with Japanese regulations and maintain a high standard of quality.

Jordan

1) Risk Management Approach:
   - ISO 13485: Requires a proactive approach to risk management, integrating it throughout the quality management system. Organizations must identify, analyze, and control risks associated with medical devices across their lifecycle, including design, manufacture, and distribution. This ensures that potential hazards are addressed systematically.
   - Jordan GMP: Take a high prescriptive approach and is less integrated compared to ISO 13485. The focus is on ensuring safety and efficacy, with specific guidelines provided for risk assessment and control measures. The emphasis might be more on compliance with local regulations rather than a holistic lifecycle approach.
2) Lifecycle Management:
   - ISO 13485: Provides a framework covering the entire lifecycle of medical devices, from concept to disposal. It includes requirements for design and development, production, and post-production activities, such as servicing and product surveillance, ensuring a continuous focus on quality and safety.
   - Jordan GMP: Covers the full lifecycle with more emphasis on certain stages, such as pre-market approval and post-marketing surveillance, which are specific to the regulatory environment in Jordan. The guidelines may be more for certain phases to align with local requirements and practices.
3) Regulatory Requirements:

- ISO 13485: Serves as a global standard, not tied to any specific country's regulations. It is widely recognized and can facilitate international trade by meeting the quality requirements of multiple regulatory bodies.
- Jordan GMP: Is tailored to meet the regulatory requirements of Jordan's healthcare sector. It includes specific provisions that are unique to the Jordanian market, such as the need for local registration and compliance with local standards, which may differ from international norms.

4) Documentation and Record-Keeping:
   - ISO 13485: Requires extensive documentation and record-keeping to demonstrate compliance with the standard and support the organization's quality management system. This ensures transparency and provides a basis for continuous improvement.
   - Jordan GMP: Incorporates specific requirements for documentation and record-keeping that align with Jordanian regulations. This may include the need for records to be kept in Arabic and adherence to specific formats for regulatory submissions, reflecting the local regulatory and linguistic context.
5) Post-Market Surveillance:
   - ISO 13485: Underscores the significance of ongoing post-market surveillance to monitor the performance of medical devices after they have been released to the market. This helps in identifying any unforeseen issues and taking appropriate actions.
   - Jordan GMP: Incorporates specific requirements for post-market surveillance, including the need to report adverse events and take corrective actions. These requirements aligned with the regulatory framework in Jordan to ensure public health and safety.
6) Audit and Inspection:
   - ISO 13485: Does not prescribe the audit and inspection process in detail, offering flexibility to the organization to define as part of its quality management system. This provides flexibility while ensuring that internal and external audits are conducted effectively.
   - Jordan GMP: Provides guidelines on the audit and inspection process, including the responsibilities of the manufacturer and the regulatory authority during audits. This ensures a structured and consistent approach to compliance verification, tailored to the local regulatory environment.

Kingdom of Saudi Arabia

1) Risk Management Approach:

   - ISO 13485: This standard emphasizes the importance of risk management throughout the quality management system. It requires organizations to identify, assess, and control risks associated with medical devices, including those related to design, manufacturing, and post-market activities. Risk management processes must be documented and regularly reviewed.
   - Saudi Arabia GMP: The Saudi regulations also require a risk-based approach, ensuring that manufacturers identify and control risks associated with medical devices. This includes risk assessment during design and development, as well as ongoing risk management throughout the product's lifecycle.

2) Lifecycle Management:

   - ISO 13485: The standard covers the entire lifecycle of medical devices, from design and development to production, distribution, installation, and post-market surveillance. It requires organizations to demonstrate their ability to consistently meet customer and regulatory requirements at every stage of the device's lifecycle.
   - Saudi Arabia GMP: Focus on lifecycle management, manufacturers are required to ensure the quality, safety, and performance of medical devices throughout the product lifecycle, including post-marketing activities.

