Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

26th Annual Meeting
Riyadh, Saudi Arabia

Technical Committee Meeting
15 February 2023

Working Group 7

Quality Management System - Operation and Implementation

WG7 Leadership Update

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Chair : Ms. Yan Chen (since 2022)
Director, Division of Inspection Five (Medical Device), CFDI, NMPA - China

Co-Chair : Mr. Ee Bin Liew
ISO TC210 WG1, JWG1, WG6 drafting committee - Singapore

Secretary : Ms. Annie Yin
Vice President, Medical, Regulatory & Quality, Roche Diagnostics - China

Advisor : Mr. Hideki Asai
ISO TC210 WG1, WG6 drafting committee - Japan

Advisor : Mr. Ir. Peter W.J. Linders (since 2022)
The Netherlands

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Ms. Yan Chen

Director, Division of Inspection V (Medical Device)

Center for Food and Drug Inspection (CFDI) of NMPA

Inspector for medical device

CFDI
CENTER FOR FOOD AND DRUG INSPECTION OF NMPA
NATIONAL CENTER FOR VACCINE INSPECTION

CFDI is affiliated to NMPA,China. Its main responsibilities include: undertake inspections for drugs, medical devices and cosmetics, overseas inspections, GCP inspections.

DivisionV responsibilities: formulating the rules and technical documents for medical device inspection system, organizing and carrying out unannounced and overseas inspections on medical device manufacturers. Additionally, role includes, team construction of the national medical device inspectors, as well as international exchange and cooperation and technical research.

I joined the Inspection Center in 1997 and had more than 10 years experiences as Deputy Director of Drug Inspection Divsion and Quality Division.

