30th GHWP Annual Meeting and 30th GHWP Technical Committee Meeting

8-11 December 2026
Hong Kong SAR, The People's Republic of China

Draft Agenda

Time	Session	Speakers / Affiliations
08:30-09:00	Registration	
09:00-09:40	Opening Ceremony	
	- Welcome Addresses (5mins+5mins+5mins)	**Remarks by leader**
		Prof. Chung-mau LO Secretary for Health, The Government of the Hong Kong Special Administrative Region, China
		Dr Ronald LAM Director of Health, The Government of the Hong Kong Special Administrative Region, China
	- Opening Address (5mins)	**Dr Muralitharan PARAMASUA** GHWP Chair, Chief Executive, Medical Device Authority, Malaysia
	- Kick-off Ceremony & Welcome Video (10 mins)	/
	- Group photo (10 mins)	/

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Capacity Building Session 1: Setting the Scene & Macro Policy		
09:40-09:55	Keynote speech: Global Benchmarking Tool Plus for Medical Devices	**Ms Agnes Sitta KIJO** Technical Officer, Regulatory System Strengthening (RSS), World Health Organization (WHO)
09:55-10:10	Presentation: A Proposed Governance Framework for Medical AI in Hong Kong	**Prof. Gilberto K.K. LEUNG** Convenor, Institute for Medical Advancement and Clinical Excellence (IMACE)
10:10-10:25	Presentation: Macro Policy Elements for Trustworthy AI in Healthcare	**Mr Johan ORDISH** Global Head of Medical Device Policy, Apple Health
10:25-10:40	Presentation: Latest development of the Loop Hong Kong Park	**Ms Anita CHAU** Director, Ecosystem Development, Hong Kong-Shenzhen Innovation and Technology Park
10:40-11:00	Panel Discussion / Q&A Global Approaches to AI Governance: Convergence, Divergence and the Way Forward	Moderator: • **Dr Muralitharan PARAMASUA, GHWP Chair**

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		Panelists: ● 4 speakers from this section
11:00-11:30	Refreshment Break	
11:30-11:45	Presentation: Actions for Global Regulatory Harmonization & Total Product Lifecycle Reliance for AI Medical Devices	**Ms Norlela HATTA** Senior Director, International and Industry Affairs Division, Medical Device Authority, Ministry of Health, Malaysia
11:45-12:00	Presentation: How to Assess the Benefits, Risks and ROIs of AI Systems	**Ms Monika MCDOLE-RUSSELL** Senior Director, Global Regulatory Intelligence, Intuitive Surgical
12:00-12:15	Presentation: AI Medical Devices: Building a Fit-for-Purpose and Globally Convergent Regulatory Framework	**Mr Brad SPRING** Global Head, Regulatory Policy and Intelligence, Roche Diagnostics
12:15-12:30	Panel Discussion / Q&A From Global Harmonization to Responsible AI – What Should Regulators Do Next?	Moderator: ● **Ms EunHee CHO**, GHWP Vice Chair (Industry) RA Director, Abbott Medical Korea,

		Republic of Korea Panelists: • 3 speakers as above
12:30-14:00	Lunch	
Capacity Building Session 2: Total Product Lifecycle (TPLC), Risk, and Transparency		
14:00-14:15	Presentation: The Next Era of Robotic Surgery and AI Medical Devices	**Prof. Philip CHIU** Dean, Faculty of Medicine, The Chinese University of Hong Kong
14:15-14:30	Presentation: Transitioning to the TPLC Approach	**Dr Yuan FANG** Divisional Vice President, Corporate Global Strategic Regulatory, Abbott Laboratories
14:30:14:45	Presentation: The Future of Surgery: Accessibility, Connectivity, and Physical AI in Robotic Surgery	**Prof. Kwok Wai Samuel AU** Director, Multi-Scale Medical Robotics Center Professor, Department of Mechanical and Automation Engineering, The Chinese University of Hong Kong

