

# Overview of Quality Management System Requirements in GHWP Member Countries or Regions

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# PART 01

## The Significance of Comparing ISO 13485 and GMP



The Significance of Comparing  
ISO 13485:2016 and GMP

01

Quality Management System Requirements  
in GHWP Member Countries and Regions

02

Practical Applications of  
Comparative Analysis

03

C O N T E N T S



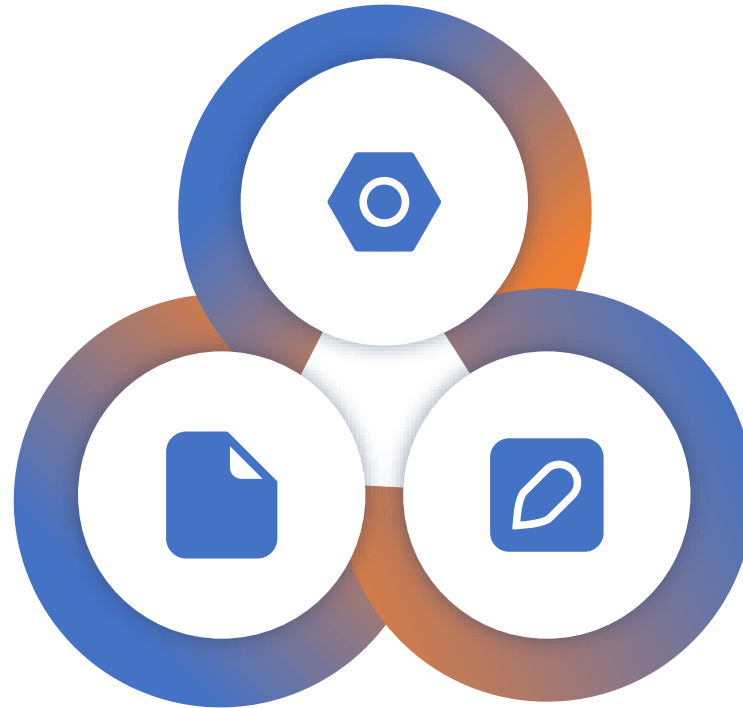
## The Importance of Global Harmonization in Medical Device Regulation

### Facilitating International Trade

Harmonized regulatory standards reduce compliance costs in international trade. ISO 13485, as an internationally recognized standard, helps clarify the requirements for medical devices entering global markets, thus lowering trade barriers.

### Enhancing Regulatory Efficiency

Comparative analysis helps regulatory bodies understand the differences between standards and regulations in different countries or regions, optimize local regulatory processes, and explore global harmonization and regulatory reliance.



### Promoting Innovation & Compliance

Identifying the differences between various GMPs and ISO 13485 helps companies consider compliance requirements during product development, fostering innovation while ensuring regulatory adherence.



## Methodology for Comparison Study



### Systematically Comparative Analysis

Systematic comparison of ISO 13485 against all the 32 GHWP member countries or regions' GMP or QMS related regulations, including clause-by-clause comparison, case studies, and expert interpretation.



### In-depth Analysis of Key Clauses

Detailed interpretation of key clauses, such as risk management, quality control, and regulatory compliance, to understand and interpret the regulatory logic and the reasons behind.



### Practical Challenges

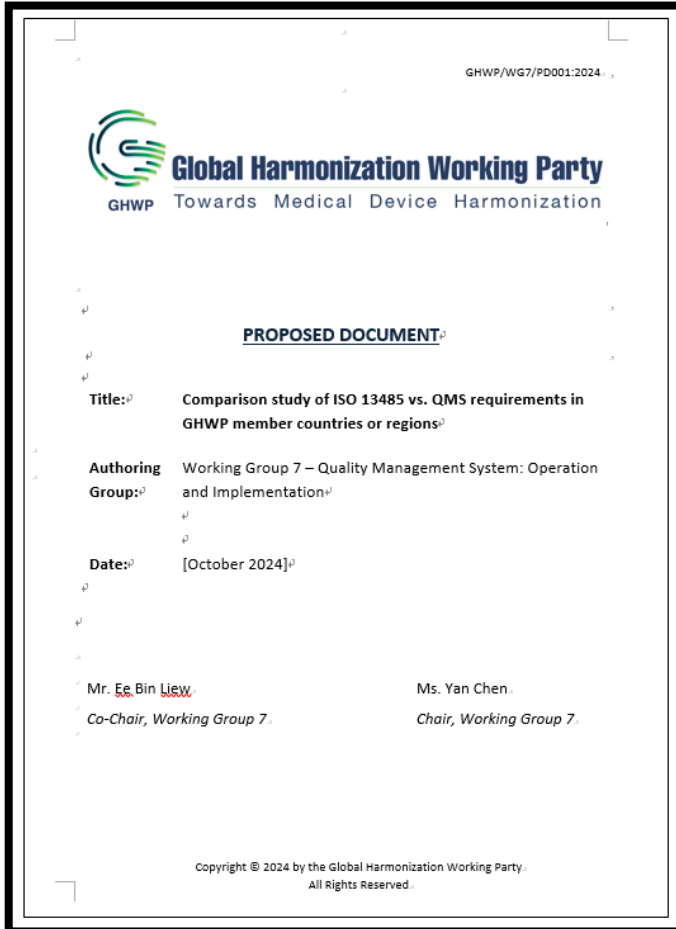
Identify potential challenges in applying the comparison in practice, such as cultural differences, language barriers, regulatory evolution.



