

The 26th GHWP Annual Meeting Program

Riyadh, Saudi Arabia
13-16 February 2023

DRAFT Program (Version 4E Public)

		Day 1 Agenda: 13 February 2023 (Monday)	
		Venue: Crowne Plaza Riyadh RDC Hotel & Convention, Riyadh, Saudi Arabia	
0815-0900		Registration	
ITEMS	TIME		
1	0900-0910	Welcome Address	Dr. Hisham bin Saad Aljadhey Chief Executive Officer Saudi Food and Drug Authority, Kingdom of Saudi Arabia
2	0910-0920	Opening Address	Mr. Ali M. AL-DALAAAN GHWP Chair Vice Executive President, Medical Devices Sector, Saudi Food and Drug Authority, Kingdom of Saudi Arabia
3	0920-0930	Remarks by GHWP Vice-Chair (Regulatory Authority)	Mr. Guobiao Gao GHWP Vice-Chair Secretary of Leading Party Group Center for Medical Device Evaluation, NMPA People's Republic of China
4	0930-0945	GHWP Strategic Framework (15mins)	Ms. Quan Tran GHWP Vice-Chair Vice President, QARA, APAC, Baxter Singapore
5	0945-1010	Panel Discussion: GHWP Strategic Framework (20mins) + Q&A (5mins)	To be confirmed
6	1010-1015	GHWP Secretariat Announcement (5mins)	Ir. Bryan SO GHWP Executive Secretary General CYH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong
1015-1045		TEA BREAK	
TECHNICAL SESSION - Regulatory Agility and Reliance			
7	1045-1105	Regulatory Agility (15mins) + Q&A (5mins)	Ms. Yasha Huang, Head of Regulatory Policy, Roche Asia Pacific
8	1105-1125	Benefits of Regulatory Reliance (15mins) + Q&A (5mins)	Dr. Rama, HAS, Singapore
9	1125-1145	Panel Discussion : Expanding Global access to Medical Devices – Reliance (25mins) + Q&A (5mins)	Moderator : Ms. Miang Tanakasemsub Speakers: a) Dr. Rama, HSA b) Ms. Yasha Huang c) TBC
TECHNICAL SESSIONS - Increasing the Opportunities of Digital Health			
TECHNICAL SESSION I : Digital Health : Innovation and Technology [Industry Perspective]			
10	1145-1205	Digital Therapeutics - "Industry Perspective" (15mins) + Q&A (5mins)	Sean (Seong-ji) Kang, MD, MPH. Co-founder, CEO of WELT
11	1205-1230	Digital Twins (15mins) + Q&A (5mins)	Mark Palmer, MD, PhD Research Director & Technical Fellow Core Technologies Lead Enterprise Modeling & Simulation Working Group Medtronic
12	1230-1250	Metaverse using AR/VR/XR (15mins) + Q&A (5mins)	To be confirmed
1250-1400		LUNCH	
TECHNICAL SESSION II : Digital Health : Regulatory Approaches [Government perspectives]			
13	1400-1420	Digital Health Regulation Development in China (15mins) + Q&A (5mins)	NMPA (TBC)
14	1420-1440	Digital Therapeutics - "Exploring Regulatory Pathways of Digital Therapeutics" (15mins) + Q&A (5mins)	Chung Keun Lee, Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Korea
15	1440-1500	Regulations for Artificial Intelligence (15mins) + Q&A (5mins)	To be confirmed
16	1500-1530	Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins)	To be confirmed
1530-1600		TEA BREAK	
TECHNICAL SESSION III : Digital Health : Advancing Healthcare Access [Government, Industry, International Org Perspectives]			
17	1600-1620	Equitable Access to the Patient and Product / Virtual Hospital / Medical Imaging (15mins) + Q&A (5mins)	To be confirmed
18	1620-1650	Panel Discussion: Digital Transformation and Connected Care in the Hospital (25mins) + Q&A (5mins)	Moderator: Serkan Sezer, Director of QARA, EMEA Baxter Panelists: (TBC) 1) Hospital representative – TBC 2) Health authority – Dr. Seil Park, MFDS 3) Notified Body – TBC 4) Industry Association – TBC
TECHNICAL SESSION IV : Standards			
19	1650-1710	Using Standards for Regulatory Purposes (15mins) + Q&A (5mins)	To be confirmed
20	1710-1730	Cyber security standard development (15mins) + Q&A (5mins)	To be confirmed
21	1730-1750	Patient data protection regulatory framework development (15mins) + Q&A (5mins)	To be confirmed
22	1750-1755	Closing Remarks for Day 1 (5mins)	Mrs. Salbiah Yaakop GHWP TC Chair Director of Policy, International Affairs & Industry Facilitation Division, Medical Device Authority, Ministry of Health, Malaysia
23	1755	Adjourn	
END OF DAY 1			