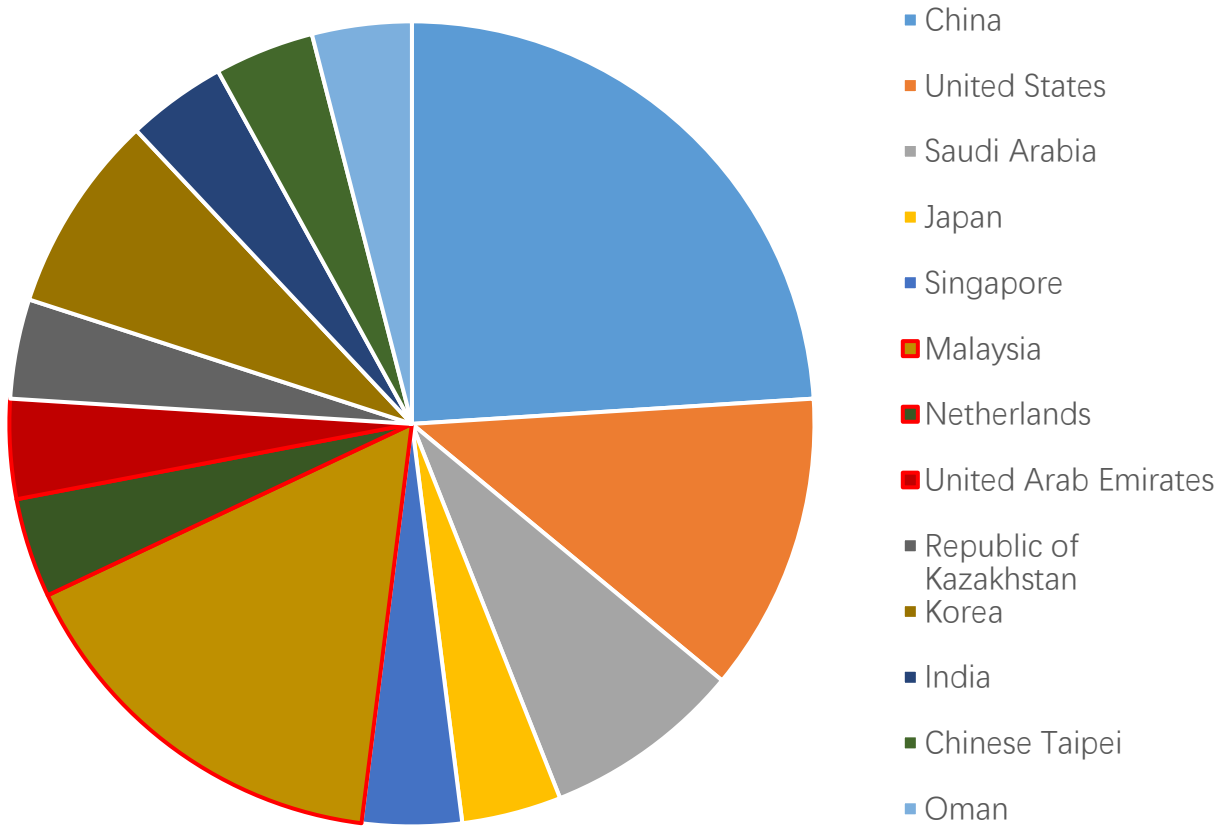
WG7 Membership Update - 2023

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

- Number of members: 25
- Number of countries(regions): 13

Breakdown by Country(regions)

Country(regions)	Number
China	6
United States	3
Saudi Arabia	2
Japan	1
Singapore	1
Malaysia	4
Netherlands	1
United Arab Emirates	1
Republic of Kazakhstan	1
Korea	2
India	1
Chinese Taipei	1
Oman	1
Total	**25**



WG7 Work Plan 2018 ~ 2022

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

No	Work Item	Deliverables	Status
1	Comparison study of new ISO13485 vs. QMS requirements in members	• Matrix of AHWP member QMS requirement status	Completed, in formatting phase
2	Guidance Document on the QMS considerations required by manufacturers and importers for localization	• Create guidance document and introduce to GHWP member economies	Completed, sent for public comment
3	Guidance document on the risk-based approach to quality management system aspects: ISO13485:2016	• Create guidance document and introduce to GHWP member economies	First draft to be completed by end Dec 2022 Overall completion Q2 2023

Work Item: Comparison study of new ISO13485 vs. QMS requirements in members

- Matrix of GHWP member QMS requirement status

GHWP 33 Members - East Asia (16)	QMS	
	Manufacturer	Distributor
Brunei Darussalam	-	-
Cambodia	-	-
China	GMP	GSP
Chinese Taipei	GMP	GDP
Hong Kong SAR, China	-	GDP
Indonesia	ISO13485	CDAKB
Japan	JQMS	QMS Ordinance
Korea	GMP	GDP
Laos PDR	-	-
Malaysia	ISO13485	GDPMD
Mongolia	-	-
Myanmar	-	-
Philippines	GMP	GDP
Thailand	GMP	GDP
Vietnam	GMP	-
Singapore	ISO13485	GDPMDS

GHWP 33 Members - The rest of 33 Members (17)	QMS	
	Manufacturer	Distributor
Chile	–	-
India	ISO13485	-
Jordan	GMP	GDP
Kazakhstan	-	-
Kingdom of Bahrain	-	-
Kingdom of Saudi Arabia	ISO13485	GDP
Kyrgyz Republic	-	-
Pakistan	ISO13485	-
Kenya	GMP	GDP
South Africa	GMP	-
State of Kuwait	-	-
Sultanate of Oman	ISO13485	-
Tanzania	-	-
United Arab Emirates	-	-
USA	QSR	-
Yemen	-	–
Zimbabwe	-	-

How do they look like?

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

- QMS considerations required by manufacturers and importers for localization

- Risk-based approach to quality management system aspects

Focus for 2023

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

- Global trend of Good Distribution Practice with GHWP member countries

Guidance Document for GDP

- Guidance Document is included in MD9 from IAF

IAF MD9

- Based out of ISO13485:2016, to **drive further adoption across** GHWP member countries.

Proposed Online Q&A Forum for WG7

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

INITIAL THOUGHTS . . . .

- Receive questions, comment from the public about our guidance documents
- Drive public engagement on quality management systems
- Answer questions posted, by WG7 members, secretary, co-chairs, advisors

NOTE

- Not meant to replace public comment prior to GD release
- Currently searching for the most appropriate mechanism to launch

OUR VISION for WG 7

Expand coverage,

to serve member economies

Support global harmonization,

to elevate medical device quality and safety,

for patients and public health

From WG7 Chair:

Many Thanks for your support and contribution to WG7

all WG7 members, especially

Mr. Ee Bin, Ms. Annie Yin, Mr. Hideki Asai,
Ms. Aijun Wang, Mr. Ir. Peter W.J. Linders

Thank you for your support:

GHWP Leadership
GHWP Secretariat and other working groups.

Looking forward towards more collaborations to jointly grow GHWP and WG7.