3) Regulatory Requirements:

- ISO 13485: The standard is not specific to any one country's regulations, it is designed to be compatible with various regulatory requirements worldwide. It provides a framework that can be adapted to meet specific regulatory needs.
- Saudi Arabia GMP: Specific to Saudi Arabia and are in line with the country's medical device laws and executive regulations. They outline the requirements for inspections, quality management systems, and post-market surveillance, ensuring compliance with local standards.

4) Documentation and Record-Keeping:

- ISO 13485: Requires documentation of quality management systems, including procedures, processes, risk assessments, and records of product realization. It emphasizes the importance of maintaining accurate and up-to-date records.
- Saudi Arabia GMP: Mandate documentation and record-keeping, this includes maintaining records of inspections, quality management systems, and post-market surveillance activities, ensuring transparency and traceability.

5) Post-Market Surveillance:

- ISO 13485: Includes requirements for post-market surveillance, where organizations must monitor and gather data on the performance and safety of medical devices after they have been released to the market. This information is used to identify and address any potential issues.
- Saudi Arabia GMP: Manufacturers are required to monitor and report any adverse events or issues related to their medical devices, ensuring ongoing safety and compliance.

6) Audit and Inspection:

- ISO 13485: Requires organizations to conduct internal audits at planned intervals to verify the effectiveness of their quality management systems. It also outlines the requirements for external audits and inspections by regulatory authorities.
- Saudi Arabia GMP: Mandate regular inspections and audits to ensure compliance with the quality management system and regulatory requirements. This includes both internal audits conducted by the organization and external audits by the Saudi Food and Drug Authority (SFDA).
- ISO 13485: Procedures should include requirements and responsibilities for handling complaints, which may involve disposal of non-conforming products.
- Philippines: Requires proper disposal of expired, contaminated, damaged, or defective devices in accordance with government regulations.

South Korea

KGMP audit criteria:

GMP audits are conducted in accordance with KGMP Annex [2] GMP Audit Criteria for Medical Devices, which are generally consistent with ISO 13485:2016 standard requirements, with the following adjustments made in accordance with the medical device regulatory requirements of Korea:

4.2.5 Records Control, Regarding Records Retention Period, KGMP states that "The period for which records are retained by the organization shall be at least the lifetime of the medical device established by the organization. The period shall be five years or more from the date of manufacture and two years or more after release."

5.5.2 Management Representative, referred to in KGMP as "Quality Manager", with qualification requirements such as "6+ years of quality control experience with a medical device manufacturer or importer".

7.5.8 Labeling, KGMP specifying labeling, registration requirements for manufacturer information and product information in electronic systems, etc.

8.2.3 Reporting to Regulatory Authorities KGMP stipulates adverse event management, reporting, etc.

3. Executive Summary

Compared to the eight member countries or regions with local laws and regulations with ISO 13485:2016, there are some differences between them and ISO 13485 as a whole, but the style and management philosophy tend to be the same.

3.1 Risk Management Approach:

- ISO 13485: Integrates risk management throughout the quality management system, emphasizing a proactive approach to identifying, analysing, and controlling risks associated with medical devices throughout their lifecycle.
- China: Emphasizes risk management but may approach it differently, with a focus on ensuring safety and efficacy.
- Chinese Taipei (TGMP): Requires risk management in line with ISO 13485, with additional local requirements.
- India: Risk management is an integral part of the GMP, with a focus on safety and efficacy.
- Indonesia: Risk management is implied through quality management system requirements.
- Japan (MHLW Ordinance No. 169): Outlines specific risk assessment and control measures, aligned with the Japanese regulatory framework.
- Jordan: Risk management is addressed with a focus on compliance and safety.
- Kingdom of Saudi Arabia: Risk management is integrated into the GMP, following local regulatory requirements.
- South Korea: Has a risk-based approach similar to ISO 13485, integrated within the quality management system.