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14:45-15:00	Presentation: Holistic Risk Management and Cybersecurity for AI Medical Devices or Transparency, Human-AI Interaction and Trustworthy AI	**Mr Sharad Mi SHUKLA** Senior Director, Regulatory Affairs, Johnson & Johnson
15:00-15:20	Panel Discussion / Q&A Embedding Safety, Transparency and Trust Across the AI Product Lifecycle	Moderator: • **Mr Tony YIP**, TC Co-Chair (Industry) Associate Director, Regulatory Affairs, Asia Pacific, Grifols (HK) Limited Panelists: • 4 speakers as above
15:20-15:40	Refreshment Break	
Capacity Building Session 3: Data Quality, Clinical Validation and Real-World Evidence for AI Medical Devices		
15:40-15:55	Data Quality and Validation of AI-Enabled Medical Devices: Regulatory Considerations	**Mr Hyun-soo KIM** Assistant Director, Medical AI Software Division Ministry of Food and Drug Safety, Republic of Korea

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15:55-16:10	Clinical Validation and the "Human-AI Team"	**Dr Madoka MURAKAMI** Deputy Division Director, Pharmaceuticals and Medical Devices Agency, Japan
16:10-16:25	Presentation: Accelerating AI Medical Device Development: Leveraging Real-World Evidence and Multi-Centre Collaboration Across the GBA	**Prof. Bernard CHEUNG** Chief Executive Officer, The Greater Bay Area International Clinical Trial Institute
16:25-16:40	Panel Discussion / Q&A From Data Quality to Real-World Evidence – Building Trustworthy Evidence for AI Medical Devices	Moderator: • **Ms Miang TANAKASEMSUB**, GHWP Vice-Chair (Industry) Panelists: • 3 speakers as above
Capacity Building Session 4: Post-Market Monitoring and Change Management		
16:40-16:55	Presentation: Learning from Post-market Problems Observed with AI Enabled Medical Devices	**Ms Elizabeth HILLEBRENNER** Global Head, Digital Health and Innovation Policy, Roche Diagnostics

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16:55-17:10	Presentation: Post-Market Monitoring and Change Management for AI/ML SaMD	**Mr Sangjun LEE** Regulatory Affairs Manager, AITRICS
17:10-17:25	Presentation: Pre-determined Change Control Plans	**Ms Nadine NASR** Director Regulatory Affairs, da Vinci SinglePort Intuitive
17:25-17:40	Panel Discussion / Q&A Change to Ensuring AI-enabled Medical Device Performance Across the AI Medical Device Lifecycle	Moderator: • **Ms Aidahwaty M. OLAYBAL,** TC Co-Chair (Regulatory Authority) Panelists: • 3 speakers as above (For Roche, it will be Dr. Tanuj Shukla instead of Ms Elizabeth Hillebrenner to join the panel)
17:40-17:45	Day 1 Closing Reflections	**Ms LI Jun**, GHWP TC Chair Deputy Director General, Center for Medical Device Evaluation, National Medical Products Administration (NMPA), China

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08:30-09:00	Registration	
09:00-09:05	Day 2 Welcome & Recap	**Ms DONG Jiangping** GHWP Vice Chair (Regulatory Authority)
Capacity Building Session 5: Regulatory agility in the age of AI		
09:05-09:20	Presentation: (TBC)	**Mr Shuting GUO** Deputy Director, Shanghai Medical Products Administration, China
09:20-09:35	Presentation: Building Agile Pathways: Global Convergence for AI-Enabled Medical Devices	**Ms Idamazura IDRIS** Senior Director, Policy and Strategic Planning Division, Medical Device Authority, Ministry of Health, Malaysia
09:35-09:50	Presentation: AI-Powered Active Post-Market Surveillance of Medical Devices: Integrating Multi-Source Data for Safety Evaluation	**Prof. GAO Pei** Research Professor, School of Public Health, Peking University
09:50-10:00	Panel Discussion / Q&A How to implement regulatory agility in the age of AI	Moderator: ● **Ms Yasha HUANG,** GHWP TC Co-Chair (Industry)