Day 2 Agenda: 14 February 2023 (Tuesday)		
Venue: Crowne Plaza Riyadh RDC Hotel & Convention, Riyadh, Saudi Arabia		
TECHNICAL SESSIONS (Cont) – Increasing the Opportunities of Digital Health		
ITEMS	TIME	
1	0900-0905	Opening Address for DAY 2 Mr. Guobiao Gao Vice-Chair GHWP Secretary of Leading Party Group Center for Medical Device Evaluation, NMPA People's Republic of China
TECHNICAL SESSION V : Digital Health : Clinical Applications [Industry, Hospitals and Government Perspectives]		
2	0905-0925	Improving Healthcare Services (15mins) + Q&A (5mins) Ho Young Lee, M.D. Professor, Nuclear Medicine, CIO, Digital Medicine & Office of eHealth Research & Business, Seoul National University Bundang Hospital, South Korea
3	0925-0945	Decentralized Clinical Trials (15mins) + Q&A (5mins) To be confirmed
4	0945-1005	New Approaches to Post-market Clinical Follow-Ups (15mins) + Q&A (5mins) To be confirmed
5	1005-1025	Real World Evidence - Using Real-world Data (15mins) + Q&A (5mins) To be confirmed
TEA BREAK		
TECHNICAL SESSION VI : New Innovations		
6	1055-1115	Post Market Surveillance (15mins) + Q&A (5mins) To be confirmed
7	1115-1135	Regulatory Framework for Innovative Products (15mins) + Q&A (5mins) Innovations to accelerate access to diagnostics To be confirmed
8	1135-1205	Panel : Fit-for-Purpose Change Management (25mins) + Q&A (5mins) Moderator: Ms. Adelheid Schneider Panelists (TBC): a) Dr. Rama , HSA, Singapore b) Japan MHLW - TBC c) Mr. Ali Al-Dalaan, SFDA, Saudi Arabia d) Ms. Mariammah Krishnasamy, Malaysia MOH e) USFDA - TBC
9	1205-1225	Biotech applications in Medical Device Industry and the Regulatory Concerns (15mins) + Q&A (5mins) To be confirmed
LUNCH		
Capacity Building		
10	1350-1410	GHWP Capacity Building Journey and Training Curriculum (15mins) + Q&A (5mins) Ms. Quan Tran and Ms. Adelheid Schneider
11	1410-1440	Panel Discussion on GHWP Capacity Building (25mins) + Q&A (5mins) Proposal - Moderator APACMed (TBC) Panelists- a) NMPA, China -TBC b) Prof John Lim c) MDA, Malaysia - TBC d) Kenya - TBC
12	1440-1500	Updates on ISO14155 and ISO20916 (15mins) + Q&A (5mins) To be confirmed
TEA BREAK		
13	1530-1550	UDI (15mins) + Q&A (5mins) Ms. Victoria Qu
14	1550-1610	IAF CertSearch (15mins) + Q&A (5mins) Mr. Grant Ramaley and Mr. Nigel Johnston
15	1610-1630	Internet tools kit for medical devices (15mins) + Q&A (5mins) Mr. Jeff Gren
16	1630-1635	Closing Remarks for Day 2 (5mins) Dr. Lee, TC Co-Chair, GHWP
17	1635	Adjourn
END OF DAY 2		

Day 3 Agenda: 15 February 2023 (Wednesday)		
Venue: Crowne Plaza Riyadh RDC Hotel & Convention, Riyadh, Saudi Arabia		
26th GHWP Technical Committee (GHWP TC) Meeting		
ITEMS	TIME	
1	0900-1040	GHWP TC & WG Leaders Meeting with TC Advisors (Closed Meeting) Mr. Ali M. Al-Dalaan (proposed) GHWP Chair Vice Executive President, Medical Devices Sector, Saudi Food and Drug Authority, Kingdom of Saudi Arabia Mr. Guobiao Gao (proposed) GHWP Vice-Chair Secretary of Leading Party Group, Center for Medical Device Evaluation, NMPA, People's Republic of China Ms. Quan Tran (proposed) GHWP Vice-Chair Vice President, QARA, APAC, Baxter, Singapore Mrs. Salbiah Yaakop GHWP TC Chair Director of Policy, International Affairs & Industry Facilitation Division, Medical Device Authority, Ministry of Health, Malaysia Dr Jeong-Rim LEE GHWP TC Co-Chair Ministry of Food and Drug Safety , Republic of Korea Er. Alfred KWEEK GHWP TC Co-Chair Director, Public Affairs, Edwards Lifesciences Asia Pte. Ltd. Supported by Ms. Miang TANAKASEMSUB GHWP TC Secretary Head of Regulatory Affairs, Asia Pacific, Johnson & Johnson Vision Ms. Carol Jirui YAN GHWP TC Secretary Senior Consultant, Founder of Yrsagacity Limited, People's Republic of China
TEA BREAK		
2	1110-1115	Welcome Speech Mr. Ali M. AL-DALAAAN GHWP Chair Vice Executive President, Medical Devices Sector, Saudi Food and Drug Authority, Kingdom of Saudi Arabia

