Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

Day 1 Agenda: 9 December 2024
Venue: Kuala Lumpur Convention Centre

		Theme Regulatory Excellence/ Best regulatory practices	
	TIME		
1	**0915-0930**	**Welcome address**	**GHWP Vice Chair**
		Regulatory Excellence	
2	**0930-0945**	Introduction to Regulatory Excellence - What is Regulatory Excellence - Defining and Assessing Regulatory Excellence	Mr. Brad Spring - Global Head of Policy and Intelligence -Roche Diagnostics
3	**0945-1000**	How To Regulate With Excellence- Achieving Regulatory Excellence	MDA, Malaysia Dr. Muralitharan Paramasu
4	**1000-1015**	Excel Regulatory Excellence in the MedTech Industry	Ms. Diana Kaneka Strategies, Special Projects & International Affairs, Senior Manager International Affairs, Global Medical Technology Alliance (GMTA)
5	**1015-1030**	Development of the Global Benchmarking Tool (GBT)	Mr. SILLO, Hiiti Baran Unit Head, Regulation and Safety, Department of Regulation and Prequalification, WHO
	1030-1050	TEA BREAK	
		Global Regulatory Framework	
6	**1050-1105**	GHWP Playbook for Implementation of Medical Device Regulatory Frameworks and support from GHWP to establish a regulatory framework	Dr. Adelheid Schneider, GHWP WG 2 Vice Chair
7	**1105-1120**	WHO Global model regulatory framework for medical devices including in vitro diagnostic medical devices (GMRF)	Ms. Agnes Sitta Kijo, Technical Officer, WHO
8	**1120-1135**	IMDRF Regulatory framework	Ms. Nicole Smith, Head of Regulatory Affairs & Policy - PSQ Regulatory Affairs, Philips
9	**1135-1205**	Sharing best practices of implementing a national regulatory framework (1)Experience sharing on enforcing regulatory requirements to ensure continuous compliance (Malaysia) (2)Implementing the regulatory framework in Egypt (3) Implementing the regulatory framework in Bahrain	Malaysia, Egypt, Bahrain - 10 minutes each Mr. Dery Akmal bin Abdul Rahman, MDA Malaysia Dr.Rania Ahmed, EDA Eng.Nada Al Sayegh, NHRA Bahrain

10	**1205-1230**	PANEL - How does an ideal regulatory framework look like?	Moderator- Ms. Miang Tanakasemsub Head of Regulatory Affairs (RA) Asia Pacific (AP) Johnson & Johnson Vision Panelists - Dr. Adelheid Schneider, Ms Agnes Sitta Kijo, Malaysia, Dr. Rania Ahmed and Eng. Nada Al Sayegh
	1230-1345	LUNCH	
		Regulatory Skills and Talent Pipeline	
11	**1345-1400**	Insights to GHWP Regulatory Competency Framework and Curriculum for Industry and Regulators	Ms. Kitty Mao RA Director GE Healthcare Singapore
12	**1400-1415**	Regulatory Excellence Ecosystem Industry : sharing best practise to actively support growth and development of regulatory professionals	Mr. Daniel Moeland Johnson & Johnson MedTech
13	**1415-1430**	Regulatory Excellence Ecosystem Regulators : sharing best practise to actively support growth and development of regulators	Dr. Razan Asally Head of medical evaluation section SFDA
14	**1430-1445**	Conversations That Matter - Interactions with Health Authorities	Ms. Raina E. Dauria, RAC, MS Vice President, Global Regulatory Policy and Talent, MedTech Johnson & Johnson MedTec
15	**1445-1515**	PANEL - Working in regulatory affairs - Sharing tips and experiences (beginners and mature regulatory personal of Industry and Authorities)	Moderator Ms. Marianne Yap, Alcon Mr. Muhammad Sabirrin Md Zahar, MDA Ms. Jacqueline Fok, RA Manager, Alcon Mr. Sharad Shukla, J&J, Dr. Razan Asally, SFDA Ms. Raina E.Duaria
	1515-1545	TEA BREAK	
		Clinical Evidence & RWE	
16	**1545-1600**	How to demonstrate Clinical Evidence	Mr. Rajakumaran Karnagaran (BSI)- confirmed
17	**1600-1615**	Acceptance of clinical oversea data for Clinical Evidence versus Local Testing	Dr. Adelheid Schneider GHWP WG 2 Vice Chair (confirmed)
18	**1615-1630**	Best practise on Real World Evidence Usability in Device Applications	Dr. Rama Sethuraman Head of Quality and Regulatory Asia Pacific Roche Diagnostics Asia Pacific Pte Ltd
19	**1630-1645**	Evaluating the Quality of Real-World Evidence Used to Support Regulatory Decision-Making for Medical Devices	Prof. Gao WG-4 Advisor
20	**1645-1715**	Panel on Challenges and Opportunities on Clinical Evidence using RWE	Moderator Mr. Mohammed Y. Majrashi (SFDA) confirmed Panelists Presenters
	1715-1730	**Summary Day 1**	TC Chair or Co Chair, or Capacity Building respresentative
		Adjourn	
END OF DAY 1			