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		Head Regulatory Policy Asia Pacific (Global Regulatory Policy and Intelligence) Roche Diagnostics Panelists: • 2 speakers as above
10:00-10:15	Refreshment Break	
Capacity Building Session 6: AI Use Cases for Device Developments		
10:15:10:30	Presentation: Harnessing AI to Strengthen Regulatory Intelligence, Compliance and Innovation at BD	**Mr Winson TENG** Senior Manager, Global Regulatory Intelligence & Policy, Becton, Dickinson and Company
10:30-10:45	Presentation: Harmonizing Trust: Risk-Based Approaches to AI-Enabled Medical Devices	**Ms Carla CARTWRIGHT** Vice President, Global Digital & Regulatory Policy Johnson & Johnson
10:45-11:00	Presentation: AI Use Cases for Device Developments	**Mr. Zhenkui WANG** Vice President, MR-BU, Shanghai United Imaging Healthcare Co., Ltd. (UIH)
11:00-11:15	Panel Discussion / Q&A	Moderator:

	From AI-Assisted Development to AI-Native Medical Devices: Opportunities, Challenges and Lessons Learned	• **Dr Rania SOLIMAN**, TC Co-Chair (Regulatory Authority) General Manager, General Administration of Market Authorization of Medical Devices Egyptian Drug Authority, Egypt Panelists: • 3 speakers as above
11:15-11:30	Refreshment Break	
Capacity Building Session 7: AI Use Cases for National Regulatory Authorities (NRAs)		
11:30-11:45	Presentation: Advances in Regulatory Science for AI Medical Devices in China	**Dr PENG Liang** Deputy Director, Centre for Medical Device Evaluation, National Medical Products Administration, China
11:45-12:00	Presentation: Leveraging AI and Real-World Data to Support Regulatory Decision-Making	**Dr Rania SOLIMAN** GHWP TC Co-Chair (Regulatory Authority) General Manager, General Administration of Market Authorization of Medical Devices Egyptian Drug Authority, Egypt

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12:00:12:15	Wrap-up of capacity building programme	**Ms EunHee CHO** GHWP Vice-Chair (Industry)
12:15-14:00	Lunch	
14:00-14:10	Roll call Adoption of Agenda	**Ms LI Jun** GHWP TC Chair Deputy Director General, Center for Medical Device Evaluation, National Medical Product Administration (NMPA), China
14:10-14:20	Adoption of 29th GHWP TC Meeting Minutes	**Ms GAO Yinghui** GHWP TC Secretary Director, Policy and Intelligence, J&J Medtech
14:20-14:50	GHWP TC Progress Update	**Ms LI Jun** GHWP TC Chair Deputy Director General, Center for Medical Device Evaluation, National Medical Product Administration (NMPA), China
14:50-15:20	Refreshment Break	

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15:20-16:20	GHWP Guidance Introduction - Premarket	**Mr Tony YIP** GHWP TC Co-chair (Industry) Associate Director, Regulatory Affairs, Asia Pacific, Grifols (HK) Limited
16:20-17:20	Panel Discussion - Premarket	Representatives from Working Group 1, 2, 3, 5: **Ms Hye-Kyung Son,** WG1 Chair **Dr Razan Asally,** WG2 Acting Chair **Mr Chun-Jen Chien**, WG3 Chair **Ms Aidahwaty M. Olaybal**, WG5 Chair Moderator: **Dr Rania SOLIMAN** GHWP TC Co-chair (Regulatory Authority) General Manager, General Administration of Medical Devices Marketing Authorization, Central Administration of Medical Devices, Egyptian Drug Authority, Egypt
17:20-17:30	Day 2 Closing Remarks	**Ms Aidahwaty M. OLAYBAL** GHWP TC Co-chair (Regulatory Authority) Senior Director, Pre-Market Control Division,

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		Medical Device Authority, Ministry of Health, Malaysia
18:30-20:30	Networking event (by invitation)	