3	1115-1130	Opening of TC Meeting -Roll call -Adoption of Agenda -Adoption of 25th GHWP TC Meeting Minutes	Mrs. Salbiah Yaakop (Chair) Director of Policy, International Affairs & Industry Facilitation Division Medical Device Authority, Ministry of Health - Malaysia ☒ Dr. Jeong-Rim LEE (Co-Chair) Director, Cardiovascular Devices Division Ministry of Food and Drug Safety (MFDS) - Republic of Korea Mr. Alfred KWEK (Co-Chair) Director, Public Affairs Edwards Lifesciences Asia Pte. Ltd. - Lao PDR☒ <i>Supported by TC Secretary</i> Ms. Miang TANAKASEMSUB Head of Regulatory Affairs, Asia Pacific, Johnson & Johnson Vision ☒ Mr. Jack WONG Associate Vice President Regulatory Affairs, Asia Pacific, Middle East & Africa, Allergan - Hong Kong SAR, China ☒ Ms. Carol YAN Senior Consultant, Founder of Yrsagacity Limited, People's Republic of China Dr. Adelheid Schneider Head of Quality and Regulatory Affairs Asia Pacific Roche Diagnostics Asia Pacific, Singapore
4	1130-1230	Discussion of GHWP STRATEGIC PLANNING TOWARDS HARMONISATION OF MD REGULATORY REQUIREMENT - WG Chairs & Co-Chairs - TC Advisors	Mrs. Salbiah Yaakop (Chair) Director of Policy, International Affairs & Industry Facilitation Division Medical Device Authority, Ministry of Health - Malaysia ☒ Dr. Jeong-Rim LEE (Co-Chair) Director, Cardiovascular Devices Division Ministry of Food and Drug Safety (MFDS) - Republic of Korea Mr. Alfred KWEK (Co-Chair) Director, Public Affairs Edwards Lifesciences Asia Pte. Ltd. - Lao PDR☒ <i>Supported by TC Secretary</i> Ms. Miang TANAKASEMSUB Head of Regulatory Affairs, Asia Pacific, Johnson & Johnson Vision ☒ Mr. Jack WONG Associate Vice President Regulatory Affairs, Asia Pacific, Middle East & Africa, Allergan - Hong Kong SAR, China ☒ Ms. Carol YAN Senior Consultant, Founder of Yrsagacity Limited, People's Republic of China Dr. Adelheid Schneider Head of Quality and Regulatory Affairs Asia Pacific Roche Diagnostics Asia Pacific, Singapore
1230-1345			LUNCH
26th GHWP Technical Committee (GHWP TC) Meeting			
5	1345-1500 (10mins + 5mins Q&A each)	Working Group Updates and Next Steps: Work Group 1 (WG1) - Pre-Market Submission and CSDT Work Group 2 (WG2) - Pre-market: IVDD Work Group 3 (WG3) - Pre-market: Software as a Medical Device Work Group 4 (WG4) - Post-Market Work Group 5 (WG5) - Clinical Evidence for Performance and Safety	Work Group 1 (WG1) Chair - Dr. Sell Park, Ministry of Food and Drug Safety, Republic of Korea Co-Chair - Ms. Mandy Myoung Shim Kim, Johnson & Johnson Medical, Republic of Korea Work Group 2 (WG2) Chair - Mr. Wen-wei TSAI, Food and Drug Administration, Chinese Taipei Co-chair - Ir. Prof. Albert K.F. Poon, Hong Kong Polytechnic University, Hong Kong Work Group 3 (WG3) Chair - Mr. Abdullatif Al Watban, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Tony Yip, APAC Grifols (HK) Limited, Hong Kong Work Group 4 (WG4) Chair - Mr. Yorkie Chow, Department of Health, Hong Kong Co-chair - Ms. Kitty MAO, GE Healthcare, Singapore Work Group 5 (WG5) Chair - Mr. Fikriansyah Bin Imran, Ministry of Health, Republic of Indonesia Co-chair - Ms. Sumati Randeo, Danaher Corporation, India
1500-1530			TEA BREAK
6	1530-1630 (10mins + 5mins Q&A each)	Work Group 6 (WG6) - Quality Management System: Audit & Assessment Work Group 7 (WG7) - Quality Management System: Operation & Implementation Work Group 8 (WG8) - Standards Work Group 9 (WG9) - UDI & Nomenclature	Work Group 6 (WG6) Chair - Mr. Abdullah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Vincent Chee-Choong Lam, TUV SUD Product Service, Malaysia Work Group 7 (WG7) Chair - Mrs. CHEN Yan, National Medical Products Administration, China Co-chair - Mr. Ee Bin Liew, Access-2-Healthcare, Singapore Work Group 8 (WG8) Chair - Mrs. Salbiah Yaakop, Ministry of Health, Malaysia Co-chair - Mr. Tony Low, Commissioning Agents International, Malaysia Work Group 9 (WG9) Chair - Ms. Jun Li, National Medical Products Administration, China Co-chair - Ms. Victoria Qu, Global Strategic Regulatory Abbott, China
7	1630-1715 (3mins each)	Introduction by Candidates for Election of GHWP TC Chair & Co-chairs, WGs Chairs & Co-chairs	To be confirmed
8	1715-1750	Feedback from Members on Workgroup Activities	This is the opportunity for additional discussion, ideas for future topics, other recommendations, etc.
9	1750-1755	Closing Remarks for Day 3 (5mins)	Mrs. Salbiah Yaakop GHWP TC Chair Director of Policy, International Affairs & Industry Facilitation Division Medical Device Authority, Ministry of Health - Malaysia
10	1755	Adjourn	
END OF DAY 3			
GALA DINNER (Dinner starts at 1900)			

