Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Day 1 Agenda: 1 December 2025

Nexus of Regulation and Innovation- Global Convergence, Harmonization

Background: The world of medical technology is moving faster than ever. As a global community of regulators and industry, our shared challenge is to keep pace—to be a gateway for innovation, not a roadblock. This meeting is built around four key themes that address this challenge directly, i.e. regulatory science, regulatory agility, fit-for-purpose regulatory framework, and applying regulatory science to cutting edge technologies.

No.	Time	Item	
1	0900-0910	Welcome address	Thai Ministry of Public Health (MoPH)
2	0910-0915	Opening address	Ms. Eka Purnamasari GHWP Vice Chair
3	0915-0920	Klong Salud Cahi Ceremony and Photo Session	
4	0920-0940	Keynote speech: Reflecting and Envisioning Regulatory Science	Dr. John Lim Professor, Centre of Regulatory Excellence Executive Director, Centre of Regulatory Excellence Lead (Policy), SingHealth Duke-NUS Global Health Institute
		Regulatory Science: Concepts & Key Pillars	
		What to Expect: This session is about the evidence behind our decisions. We'll explore the tools, methods, and data we use to determine if a medical device is safe and effective. This isn't about the regulations themselves, but the science that supports them—like new ways to use computer modeling, how to define a product's 'intended use' to properly assess its risk, and what standards we can all rely on.	
5	0940-1000	What is Regulatory Science and the Role of Regulatory Science in Global Harmonisation	(Online) Mr. Scott Sardeson GHWP TC Advisor
6	1000-1015	Regulatory Science--Tools	Ms. Jimenez Garcia Noemi Director, Regulatory Science & Policy, Regulatory Standards, Philips
7	1015-1030	Regulatory Science --Approaches "From Risk to Regulation: Intended Use as the Foundation of Medical Device Development"	Dr. You K. Lee Professor, Laboratory Medicine Soonchunhyang University Bucheon Hospital
8	1030-1045	Regulatory Science --Standards	(Online) Dr. Peter W.J. Linders GHWP TC Advisor
	1045-1115	COFFEE BREAK	
		Regulatory Science in practice	
		What to Expect: This session will have sharings from various regulatory authorities and industry about the opportunities and challenges in regulatory science, followed by a panel discussion around roadmap towards regulatory science.	
9	1115-1145	Opportunities and Challenges on Regulatory Science: industry perspective	Ms. Diana Kaneko Senior Manager International Affairs, MedTech Europe
10	1145-1210	PANEL Discussion -Roadmap towards Regulatory Science	Moderator Diana Kanecka Panelist Speaker of the sessions
	1210-1400	LUNCH	
		Regulatory Agility: Principles and Approaches	
		What to Expect: This section is about how regulatory systems can be future-proof, such as being adaptive, forward-looking, and continously learning, without compromising safety. We'll discuss principles, processes, as well as opportunites and challenges in practicing regulatory agility.	
11	1400-1415	Embracing Agility in a Complex Regulatory Environment - Core Principles and Approaches of Regulatory Agility	Ms. Yasha Huang Head of Regulatory Policy APAC, Roche Diagnostics

12	1415-1430	Regulatory Agility in Action: Adaptive Processes	Ms. Idamazura Idris Harun Director Post-market and Enforcement Division MDA, Malaysia
13	1430-1445	Regulatory Agility in Action: Forward-Looking Governance	Dr. Sirinmas Katchamart Pharmacist, Senior Professional Level Thai FDA
14	1445-1500	Regulatory Agility in Action: Continuous Learning	Mr. Sharad Shukla Director Regulatory Affairs, MedTach Johnson & Johnson
15	1500-1530	Panel Discussion: Opportunities and Challenges in Practicing Regulatory Agility	Moderator: Yasha Huang Panelist Speaker of the sessions
	1530-1600	COFFEE BREAK	
Regulatory Agility: Implementation Case Studies			
What to Expect: This section is about sharing case studies on regulatory agility implementation, such as reliance, change management, and re-evaluation of product risk classification.			
16	1600-1615	Good Reliance Practice to achieve regulatory agility	Ms. Agnes Kijoa Technical Officer, WHO
17	1615-1630	Regulatory Agility in change management	Dr. Adelheid Schneider Ads Consulting and Coaching
18	1630-1645	Re-evaluation of Product Risk Classification	Ms. Wenwen Zhou Deputy Director Medical Device Registration Department NMPA, China
19	1645-1700	**Summary Day 1**	**Dr. Mohammed Y. Majrashi** **GHWP TC Chair**
		Adjourn	
END OF DAY 1			