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08:30-09:00	Registration	
09:00-10:00	GHWP Guidance Introduction – Post Market	**Prof. GAO Pei** Research Professor, School of Public Health, Peking University
10:00-10:40	Panel Discussion – Post Market	Representatives from Working Group 4, 7, 8, 9: **Dr Aaron Hung**, WG4 Chair **Eng. Faiza Al Zadjali**, WG7 Co-chair **Ms Idamazura Bt Idris @ Harun**, WG8 Chair **Mr Li YI**, WG9 Acting Chair Moderator: **Ms Yasha HUANG** GHWP TC Co-chair (Industry) Head of Regulatory Policy APAC, Roche Diagnostics, Singapore
10:40-11:00	Refreshment Break	
11:00-11:15	Medical Device Authority, Malaysia sharing on GHWP Guidance Adoption: Best Practices and Key Learnings	**Ms Aidahwaty M. OLAYBAL** GHWP TC Co-chair (Regulatory Authority) Senior Director, Pre-Market Control Division, Medical Device Authority, Ministry of Health,

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		Malaysia
11:15-11:30	Special Task Group – Common Evaluation Reliance Practice Update	**Dr ZHANG Shiqing** STG CERP Chair Director of Quality Management Department, Center for Medical Device Evaluation, NMPA, China
11:30-11:45	Special Task Group - STG Emergency Supply Chain Update	**Dr Muralitharan PARAMASUA** GHWP Chair and STG Emergency Supply Chain Chair Chief Executive, Medical Device Authority, Ministry of Health, Malaysia
11:45-12:00	TC Advisors Summary Report	**Mr Greg LEBLANC** TC Advisor Director, Regulatory Affairs and Quality Systems, Cook (Canada) Inc., Canada
12:00-12:10	Closing Remarks for TC Annual Meeting	**Ms LI Jun** GHWP TC Chair Deputy Director General, Center for Medical Device Evaluation, National Medical Product Administration (NMPA), China
12:10-14:00	Lunch	

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14:00-14:10	Welcome Address	**Dr Muralitharan PARAMASUA** GHWP Chair Chief Executive, Medical Device Authority, Ministry of Health, Malaysia
14:10-14:20	Group Photo (10 mins)	
14:20-14:30	**GHWP Annual Meeting** - Roll Call (8 mins) - Adoption of the Agenda (1 min) - Adoption of the 29th 0GHWP Annual Meeting Minutes (1 min)	**Dr Muralitharan PARAMASUA** GHWP Chair Chief Executive, Medical Device Authority, Ministry of Health, Malaysia **Dr XIE Tingting** GHWP Executive Secretary General
14:30-15:00	**GHWP Status Report** (10 mins each)	
	a) GHWP Status Report	**Dr Muralitharan PARAMASUA** GHWP Chair Chief Executive, Medical Device Authority, Ministry of Health, Malaysia
	b) GHWP Technical Committee Status Report	**Ms LI Jun**

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		GHWP TC Chair Deputy Director General, Center for Medical Device Evaluation, National Medical Product Administration (NMPA), China
	c) GHWP Capacity Building Status Report	**Ms TRAN Quan and Prof. Hang Fei** CB Director and GHWP(China) Academy
15:00-15:30	**International Organizations & Harmonization Efforts** (15 mins each)	
	1. World Health Organization (WHO) Topic: Pre-qualification of IVD Assessment Procedure	1. **Ms. Agnes Sitta KIJO** Technical Officer, Regulatory System Strengthening, World Health Organization
15:30-15:50	Refreshment Break	
15:50-17:00	**GHWP Liaison Member Updates** (10 mins each)	
	1. Asia Pacific Medical Technology Association (APACMed)	1. **Ms Cindy PELOU** Lead for Regulatory Affairs, APACMed
	2. Global Diagnostic Imaging, Healthcare IT& Radiation Therapy Trade Association (DITTA)	2. **Ms Sunny WOO** Team Leader, Korea Medical Devices Industry Association, International Affairs Team, DITTA

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	3. GS1	3. **Ms. Chiara Bernini** Senior Manager Healthcare Public Policy, GS1
	4. Global Medical Devices Nomenclature Agency (GMDN Agency)	4. **Mrs Deniz BRUCE** Chief Executive Officer, GMDN Agency Ltd.
	5. Global Medical Technology Alliance (GMTA)	5. **Ms Diana KANECKA** Strategies, Special Projects & International Affairs, Senior Manager International Affairs, Global Medical Technology Alliance (GMTA)
	6. Mecomed Medical Technology Association (Mecomed)	6. **Ms. Rana CHALHOUB** Regulatory Affairs Director, Mecomed
18:30 - 19:30	Cultural Experience & Networking Reception	
19:30 - 21:30	Gala Dinner	