	Day 2 Agenda: 10 December 2024 Venue: Kuala Lumpur Convention Centre		
		Theme Regulatory Excellence/ Best regulatory practices	
	TIME		
		Welcome DAY 2	
1	**0830-0845**	GHWP Capacity Building Initatives	Ms. Quan Tran
		Cybersecurity and Robotics	
2	**0845-0900**	EU AI Act	Mr. Robert Froehlich Head of MHS ASEAN (VP) TÜV SÜD PSB Pte Ltd
3	**0900-0915**	Cybersecurity: Integrating Medical Device Cybersecurity in the Quality Management System	Ms. Jennifer Khow Chui Ping (Synapxe)Deputy Director - Synapxe (Subsidiary of Singapore MOH) (Video)
4	**0915-0930**	Consideration for innovative robotic assisted Surgical Devices	Mr. Sharad Shukla Director Regulatory Affairs Johnson & Johnson International (Singapore) Pte. Ltd
5	**0930-0945**	PANEL	Moderator Jennefer Ramos Head of RA Growth Region – PSQ Panelist-Mr. Robert Froehlich (TÜV) Mr. Sharad Shukla (Johnson & Johnson)
	0945-1015	TEA BREAK	
		Labeling and UDI	
6	**1015-1030**	Key trends on digital labeling	Mr. Shekhar Nambi Johnson & Johnson MedTech
7	**1030-1045**	Update from the MEA region on Electronic Instructions for Use (EIFU)	Ms. Heba Tork- Regulatory and Quality Manager - Roche Diagnostics (Egypt)
8	**1045-1100**	Regulatory perspective on elabeling	Mr. Winson Teng (BD)- APACMed
9	**1100-1115**	Industry perspective on UDI - Opportunities and challenges	Ms. Yuyi from Wego Group
10	**1115-1130**	The role of UDI in whole product life cycle management	Mr. Dennis Black from BD
11	**1130-1145**	The role of standards	Mr. Gite Sadanand, Abbott Associate Director, Regulatory Affairs Strategic Programs
12	**1145-1215**	PANEL - Benefits, opportunities and approaches on e-labeling	Dr. Petra Kaas Wiele - TC Advisor and Consultant
	1215-1330	LUNCH	
		QMS and PMS	
13	**1330-1345**	Briefing of ISO/TC 210 progress on ISO13485	Dr. Ir. Peter W.J. Linders, GHWP TC Advisor/Former Director, Global Standards & Regulations, Former Philips Healthcare (Video)
14	**1345-1400**	Overview of QMS implementation in GHWP member economies	Ms. Annie Yin, WG7 Secretary/Vice President, Roche Diagnostics China
15	**1400-1410**	Case sharing of QMS implementation in China	Ms. Jie Zhu, Quality Manager, Mindray Bio-Medical Electronic Co. LTD
16	**1410-1425**	Guidance for Audit Supplier for Medical device Manufacturers	Ms. Ning Li, Sr. Director of Q&R, Miceo-Tech
17	**1425-1440**	Industry Perspective on MDSAP	Ms. Asmaa Awad Global Head of Eastern Europe, Middle East, and Africa Regulatory Policy Roche Diagnostics ME