GHWP Global Harmonization Working Party
Towards Medical Device Harmonization

Day 2 Agenda: 2 December 2025			
No.	**Time**	**Item**	
Fit for purpose regulatory frameworks: Global Frameworks			
What to Expect: Due to immense interest from the community, we will zoom into "innovative pathways" specifically, and discuss how to foster innovation through alternative regulatory pathways in general.			
1	0900-0915	Playbook	Dr. Michael Flood
2	0925-0940	WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices	Ms. Agnes Kijoa Technical Officer, WHO
3	0940-0955	IMDRF outlook on maturity model	Dr. Miho Sato Office of International Strategy and Planning (OISP), Pharmaceuticals and Medical Devices Agency (PMDA)
4	0955-1025	Panel Discussion: How to translate a global model into a local context	Moderator: Brad Spring Panelist Speaker of the sessions
	1025-1045	COFFEE BREAK	
Fit for purpose regulatory frameworks: Case Studies in Alternative Pathways			
What to Expect: Due to immense interest from the community, we will zoom into "innovative pathways" specifically, and discuss how to foster innovation through alternative regulatory pathways in general.			
5	1045-1100	Opportunities and Challenges with Alternative Regulatory Pathways: a global overview	Ms. Miang Tanakasemsub Head of Regulatory Affairs (RA), Asia Pacific (AP) Johnson & Johnson Vision
6	1100-1145	Sharing best practices on alternative regulatory pathways from GHWP Member Country/Region	Dr. Mohammed Y. Majrashi, GHWP TC Chair Mr. Greg LeBlanc, GHWP TC Advisor Ms. Li Jun, NMPA

7	1145-1215	PANEL: Fostering medical innovation through alternative regulatory pathways	Moderator: Moelands, Daniel Panelist Speaker of the sessions
	1215-1400	LUNCH	
Applying regulatory science for cutting edge technologies --AI/ML			
What to Expect: What happens when a new technology doesn't fit our old rules? We will focus on Artificial Intelligence (AI): How do you regulate software that learns and changes on its own?			
8	1400-1415	Lifecycle approach in regulating AI/ML enabled devices	Mr. Hyukjun Seo MFDS
9	1415-1430	Establishing the "Regulatory Sandbox" for Change such as PCCP	Ms. Asmaa Awad Global Regulatory Policy Lead EE, ME& Africa Roche Diagnostics Middle East Dubai, United Arab Emirates
10	1430-1445	How to demonstrate Clinical Evidence for cutting edge technologies	Mr. Heather Colvin Director of Evidence and. Outcomes Policy for Johnson & Johnson MedTech
11	1445-1500	PMS considerations for AI/ML enabled devices	Dr. Rama Sethuraman Head of Quality and Regulatory Asia Pacific Roche Diagnostics Asia Pacific Pte Ltd
12	1500-1530	Panel Discussion: How can regulations be the enabler instead of barrier for innovation	Moderator: Asamaa Awad Panelist Speaker of the sessions
	1530-1550	COFFEE BREAK	
Applying regulatory science for Rare Disease/Orphan Devices			
What to Expect: What happens when the current regulatory systems are not able to fully accommodate Orphan Devices? How do you approve a device for a rare disease when there are very few patients for a clinical trial? We will hear from both regulatory authority, academia and industry about their views, and have a panel discussion around how can regulatory framework be adapted to ensure safety and quality for low-volume devices.			
13	1550-1605	Challenges and Mandate of applying regulatory science for Rare Disease/Orphan Devices	Mr. Alfred Kwek GHWP Strategic Advisory Board Member
14	1605-1620	Evidence Generation & Trial Design for rase disease	(online) Dr. Madoka Murakami PMDA
16	1620-1635	Global Reliance on Limited Data: Orphan Devices	Ms. Mandy Kim Director, Regulatory Affairs North Asia Johnson & Johnson MedTech Republic of Korea
17	1635-1705	Panel Discussion: How can the regulatory framework be adapted to ensure safety and quality for low-volume devices	Moderator: Cindy Pelou Panelist Speaker of the sessions
18	1705-1715	**Closing and Summary Day 2**	**Ms. Miang Tanakasemsub** **TC Chair Vice Chair**
		Adjourn	
END OF DAY 2			

Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

Day 3 Agenda: 3 December 2025			
29th GHWP Technical Committee (GHWP TC) Meeting			
Moderator:			
No.	**Time**	**Item**	**Speaker**
1	0900-1200	GHWP TC & WG Leaders Meeting with TC Advisors	
Afternoon: Open Meeting			
Moderator: Ms. LI Jun			
2	1400-1410	Opening Speech	Dr. Mohammed Y Majrashi GHWP 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 28th 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	COFFEE 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
		Adjourn	
END OF DAY 3			
1800		Gala Dinner	

