

Day 4 Agenda: 30th Nov 2023 (Thursday)		
Venue: Shanghai International Convention Center, Shanghai, China		
ITEMS	TIME	27 th GHWP Annual Meeting (Main Meeting)
1	0855-0900	Announcement by MC (5mins) Moderator: Ms. Dong Jiangping, Director General, CCFDIE, China
2	0900-0940	Opening Ceremony (35mins) - Welcome Video (5mins) - Welcome Address (5mins+5mins) - GHWP Overall Status Report (15mins) - Group Photo (10mins) Moderator: Ms. Dong Jiangping, Director General, CCFDIE, China <u>Welcome Addresses:</u> (TBC) <u>GHWP Overall Status Report -</u> Dr. Xu Jinghe GHWP Chair Deputy Commissioner, National Medical Products Administration, People's Republic of China
0940-1010		
TEA BREAK		
3	1010-1020	Main Meeting - Roll Call (8mins) - Adoption of the Agenda (1min) - Adoption of the 26th GHWP Annual Meeting Minutes (1min) Dr. Xu Jinghe GHWP Chair Deputy Commissioner, National Medical Products Administration, People's Republic of China Ir. Bryan SO GHWP Executive Secretary General Managing Director, Multi-Scale Medical Robotics Center, The Chinese University of Hong Kong, Hong Kong SAR, China
4	1020-1035	GHWPTC Status Report (10mins + 5mins Q&A) Mr. Abdullatif S. AlWatban GHWP TC Chair Executive Director, Medical Devices Evaluation, Saudi Food & Drug Authority, Kingdom of Saudi Arabia
5	1035-1045	IMDRF Updates (10mins) TBC
6	1045-1125	International Organizations & Harmonization Efforts (10mins+5mins Q&A each) a) African Medical Devices Forum (AMDF) b) WHO c) PAHO a) Ms. Paulyne Wairimu, Chair, African Medical Devices Forum (AMDF) b) Ms. Agnes Sitta Kijo, Technical Officer, WHO c) TBC
7	1120-1205	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) GSI 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) Ms. Harjit Gill, Chief Executive Officer, APACMed b) Mr. Sunny Woo, Team Leader, Korea Medical Devices Industry Association, International Affairs Team, DITTA c) Ms. Géraldine Lissalde-Bonnet, Vice President Healthcare, GSI 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	1210-1245	Country/Region Updates (5mins+2mins Q&A each) a) Chile b) European Commission c) India d) Indonesia e) Japan a) Ms. Maria Cecilia Lopez, Head of the Authorization and Registration of Medical Devices Subdepartment - ANDID/ISP Department, Chile b) TBC, EU c) TBC, India d) Ms. Ismiyati Surata, Senior Health Administrator, Ministry of Health, Indonesia e) Dr. MURAKAMI Madoka, Principal Reviewer, Office of Software as a Medical Devices, Pharmaceuticals and Medical Devices Agency (PMDA), Japan
1245-1400		
LUNCH		
9	1400-1505	Country/Region Updates (Cont') (5mins+2mins Q&A each) - TBC f) Kingdom of Saudi Arabia g) Laos h) Malaysia i) Philippines j) People's Republic of China k) Republic of Korea l) Thailand m) United States of America n) Vietnam f) Representative of Mr. Ali M. AL-DALAAAN, Vice Executive President, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia g) Ms. Davone Douangdany, Chief of Drug and Medical Device Control Division, Food and Drug Department, Ministry of Health, Laos h) Mrs. Salbiah Yaakop, Director of Policy, International Affairs & Industry Facilitation Division, Medical Device Authority, Ministry of Health, Malaysia i) Dr. Samuel A. Zazate, Director General, Food and Drug Administration, Philippines j) Dr. LV Ling, Director General, Department of Medical Devices Registration, NMPA, China k) Dr. Hye Won ROH, Director of cardiovascular and imaging device division, MFDS, Korea l) Mrs. Sirimas Katchamart, Senior Pharmacist, Medical Device Control Division, Food and Drug Administration, Ministry of Public Health, Thailand m) TBC, USA n) Mr. Nguyen Tu Hieu, Deputy Director, Infrastructure and Medical Device Administration, Ministry of Health, Vietnam