18	**1440-1455**	Good Distribution Practices for Medical Device GDPMD	Mr. Tony Low Director of Human Performance and Medical QA/RA Commissioning Agents International (CAI)
19	**1455-1510**	Reporting and investigating adverse events and complaints of medical devices or Safety alerts and field safety corrective action (FSCA) for medical devices	Dr. Mohammed Majrashi Executive Director Surveillance and Biometric Saudi Food & Drug Authority (SFDA) Kingdom of Saudi Arabia
20	**1510-1525**	Fit for purpose change management - GHWP Guideline (draft) - Change Management - Industry Perspective	Ms. Cindy Pelou (APACMed)
21	**1525-1545**	PANEL - The criticality of PMDA and QMS in regulatory framework.	Moderator Mr. Raghavan Nair, Mr. Asok Kumar, Abbott Quality and Regulatory Director - Global Strategic Regulatory Affairs
	1545-1615	TEA BREAK	
		Convergence and Reliance	
22	**1615-1630**	Common Evaluation Reliance Practice Updates	Mr. ZHANG Shiqing, STG CERP Chair
23	**1630-1645**	Good Reliance Practice	Ms. Agnes Sitta Kijo Technical Officer, WHO
24	**1645-1700**	Regulatory convergence & reliance in Africa - sharing good practice	Ms. Paulyne Wairimu Chair of the African Medical Devices Forum
25	**1700-1715**	Regulatory convergence & reliance in Asia - sharing good practice - on behalf of APACMed	Ms. Yasha Huang Roche
26	**1715-1730**	Regulatory convergence & reliance in ME - sharing good practice - MEA- MECOMED	Ms. Rana Chalhoub Regulatory Affairs Director, MECOMED
27	**1730-1750**	Panel Convergence and Reliance	Moderator Ms. Cindy Pelou -APACMed (confirmed) Panelists-Ms. Agnes Sitta Kijo (WHO) Ms. Paulyne Wairimu (AMF) Ms. Yasha Huang (Roche) Ms. Nicole Smith (Philips) Ms. Rana Chalhoub (Mecomed)
28	**1750-1800**	Closing and Summary Day 2	TC Chair or Co Chair, or Capacity Building respresentative
		Adjourn	

Day 3 Agenda: 11 December 2024
Morning: Closed-door Meeting
Venue: Kuala Lumpur Convention Centre

28th GHWP Technical Committee (GHWP TC) Meeting
Attendees: GHWP LT, TC LT, TC Advisor, TC Secretariat, WG Chair/Co-chair

Moderator: Dr. Mohammed Y Majrashi
GHWP Acting TC Chair
Executive Director, S&B, SFDA, Kingdom of Saudi Arabia

No.	TIME	ITEM	SPEAKER
1	0900-1200	GHWP TC & WG Leaders Meeting with TC Advisors (Closed-Door Meeting)	
Day 3 Agenda: 11 December 2024 Afternoon: Open Meeting Venue: Kuala Lumpur Convention Centre			
2	1400-1410	Opening Speech	Dr. Mohammed Y Majrashi GHWP Acting TC Chair Executive Director, S&B, SFDA, Kingdom of Saudi Arabia
3	1410-1415	Roll call Adoption of Agenda	Ms. LI Jun GHWP TC Co-Chair (Regulatory Authority) Deputy Director General, Center for Medical Device Evaluation, NMPA, People's Republic of China
4	1415-1420	Adoption of 27th GHWP TC Meeting Minutes	Ms. Miang Tanakasemsub GHWP TC Co-chair (Industry) Head of Regulatory Affairs, Asia Pacific Johnson & Johnson Vision, Thailand
5	1420-1500	Work Group 1 (WG1) - Pre-Market Submission and CSDT	Work Group 1 (WG1)
6		Work Group 2 (WG2) - Pre-market: IVDD	Work Group 2 (WG2)
7		Work Group 3 (WG3) - Pre-market: Software as a Medical Device	Work Group 3 (WG3)
8		Work Group 4 (WG4) - Post-Market	Work Group 4 (WG4)
1500-1530		TEA BREAK	
9	1530-1620	Work Group 5 (WG5) - Clinical Evidence for Performance and Safety	Work Group 5 (WG5)
10		Work Group 7 (WG7) - Quality Management System	Work Group 7 (WG7)
11		Work Group 8 (WG8) – Standards	Work Group 8 (WG8)
12		Work Group 9 (WG9) – UDI & Nomenclature	Work Group 9 (WG9)
13		Special Task Group (STG) - Common Evaluation Reliance Practice (CERP)	STG CERP
14	1620-1630	Q&A	
15	1630-1650	TC Advisors Summary Report	TC Advisory Panel
16	1650-1700	Closing Remarks for Day 3	Ms. Miang Tanakasemsub GHWP TC Co-chair (Industry) Head of Regulatory Affairs, Asia Pacific Johnson & Johnson Vision, Thailand
17	1700	**Adjourn**	
END OF DAY 3			
1800		**Gala Dinner**	

