Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Day 1 Agenda: 1 December 2025
Venue: Millennium Hilton Bangkok, 123 Charoen Nakhon Rd,
Khlong Ton Sai, Khlong San, Bangkok 10600, Thailand

Nexus of Regulation and Innovation- Global Convergence, Harmonization and Reliance in Medical Device Regulation

No.	Time	Item	
1	0900-0905	**Opening address**	**Ms. EH Cho** **Vice Chair of GHWP**
2	0905-0910	**Welcome address**	**Thai FDA**
2	0910-0930	**Keynote speech: Reflecting and Envisioning Regulatory Science**	
		Regulatory Science: Concepts & Key Pillars	
3	0930-0945	What is Regulatory Science?	
4	0945-1000	The Role of Regulatory Science in Global Harmonization	Dr. Philippe Auclair GHWP TC Advisor
5	1000-1015	Regulatory Science--Tools	
6	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
7	1030-1045	Regulatory Science --Standards	
	1045-1115	COFFEE BREAK	
		Regulatory Science in practice	
8	1115-1145	Opportunities and Challenges on Regulatory Science: regulatory authority perspective Member Country/Region 1 Member Country/Region 2 Member Country/Region 3	
9	1145-1200	Opportunities and Challenges on Regulatory Science: industry perspective	Ms. Diana Kaneko Senior Manager International Affairs, MedTech Europe
10	1200-1230	PANEL Discussion -Roadmap towards Regulatory Science	
	1230-1400	LUNCH	
		Regulatory Agility: Principles and Approaches	
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	
13	1430-1445	Regulatory Agility in Action: Forward-Looking Governance	
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	
	1530-1600	COFFEE BREAK	
		Regulatory Agility: Implementation Case Studies	
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**	
		Adjourn	
		END OF DAY 1	

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Day 2 Agenda: 2 December 2025 Venue: Millennium Hilton Bangkok, 123 Charoen Nakhon Rd, Khlong Ton Sai, Khlong San, Bangkok 10600, Thailand			
No.	**Time**	**Item**	
1	0900-0910	**Welcome address**	**Dr. Mohammed Majrashi** **GHWP TC Chair**
Fit for purpose regulatory frameworks: Global Frameworks			
2	0910-0925	Implementation of a regulatory framework – GHWP	Dr. Michael Flood
3	0925-0940	WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices	Ms. Agnes Kijoa Technical Officer, WHO
4	0940-0955	IMDRF outlook on maturity model	
5	0955-1025	Panel Discussion: How to translate a global model into a local context	
	1025-1045	COFFEE BREAK	
Fit for purpose regulatory frameworks: Case Studies in Alternative Pathways			
6	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
7	1100-1145	Sharing best practices on alternative regulatory pathways from GHWP Member Country/Region:	
8	1145-1215	PANEL: Fostering medical innovation through alternative regulatory pathways	
	1215-1400	LUNCH	
Applying regulatory science for cutting edge technologies --AI/ML			
9	1400-1415	Lifecycle approach in regulating AI/ML enabled devices	Dr. Rama Sethuraman Head of Quality and Regulatory Asia Pacific Roche Diagnostics Asia Pacific Pte Ltd
10	1415-1430	How to demonstrate Clinical Evidence for cutting edge technologies	Mr. Heather Colvin Director of Evidence and. Outcomes Policy for Johnson & Johnson MedTech
11	1430-1445	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
12	1445-1500	PMS considerations for AI/ML enabled devices	
13	1500-1530	Panel Discussion: How can regulations be the enabler instead of barrier for innovation	
	1530-1550	COFFEE BREAK	
Applying regulatory science for Rare Disease/Orphan Devices			
14	1550-1605	Challenges and Mandate of applying regulatory science for Rare Disease/Orphan Devices	
15	1605-1620	Evidence Generation & Trial Design for rase disease	
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	
18	1705-1715	**Closing and Summary Day 2**	
		Adjourn	
END OF DAY 2			

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Day 3 Agenda: 3 December 2025 **Morning: Closed-door Meeting** Venue: Millennium Hilton Bangkok, 123 Charoen Nakhon Rd, Khlong Ton Sai, Khlong San, Bangkok 10600, Thailand			
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	

Global Harmonization Working Party
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Day 4 Agenda: 4 Dec 2025

Venue: Millennium Hilton Bangkok, 123 Charoen Nakhon Rd,
Khlong Ton Sai, Khlong San, Bangkok 10600, Thailand

29th GHWP Annual Meeting (Main Meeting)

No.	Time	Item	
1	0855-0900	Announcement by MC (5mins)	
2	0900-0930	Opening Ceremony (30mins)	Opening Address-GHWP Chair Dr. Xu Jinghe Welcome Address-Thai FDA
3	0930-0940	Main Meeting	
4	0940-1015	GHWP Status Reports: (35mins) a) GHWP Technical Committee Status Report b) GHWP Capacity Building Status Report	GHWP TC Chair-Dr. Mohammed Majrashi CB Lead- Ms. Quan Tran and GHWP Academy Representative
	1015-1035	COFFEE BREAK	
5	1035-1105	International Organizations & Harmonization Efforts (5mins+5mins Q&A each) a) WHO b) African Medical Devices Forum	a) Ms. Agnes Kijoa Technical Officer, WHO
6	1125-1235	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	
	1235-1400	LUNCH	
7	1400-1510	Country/Region Updates (5mins+5mins Q&A each)	
	1510-1530	COFFEE BREAK	
8	1530-1545	Resolution and Endorsement (15mins)	
9	1545-1655	Election and Endorsement of GHWP Office Bearers	
10	1655-1705	Speech by GHWP Chair-Elect	
11	1705-1720	Presentation of Certificates and Recognition Award on Stage (15mins)	
12	1720-1725	Announcement of the next GHWP Annual Meeting Host & Short Speech (5mins)	
13	1725-1730	Closing Remarks (5mins)	
		Adjourn	

END OF DAY 4

GHWP ASL Annual General Meeting
(1735-1800 at another meeting room)