Day 4 Agenda: 16 February 2023 (Thursday) Venue: Crowne Plaza Riyadh RDC Hotel & Convention, Riyadh, Saudi Arabia		
ITEMS	TIME	26 th GHWP Annual Meeting (Main Meeting)
1	0855-0900	Announcement by MC (SFDA) (5mins)
2	0900-0930	Opening Ceremony (30mins) - Welcome Address (7mins) - Opening address (7mins) - Group Photo (16mins)
3	0930-0940	Main Meeting - Roll Call (8mins) - Adoption of Agenda (1min) - Adoption of 25th GHWP Annual Meeting Minutes (1min)
4	0940-1010	GHWP Status Reports - GHWP Overall Status Report (10mins + 5mins Q&A) - GHWPCT Status Report (10mins + 5mins Q&A)
1010-1040 TEA BREAK		
5	1040-1055	IMDRF Status Updates by IMDRF Chair (10mins+5mins)
6	1055-1155	International Organizations & Harmonization Efforts (10mins+5mins Q&A each) - APEC - ASEAN - EU Commission (MDR) - US FDA (Medical Device Single Audit Program (MDSAP))
7	1155-1255	GHWP Liaison Member Updates (5mins + 5mins Q&A each) - APACMed Update - DITTA Update - GSI Update - GMDN Agency Update - GMTA Update - IACRC Update
1255-1410 LUNCH		
8	1410-1530	Country/Region Updates (5mins+5mins Q&A each) - China - Philippines - Saudi Arabia - South Korea - Thai - USA - Japan (new member to be endorsed) - Australia
1530-1600 TEA BREAK		
9	1600-1615	Introduction by Candidates for Election of GHWP Chair and Vice-chairs (5mins each)
10	1615-1630	Resolution and Endorsement (15mins) 1. Resolutions - Amendment 8 to House Rules on SAB 2. Endorsement of White Paper on - Capacity Building Training Curriculum for Regulatory Authorities 3. Endorsement of Guidance Documents from WG - TBC 4. Endorsement of New Member(s)
11	1630-1640	Short Speech by New Member(s) (5mins x 2)
12	1640-1705	Election and Endorsement of GHWP Office Bearers (25mins) - Briefing on Election and Endorsement Procedures - Election of GHWP Chair and Vice Chairs - Election of GHWPCT Chair and Co-Chairs - Election of Working Groups Chairs and Co-Chairs
13	1705-1715	Speech by Newly Elected GHWP Chair (10mins - including any translation)
14	1715-1735	Recognition Awards and Certificates Presentations on Stage (TBC) (20mins)
15	1735-1740	Announcement of next GHWP Annual Meeting Host & Short Speech (5mins)
16	1740-1745	Closing Remarks (5mins)
17	1745	Adjourn
END OF DAY 4		
1815-1845		GHWP ASL Annual General Meeting - For ASL Members only (Transfer to another room)