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08:30-09:00	Registration	
09:00-10:20	**Country/Region Updates**	
	1. People's Republic of China	**Ms DONG Jiangping** DG, Department of Medical Device Supervision National Medical Product Administration (NMPA), China
	2. Hong Kong SAR, China	**Dr Ambrose Chi Hong WONG** Principal Medical & Health Officer (Medical Device) Department of Health, Hong Kong SAR Government, China
	3. Malaysia	**Ms Idamazura IDRIS** Senior Director, Policy and Strategic Planning Division Medical Device Authority (MDA)
	4. Oman	**Eng. Faiza ALZADJALI** Director, Medical Device Department

		Drug Safety Center Ministry of Health
	5. Japan	**Mr ISHIBASHI Kenichi** Senior Scientist, Pharmaceuticals and Medical Devices Agency (PMDA)
	6. Chile	**Ms Maria Cecilia LOPEZ** Head of Medical Devices Registration Office Medical Devices, Innovation and Development Department
	7. Botswana	**Mr. Batlegang Dallas Mosweu** Head of Medical Devices Unit Botswana Medicines Regulatory Authority (BOMRA)
	8. Chinese Taipei	**Mr CHIEN Chun-Jen** Technical Specialist in the Division of Medical Devices and Cosmetics

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10:20-10:40	Refreshment Break	
10:40-12:00		
	9. Tanzania	**Mr David MATLE** Manager, Vigilance and Post Marketing Surveillance of Medical Devices and Diagnostics
	10. Saudi Arabia	**Eng. Sameer ALHAMDAN** Director of Regulatory Affairs Department Medical Device Sector Saudi Food and Drug Authority (SFDA)
	11. Egypt	**Dr Rania SOLIMAN** General Manager of General Administration of Medical Devices Marketing Authorization Egyptian Drug Authority (EDA)
	12. Republic of Korea	**Ms. Hye-Kyung Son**

		Deputy Director, Cardiovascular and Imaging Devices Division Ministry of Food and Drug Safety
	13. India	**Mr Aseem SAHU** Deputy Drugs Controller(I) Central Drugs Standard Control Organization (CDSCO)
	14. Uzbekistan	**Mr Alisher TEMIROV** Center for Pharmaceutical Products Safety
	15. Indonesia	**Eka PURNAMASARI** Director of Medical Device Control Ministry of Health Indonesia
	16. Kuwait	**Dr Adel ALHAJJI** Head of Biomedical Engineering Administration Ministry of Health

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	17. Ethiopia	**Mr Bantie Tsegaye GELAW** Medical Device Evaluation and Market Authorization Team Leader Ethiopian Food and Drug Authority
	18. Macao SAR, China	**Mr CHAN Tak In** Chief of Division of Chemical Medicines and Medical Devices Pharmaceutical Administration Bureau (ISAF), Macao SAR Government, China
12:00-14:00	Lunch	
14:00-15:10		
	1. Endorsement of Amendments to TOR and House Rules	**Dr Muralitharan PARAMASUA** GHWP Chair Chief Executive, Medical Device Authority, Ministry of Health, Malaysia **Dr XIE Tingting** GHWP Executive Secretary General
	2. New WG Guidance Documents	

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	3. Endorsement of New Member	New Member
15:10-15:30	Refreshment Break	
15:30-16:30	**Discussion**	
	1. Supply Chain EG	**Dr Muralitharan PARAMASUA** GHWP Chair Chief Executive, Medical Device Authority, Ministry of Health, Malaysia **Dr XIE Tingting** GHWP Executive Secretary General
	2. CFS	
16:30-16:40	Announcement of the next GHWP Annual Meeting Host & Short Speech	**Dr Muralitharan PARAMASUA** GHWP Chair Chief Executive, Medical Device Authority, Ministry of Health, Malaysia 31st GHWP Annual Meeting Host
16:40-16:45	Closing Remarks	**Dr Muralitharan PARAMASUA** GHWP Chair

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		Chief Executive, Medical Device Authority, Ministry of Health, Malaysia