



Global Harmonization Working Party

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	0900-0910	Welcome address Chair of GHWP and 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
5	1000-1015	Regulatory Science--Tools
6	1015-1030	Regulatory Science --Approaches
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
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
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
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
17	1615-1630	Regulatory Agility in change management
18	1630-1645	Re-evaluation of Product Risk Classification
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
TC Chair of GHWP		
Fit for purpose regulatory frameworks: Global Frameworks		
2	0910-0925	Implementation of a regulatory framework – GHWP Playbook
3	0925-0940	WHO Global Model Regulatory Framework for medical devices including in vitro diagnostic medical devices
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
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
10	1415-1430	How to demonstrate Clinical Evidence for cutting edge technologies
11	1430-1445	Establishing the "Regulatory Sandbox" for Change such as PCCP
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 rare disease
16	1620-1635	Global Reliance on Limited Data: Orphan Devices
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		



Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

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
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Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

Day 4 Agenda: 4 Dec 2025

Venue: Millennium Hilton Bangkok, 123 Charoen Nakhon Rd,
Klong Ton Sai, Klong 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)
3	0930-0940	Main Meeting
4	0940-1025	GHWP Status Reports: (45mins)
	1025-1040	COFFEE BREAK
5	1040-1125	International Organizations & Harmonization Efforts (5mins+5mins Q&A each)
6	1125-1235	GHWP Liaison Member Updates (5mins + 5mins Q&A each)
	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)**