Day 4 Agenda: 12th Dec 2024

Venue: Kuala Lumpur Convention Centre

ITEMS	TIME	28th GHWP Annual Meeting (Main Meeting)	
1	0855-0900	Announcement by MC (5mins)	Moderator: From Malaysia MDA (TBC)
2	0900-0930	Opening Ceremony (30mins) - Welcome Video (5mins) - Welcome Address (5mins) - Opening Address (5mins) - Group Photo (15mins)	Moderator: From Malaysia MDA (TBC) Welcome Address- DR. MURALITHARAN PARAMASUA Chief Executive, Medical Device Authority (MDA), Ministry of Health (MoH) Opening Address- Xu Jinghe GHWP Chair Deputy Commissioner, NMPA, People's Republic of China
3	0930-0940	Main Meeting - Roll Call (8mins) - Adoption of the Agenda (1min) - Adoption of the 27th GHWP Annual Meeting Minutes (1min)	Dr. Xu Jinghe GHWP Chair Deputy Commissioner, NMPA, People's Republic of China Mr. Bryan SO GHWP Executive Secretary General Managing Director, Multi-Scale Medical Robotics Center, The Chinese University of Hong Kong, Hong Kong SAR, China
4	0940-1025	GHWP Status Reports: (45mins) a) GHWP Overall Status Report (10mins + 5mins Q&A) b) GHWP Technical Committee Status Report (10mins + 5mins Q&A) c) GHWP Academy Status Report (10mins + 5 mins Q&A)	Dr. Xu Jinghe GHWP Chair Deputy Commissioner, NMPA, People's Republic of China Dr. Mohammed Majrashi Acting GHWP TC Chair Executive Director, Surveillance and Biometric, Saudi Food & Drug Authority (SFDA), Kingdom of Saudi Arabia GHWP Academy Representative (TBC)
5	1025-1110	International Organizations & Harmonization Efforts (10mins+5mins Q&A each) a) WHO b) IMDRF c) African Medical Devices Forum (AMDF)	a) Mr. SILLO, Hiiti Baran Unit Head, Regulation and Safety, Department of Regulation and Prequalification, WHO b) b) Dr. Miho SATO Principal Coordinator of Pharmaceuticals and Medical Devices Agency PMDA, Japan c) MS. Paulyne Wairimu Chair, African Medical Devices Forum (AMDF)
1110-1200		Participants can proceed to Hall 2 for the Closing Ceremony of IMDEC	
1200-1300		LUNCH	