3.2 Lifecycle Management:

- ISO 13485: Covers the entire lifecycle, from design to disposal, with requirements for each stage.
- China: Lifecycle management with an emphasis on pre-market approval and post-marketing surveillance.
- Chinese Taipei: Full lifecycle coverage with additional requirements for traceability and vigilance reporting.
- India: Full lifecycle management with a focus on regulatory compliance and quality assurance.
- Indonesia: Lifecycle management with a focus on quality control and assurance.
- Japan: lifecycle management tailored to Japanese regulations.
- Jordan: Lifecycle management with a focus on regulatory requirements and post-marketing activities.
- Kingdom of Saudi Arabia: Lifecycle management in line with local regulations and post-market surveillance.
- South Korea: Lifecycle management with a focus on continuous improvement and risk management.

3.3 Regulatory Requirements:

- ISO 13485: Serves as a global standard, not tied to any specific country's regulations.
- China: Tailored to meet the regulatory requirements of China's NMPA.
- Chinese Taipei: Specific to Taiwan's regulations, including UDI and vigilance reporting.
- India: Aligns with India's Central Drugs Standard Control Organization (CDSCO) regulations.
- Indonesia: Specific to Indonesia's health ministry regulations.
- Japan: Unique to Japan's regulatory framework, including Japanese language documentation.

- Jordan: Specific to Jordan's healthcare regulations and standards.
- Kingdom of Saudi Arabia: Unique to Saudi Arabia's medical device laws and regulations.
- South Korea: Meets the regulatory requirements of the Korean Ministry of Food and Drug Safety.

3.4 Documentation and Record-Keeping:

- ISO 13485: Requires extensive documentation and record-keeping for quality management and regulatory compliance.
- China: Specific documentation requirements, including records should be in Chinese.
- Chinese Taipei: Requires documentation in line with ISO 13485, with additional local requirements.
- India: documentation and record-keeping as per Indian medical device regulations.
- Indonesia: Documentation and record-keeping as part of the quality management system.
- Japan: Requires records to be kept in Japanese and adherence to specific formats for regulatory submissions.
- Jordan: Documentation and record-keeping aligned with Jordan's healthcare regulations.
- Kingdom of Saudi Arabia: Documentation and record-keeping requirements specific to Saudi Arabian regulations.
- South Korea: Documentation and record-keeping requirements aligned with Korean regulations.

3.5 Post-Market Surveillance:

- ISO 13485: Emphasizes ongoing post-market surveillance to monitor device performance and safety.
- China: Requires post-market surveillance, including the reporting of adverse events.
- Chinese Taipei: Post-market surveillance with specific requirements for vigilance reporting.
- India: Post-market surveillance requirements to monitor device safety and performance.
- Indonesia: Post-market surveillance activities to ensure ongoing safety and efficacy.
- Japan: post-market surveillance requirements, including adverse event reporting.
- Jordan: Requires post-market surveillance and reporting of adverse events.
- Kingdom of Saudi Arabia: Post-market surveillance as part of the medical device regulations.
- South Korea: Ongoing post-market surveillance aligned with Korean regulatory standards.

3.6 Audit and Inspection:

- ISO 13485: Does not detail the audit and inspection process, allowing flexibility within the quality management system.
- China: Audit and inspection processes aligned with China's NMPA regulations.
- Chinese Taipei: Audit and inspection requirements in line with local regulations and ISO 13485.
- India: Audit and inspection processes as per India's CDSCO regulations.
- Indonesia: Audit and inspection requirements as part of the quality management system.
- Japan: Clear framework for audit and inspection, including responsibilities of manufacturers and regulatory authority.
- Jordan: guidelines on audit and inspection processes, including regulatory authority responsibilities.
- Kingdom of Saudi Arabia: Audit and inspection requirements specific to Saudi Arabian regulations.
- South Korea: Audit and inspection processes as per Korean regulatory standards.

This analysis highlights the key similarities and differences in the approach and specific requirements of ISO 13485 and the GMP regulations of the 8 GHWP member countries or regions. While ISO 13485 provides a broad, globally applicable framework, each country's GMP regulations incorporate additional, specific requirements tailored to their local regulatory environments and healthcare systems.

4. Definitions

4.1 GDP: Good Distribution Practice

4.2 GMP: Good Manufacturing Practice

4.3 QMS: Quality Management System

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