GHWP Global Harmonization Working Party
Towards Medical Device Harmonization

Day 4 Agenda: 4 Dec 2025			
29th GHWP Annual Meeting (Main Meeting)			
No.	**Time**	**Item**	
1	0855-0900	Announcement by MC (5mins)	Moderator: Ms. Miang Tanakasemsub GHWP TC Co-chair (Industry)
2	0900-0925	Opening Ceremony (25mins) -Opening Address (5mins) (Dr. Xu) -Welcome Address (5mins) (Thai FDA) - Group Photo (15mins)	Opening Address- Dr. Xu Jinghe GHWP Chair Deputy Commissioner, NMPA, People's Republic of China Welcome Address- From Thai FDA
3	0925-0935	Main Meeting - Roll Call (8mins) - Adoption of the Agenda (1min) - Adoption of the 28th GHWP Annual Meeting Minutes (1min)	Dr. Xu Jinghe GHWP Chair Deputy Commissioner, NMPA, People's Republic of China Dr. Xie Tingting GHWP Executive Secretary General

4	0935-1005	GHWP Status Reports: (30 mins) a) GHWP Status Report (10mins) b) GHWP Technical Committee Status Report (10mins) c) GHWP Capacity Building Status Report (5mins + 5mins)	a) Dr. Xu Jinghe GHWP Chair Deputy Commissioner, NMPA, People's Republic of China b) Dr. Mohammed Majrashi GHWP TC Chair Executive Director, Surveillance and Biometric, Saudi Food & Drug Authority (SFDA), Kingdom of Saudi Arabia c) Ms. Quan Tran and GHWP Academy Representative Prof. Fei Hang
5	1005-1010	White paper update	Ms. EunHee Cho and GHWP Academy Representative Prof. Fei Hang
	1010-1035	COFFEE BREAK	
6	1035-1055	International Organizations & Harmonization Efforts (10mins each) a) WHO b) African Medical Devices Forum (AMDF) discuss	a) Ms. Agnes Kijoa Technical Officer, WHO b) Dr. Emmanuel Nkrumah African Medical Devices Forum (AMDF)
7	1055-1155	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) g) Mecomed	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. Deniz Bruce CEO, 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) g) Ms. Rana Chalhoub RA Director (video)
8	1155-1200	Updates by Reeds (5mins)	Reeds
	1200-1340	LUNCH	
9	1340-1440	Country/Region Updates (5mins+3mins Q&A each) a) Thailand b) Malaysia c) Egypt d) Japan e) Oman f) People's Republic of China g) Republic of Korea	a) Thailand b) Dr. Muralitharan Paramasua c) Dr. Rania Soliman d) Dr. Modaka e) Eng. Faiza Al Zadjali f) Ms. Dong Jiangping g) Ms. Hyekyung Son
	1440-1455	COFFEE BREAK	

10	1455-1545	Resolution and Endorsement (15mins) 1. Endorsement of Amendments to TOR and House Rules 2. GHWP Strategic Framework towards 2030, 3.30th celebration decision 4 .New WG Guidance Documents 5. Endorsement of New Member (followed by short speech)	Dr. Xu Jinghe GHWP Chair Deputy Commissioner, NMPA, People's Republic of China Dr. Xie Tingting GHWP Executive Secretary General
11	1510-1620	Election and Endorsement of GHWP Office Bearers (70mins) *[including 1minute self-introduction by each candidate before election and endorsement (45mins)]* - Briefing on Election and Endorsement Procedures - Election of GHWP Working Groups Chairs and Co-Chairs - Election of GHWPTC Chair and Co-Chairs - Election of Chair and Vice Chairs	Dr. Xu Jinghe GHWP Chair Deputy Commissioner, NMPA, People's Republic of China Dr. Xie Tingting GHWP Executive Secretary General
12	1620-1625	Speech by GHWP Chair-Elect	GHWP Chair-Elect
13	1625-1655	Presentation of Certificates and Recognition Award on Stage (30mins)	Dr. Xu Jinghe GHWP Chair Deputy Commissioner, NMPA, People's Republic of China and GHWP Chair-Elect
14	1655-1700	Announcement of the next GHWP Annual Meeting Host & Short Speech (5mins)	Dr. Xu Jinghe GHWP Chair Deputy Commissioner, NMPA, People's Republic of China and 30th GHWP Annual Meeting Host
15	1700-1705	Closing Remarks (5mins)	Dr. Xu Jinghe GHWP Chair Deputy Commissioner, NMPA, People's Republic of China
	1705	**Adjourn**	
END OF DAY 4			
GHWP ASL Annual General Meeting			