

Day 4 Agenda: 16 February 2023 (Thursday)		
ITEMS	TIME	26 th GHWP Annual Meeting (Main Meeting)
1	0855-0900	Announcement by MC (SFDA) (5mins) Master of Ceremony (MC) by Saudi FDA Announcement
2	0900-0930	Opening Ceremony (30mins) - Welcome Address (7mins) - Opening address (7mins) - Group Photo (16mins) <u>Welcome Address-</u> Dr. Hisham bin Saad Aljadhey Chief Executive Officer, Saudi Food and Drug Authority Kingdom of Saudi Arabia <u>Opening Address-</u> Mr. Ali M. AL-DALAAN GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia
3	0930-0940	Main Meeting - Roll Call (8mins) - Adoption of Agenda (1min) - Adoption of 25th GHWP Annual Meeting Minutes (1min) Mr. Ali M. AL-DALAAN GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia Ir. Bryan SO GHWP Executive Secretary General CYH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong Hong Kong SAR, China
4	0940-1010	GHWP Status Reports - GHWP Overall Status Report (10mins + 5mins Q&A) - GHWPTC Status Report (10mins + 5mins Q&A) Mr. Ali M. AL-DALAAN GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia Mrs. Salbiah Yaakop GHWPTC Chair Director of Policy, International Affairs & Industry Facilitation Division Medical Device Authority, Ministry of Health, Malaysia
1010-1040 TEA BREAK		
5	1040-1055	IMDRF Status Updates (10mins+5mins) Dr. Andrzej Rys IMDRF Chair 2023 Principal Scientific Adviser Directorate-General for Health and Food Safety (DG SANTE) European Commission
6	1055-1125	International Organizations & Harmonization Efforts (10mins+5mins Q&A each) a) APEC Harmonization Center (AHC) [Online] b) ASEAN a) Dr. Jeewon Joung Ph.D., Director, Pre-submission Consultation Team, Ministry of Food & Drug Safety(MFDS), Republic of Korea, APEC Harmonization Center (AHC) b) Mrs. Salbiah Yaakop, Director of Policy, International Affairs & Industry Facilitation Division, MDA, Ministry of
7	1125-1225	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) a) Mr. Anirudh Sen, Director, Regulatory Affairs, Asia Pacific Medical Technology Association (APACMed) b) Mr. Yuji Yanagida, GRP WG Vice chair, DITTA c) Ms. Géraldine Lissalde-Bonnet, Vice-President Healthcare, GS1 Global Office, GS1 d) Mrs. Deniz Bruce, Chief Executive Officer, 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)
8	1225-1245	Country/Region Updates (5mins+5mins Q&A each) a) Australia [Online] b) European Commission a) Ms. Tracey Duffy, First Assistant Secretary, Medical Devices & Product Quality, Therapeutic Goods Administration (TGA), Australia [Online] b) Ms. Nada Alkhatat, Policy Officer, Directorate-General for Health and Food Safety (DG SANTE) European
1245-1400 LUNCH / PRAYER TIME		
9	1400-1500	Country/Region Updates (Cont') (5mins+5mins Q&A each) c) Japan d) Kingdom of Saudi Arabia e) People's Republic of China f) Republic of Korea g) Thailand h) United States of America c) Ms. TOGASHI Mika, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan d) Eng. Abdullah AlGuraibi, Saudi Food and Drug Authority (SFDA), Kingdom of Saudi Arabia e) Dr. Xu Jinghe, Deputy Commissioner, National Medical Products Administration (NMPA), People's Republic of China f) Dr. Jeong-Rim LEE, (GHWPTC Co-Chair), Director General, Medical Device Evaluation Department, Ministry of Food and Drug Safety (MFDS), Republic of Korea g) Mr. Varavoot Sermisinsiri, Director, Medical Device Control Division, Food and Drug Administration, Thailand h) Ms. Melissa Torres, Associate Director for International Affairs, The United States Food and Drug Administration (US FDA), United States of America
1500-1530 TEA BREAK		
10	1530-1545	Resolution and Endorsement (15mins) 1. Resolutions - Amendment 8 to the Global Harmonization Working Party House Rules on GHWP Strategic Advisory Board (SAB) 2. Endorsement of Strategic Framework - Global Harmonization Working Party Strategic Framework towards 2026 3. Endorsement of White Paper - Medical Device Regulatory Authorities Training Curriculum White Paper 4. Endorsement of Guidance Documents from Working Groups (WG) - WGB - Medical Gas System – Essential Principles of Safety and Performance – Standards for Demonstrating Compliance 5. Endorsement of New Member Mr. Ali M. AL-DALAAN GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia Ir. Bryan SO GHWP Executive Secretary General CYH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong Hong Kong SAR, China
11	1545-1550	Short Speech by New Member (5mins) Mr. TAKAHATA Masahiro Director, Office of Regenerative Medicines Products Evaluation Ministry of Health, Labour and Welfare (MHLW) Japan
12	1550-1645	Election and Endorsement of GHWP Office Bearers (55mins) <i>[including 1minute self-introduction by each candidate before election and endorsement (25mins)]</i> - Briefing on Election and Endorsement Procedures - Election of GHWP Chair and Vice Chairs - Election of GHWPTC Chair and Co-Chairs - Election of Working Groups Chairs and Co-Chairs Mr. Ali M. AL-DALAAN GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia Ir. Bryan SO GHWP Executive Secretary General CYH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong Hong Kong SAR, China

13	1645-1655	Speech by GHWP Chair-Elect (10mins - including any translation)	GHWP Chair-Elect
14	1655-1715	Presentation of Certificates and Recognition Award on Stage (20mins)	Mr. Ali M. AL-DALAAN GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia <u>and</u> GHWP Chair-Elect
15	1715-1720	Announcement of next GHWP Annual Meeting Host & Short Speech (5mins)	Mr. Ali M. AL-DALAAN GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia <u>and</u> 27th GHWP Annual Meeting Host
16	1720-1725	Closing Remarks (5mins)	Mr. Ali M. AL-DALAAN GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia
17	1725	Adjourn	
END OF DAY 4			
GHWP ASL Annual General Meeting [For ASL Members only] (1800-1830 at another meeting room)			