# PART 02

## Quality Management System Requirements in GHWP Member Countries and Regions

# Quality Management System Requirements in GHWP Member Countries and Regions



## Adoption of GMP Based Equivalent Regulations

- |                   |                            |
|-------------------|----------------------------|
| 1. China          | 5. Japan                   |
| 2. Chinese Taipei | 6. Jordan                  |
| 3. India          | 7. Kingdom of Saudi Arabia |
| 4. Indonesia      | 8. South Korea             |

## Adherence to ISO 13485:2016

- |                    |                          |
|--------------------|--------------------------|
| 1. Chile           | 9. South Africa          |
| 2. Kazakhstan      | 10. State of Kuwait      |
| 3. Kenya           | 11. Sultanate of Oman    |
| 4. Kyrgyz Republic | 12. Tanzania             |
| 5. Malaysia        | 13. United Arab Emirates |
| 6. Pakistan        | 14. Yemen                |
| 7. Philippines     | 15. Thailand             |
| 8. Singapore       | 16. Vietnam              |

## No mandatory QMS requirements

1. Brunei Darussalam
2. Cambodia
3. Hong Kong SAR
4. Laos PDR
5. Mongolia
6. Myanmar
7. Zimbabwe
8. Kingdom of Bahrain



## Differences and Similarities Between GMP and ISO 13485



### Risk Management Approaches

ISO 13485 emphasizes risk management throughout the product lifecycle, while some GMPs may focus more on specific stages of product lifecycle.



### Lifecycle Management

ISO 13485 covers the entire lifecycle from design to disposal, whereas GMPs may vary according to the country specific regulations.



### Nature of Statute

ISO 13485 serves as a global standard, while GMPs include specific country specific or regional regulatory requirements.





# Compare Country/Region's QMS Regulation with ISO 13485:2016

8 countries/regions have local QMS regulations: China, Chinese Taipei, India, Indonesia, Japan, Jordan, Kingdom of Saudi Arabia, South Korea

## ➤ Clause Analysis by Country/Region

Compares country/region specific GMP or QMS regulations with ISO 13485:2016 clause-to-clause to analyse differences, collate them and to form conclusions from the analysis.

- ✓ China
- ✓ Chinese Taipei
- ✓ India
- ✓ Indonesia
- ✓ Japan
- ✓ Jordan
- ✓ Kingdom of Saudi Arabia
- ✓ South Korea

## ➤ Cross Country/Region Analysis by Chapter

Highlights the key similarities and differences in the approach and specific requirements although their style and management philosophy tend to be the same. ISO 13485:2016 is a globally applicable framework, which was incorporated by each of the 8 country or region's GMP regulations with more or less additional and specific requirements tailored to their local regulatory environments and healthcare systems.

- ✓ Lifecycle management
- ✓ Regulatory requirements
- ✓ Documentation and record-keeping
- ✓ Post-market surveillance
- ✓ Audit and inspection



# PART 03

## Practical Applications of Comparative Analysis



## Application in Quality Management Systems



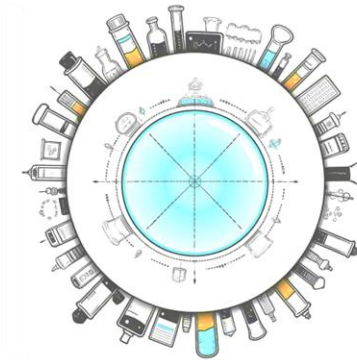
### Optimizing Quality Management Systems

Comparative analysis helps companies optimize their quality management systems to meet different regulatory requirements and enhance global competitiveness.



### Improving Risk Management

Comparative analysis aids companies in improving their risk management processes, ensuring effective risk identification and control in different regulatory environments.



### Promoting Regulatory Reliance

Comparative analysis provides the fact base for regulatory authorities in particular countries or regions to see the position of one country or region's regulation and to decide where one country or region's regulation would proceed, harmonization or country characterized.



Thank you!