6	1300-1400	GHWP Liaison Member Updates (5mins + 5mins Q&A each) a) Asia Pacific Medical Technology Association (APACMed) b) Global Diagnostic Imaging, Healthcare IT& Radiation Therapy Trade Association (DITTA) c) GS1 d) Global Medical Devices Nomenclature Agency (GMDN Agency) e) Global Medical Technology Alliance (GMTA) f) Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector (IACRC)	a) Ms. Cindy Pelou Lead for Regulatory Affairs, APACMed b) Ms. Sunny Woo Team Leader, Korea Medical Devices Industry Association, International Affairs Team, DITTA c) Ms. Chiara Bernini Senior Manager Healthcare Public Policy, GS1 d) Mrs. Chinaniso Majoni Senior Nomenclature Developer and Quality Lead, Global Medical Devices Nomenclature Agency (GMDN Agency) e) Ms. Diana Kanecka Strategies, Special Projects & International Affairs, Senior Manager International Affairs, Global Medical Technology Alliance (GMTA) f) Ms. Sandra Ligia Gonzalez Executive Secretary, Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector (IACRC) (Video)
7	1400-1530	Country/Region Updates (5mins+5mins Q&A each) a) Malaysia b) Cuba c) Egypt d) Indonesia e) Japan	a) Dr Muralitharan Paramasuaaidahwaty m.olaybal change with Dr.murali for country updare Chief Executive, MDA b) Dr. Mario Cesar Muñiz Ferrer Head of Medical Devices Department, CECMED c) Dr. Rania Soliman General manager of general administration of medical devices, Marketing authorization Egyptian Drug Authority d) Ms. Helsy Pahlemy Senior Health Administrator, Ministry of Health, Indonesia e) Ms. Yukina Ueno Deputy Director, Medical Devices Evaluation Division Ministry of Health, Labour and Welfare (MHLW), Japan

		f) Kingdom of Bahrain g) Kingdom of Saudi Arabia h) People's Republic of China i) Republic of Korea	f) Eng. Nada Al SAYEGH Consultant/ engineering safety, National Healthcare Regulatory Authority (NHRA), Kingdom of Bahrain g) Eng. Abdullah Al Guriabi Medical Devices Sector, SFDA, Kingdom of Saudi Arabia h) Ms. Dong Jiangping Director General, Department of Medical Device Regulation NMPA, People's Republic of China i) Dr. Seil Park Assistant Director, Division of High-Tech Medical Devices, Ministry of Food and Drug Safety Republic of Korea
1530-1600		TEA BREAK	
8	1600-1650	Resolution and Endorsement (50mins) 1. Election and Endorsement of the Positions a) TC Chair b) WG5 Chair c) WG8 Chair d) STG (CERP) Chair* [Conversion of STG to WG TBC] e) STG (CERP) Co-Chair* [Conversion of STG to WG TBC] 2. Endorsement of Guidance Documents from Working Groups (WG) 3. Endorsement of New Members (followed by short speeches) a) Botswana b) Ghana c) Macao SAR, China d) Uzbekistan 4. Endorsement of New Liaison Member (followed by short speech) a) MECOMED	Mr. Xu Jinghe GHWP Chair Deputy Commissioner, NMPA, People's Republic of China Mr. Bryan SO GHWP Executive Secretary General Managing Director, Multi-Scale Medical Robotics Center, The Chinese University of Hong Kong, Hong Kong SAR, China 3. New Members a) Mr. Batlegang Dallas Mosweu Manager, Medical Devices, Botswana Medicines Regulatory Authority (BOMRA), Botswana b) Mr. Emmanuel Nkrumah Director, Medical Devices, Cosmetics and Household Chemicals Directorate, Food and Drugs Authority (FDA), Ghana c) Mr. CHAN Tak In Chief, Division of Chemical Medicines and Devices, Pharmaceutical Administration Bureau, Macao SAR, China d) Mr. Alisher Temirov Director, The Center for Pharmaceutical Products Safety, Uzbekistan 4. Ms. Rana Chalhoub Regulatory Affairs Director MECOMED

9	1650-1655	Announcement of the next GHWP Annual Meeting Host & Short Speech (5mins)	Mr. Xu Jinghe GHWP Chair Deputy Commissioner, NMPA, People's Republic of China Mr. Bryan SO GHWP Executive Secretary General Managing Director, Multi-Scale Medical Robotics Center, The Chinese University of Hong Kong, Hong Kong SAR, China
10	1655-1700	Closing Remarks (5mins)	Dr. Xu Jinghe GHWP Chair Deputy Commissioner, NMPA, People's Republic of China
11	1700	Adjourn	
END OF DAY 4			
GHWP ASL Annual General Meeting (1730-1800 at another meeting room)			