1505-1535		
TEA BREAK		
10	1535-1550	Resolution and Endorsement (15mins) 1. Endorsement of Vice-Chair (Regulatory Authority) and WG5 Chair positions 2. Endorsement of Guidance Documents from Working Groups (WG) WG1-WG2-WG3 "Principles of Regulatory Requirements for Electronic Instructions for Use (eIFU)" WG1-WG2-WG3 "Change Management to Registered Medical Devices" WG2 "Guidance for Additional Considerations to Support Conformity Assessment of In vitro Companion Diagnostic Medical Devices" WG4 "Post Market Resource Center" WG7 "Guidance document on the risk based approach to quality management system aspects: ISO13485:2016" WG7 "Guidance for Auditing Supplier to Medical Device Manufacturers" WG7 "A Guide to Understanding Presently Available Audit Duration Determination Systems" WG7 "A Guide to Understanding Best Practices in Audit Life Cycle Management" WG9 "GHWP UDI Rule" 3. Endorsement of New Members a) Egypt b) Cuba Dr. Xu Jinghe GHWP Chair Deputy Commissioner, National Medical Products Administration, People's Republic of China Ir. Bryan SO GHWP Executive Secretary General Managing Director, Multi-Scale Medical Robotics Center, The Chinese University of Hong Kong, Hong Kong SAR, China
11	1550-1600	Short Speech by New Member (5mins x 2) a) Egypt b) Cuba a) Ms. Rania Soliman, General Manager Of General Administration Of Medical Devices Marketing authorization, Egyptian Drug Authority, Egypt b) MSc. Yadir Alvarez Rodriguez, CECMED, Cuba
12	1600-1615	Presentation of Certificates of Appointment for GHWP Strategic Advisory Board (SAB) [15mins] - Background on the formation of SAB - Presentation of Certificates - Short Speech by SAB Members' Representative Dr. Xu Jinghe GHWP Chair Deputy Commissioner, National Medical Products Administration, People's Republic of China Ir. Bryan SO GHWP Executive Secretary General Managing Director, Multi-Scale Medical Robotics Center, The Chinese University of Hong Kong, Hong Kong SAR, China
13	1615-1630	Presentation of Letter of Appointment for GHWP Academy and Short Presentation [15mins] - Objective on the formation of GHWP Academy - Presentation of Letter of Appointment - Short Speech by GHWP Academy Representative Dr. Xu Jinghe GHWP Chair Deputy Commissioner, National Medical Products Administration, People's Republic of China Ir. Bryan SO GHWP Executive Secretary General Managing Director, Multi-Scale Medical Robotics Center, The Chinese University of Hong Kong, Hong Kong SAR, China
14	1630-1635	Announcement of next GHWP Annual Meeting Host & Short Speech (5mins) Dr. Xu Jinghe GHWP Chair Deputy Commissioner, National Medical Products Administration, People's Republic of China Ir. Bryan SO GHWP Executive Secretary General Managing Director, Multi-Scale Medical Robotics Center, The Chinese University of Hong Kong, Hong Kong SAR, China
15	1635-1655	Presentation of Souvenirs to Company Sponsors [10mins] Dr. Xu Jinghe GHWP Chair Deputy Commissioner, National Medical Products Administration, People's Republic of China
16	1655-1700	Closing Remarks (5mins) Dr. Xu Jinghe GHWP Chair Deputy Commissioner, National Medical Products Administration, People's Republic of China
17	1700	Adjourn END OF DAY 4
GHWP ASL Annual General Meeting [For ASL Members only] (1730-1800 at another meeting room)		