

Day 4 Agenda: 08th Nov 2023 (Thursday)		
Time	Title	Chair
0855-0900	Announcement by MC (5mins)	07:00-08:00: Registration Moderator: Dong Jingdong Director General, CCFDEI, People's Republic of China
0900-0920	Opening Ceremony (30mins) - Welcome Video (5mins) - Welcome Address (5mins+5mins) - Opening Address (5mins) - Group Photo (5mins)	Moderator: Dong Jingdong Director General, CCFDEI, People's Republic of China Welcome Address: Li Li Commissioner, NMFA, People's Republic of China Chen Jie Vice Mayor, Shanghai Municipal People's Government, People's Republic of China Closing Address: Xu Jinghe GHWP Chair Deputy Commissioner, NMFA, People's Republic of China
0930-1000: TEA BREAK		
1000-1020	Main Meeting - Roll Call (5mins) - Adoption of the Agenda (10mins) - Adoption of the 26th GHWP Annual Meeting Minutes (1min)	Xu Jinghe GHWP Chair Deputy Commissioner, NMFA, People's Republic of China Bryan SO GHWP Executive Secretary General Managing Director, Multi-Scale Medical Robotics Center, The Chinese University of Hong Kong, Hong Kong SAR, China
1020-1040	GHWP Status Reports: a) GHWP Overall Status Report (15mins) b) GHWPIC Status Report (10mins + 5mins Q&A)	Xu Jinghe GHWP Chair Deputy Commissioner, NMFA, People's Republic of China Abdulatif S. Alattar GHWP IC Chair Executive Director, Medical Devices Evaluation, Saudi Food & Drug Authority, Kingdom of Saudi Arabia
1040-1055	IMDRF Updates (15mins)	Chloe Spothart Walia Althany Head of Office, Medical Devices, Directorate General for Health and Food Safety, European Commission, IMDRF
1055-1125	International Organizations & Harmonization Efforts (10mins+5mins Q&A each) a) WHO b) African Medical Devices Forum (AMDF)	A) Agnes Sita Kijo Technical Officer, WHO B) Pauline Wairimu Chair, African Medical Devices Forum (AMDF)
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) ISS 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) Cindy Palou Chief for Regulatory Affairs, APACMed B) Sunny Woon, Team Leader Geneva Medical Device Industry Association, International Affairs Team, DITTA C) Géraldine Lissalde-Bonnet Vice President Healthcare, ISS D) Deniz Bruze Chief Executive Officer, Global Medical Devices Nomenclature Agency (GMDN Agency) E) Diana Kamecka Strategic Special Projects & International Affairs, Senior Manager International Affairs, Global Medical Technology Alliance (GMTA) F) Sandra Ligia Gonzalez Executive Secretary, Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector (IACRC)
1225-1255	Country/Region Updates (5mins+5mins Q&A each) a) Chile b) European Commission c) Indonesia	A) Maria Cecilia Lopez Head of the Authorization and Registration of Medical Devices Subdepartment - ANDI/DSP Department, Chile B) Graeme Turbridge Senior Vice President, Global Regulatory and Quality, Medical Devices at BSI C) Immyati Suratna Senior Health Administrator, Ministry of Health, Indonesia
1255-1400: LUNCH		
1400-1520	Country/Region Updates (5mins+5mins Q&A each) d) Japan e) Kingdom of Saudi Arabia f) Laos PDR g) Malaysia h) People's Republic of China i) Republic of Korea j) Thailand k) Vietnam	A) Minori Sato Coordinator, Office of International Programs Pharmaceuticals and Medical Devices Agency (PMDA), Japan B) Abdulrahman Alghurabi Director of Regulation and Standard, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia C) Boumvieng Kouavong Director General, Food and Drug Department, Ministry of Health, Laos PDR D) Muralitharan Paramasiva Chief Executive, Medical Device Authority, Ministry of Health, Malaysia E) Lye Ling Director General, Department of Medical Devices Registration, NMFA, People's Republic of China F) Hye Won Huh Director, Cardiovascular and Imaging Device Division, MFDS, Republic of Korea G) Sertchai Lerthut Deputy Secretary-General, Food and Drug Administration, Thailand H) Nguyen Tu Hieu Deputy Director, Infrastructure and Medical Device Administration, Ministry of Health, Vietnam
1520-1545	Resolution and Endorsement (25mins) 1. Endorsement of Vice-Chair (Regulatory Authority) and WSS Chair positions 2. Endorsement of Guidance Documents from Working Groups (WG) a) WGS-WG2-WG3 "Principles of Regulatory Requirements for Electronic Instructions for Use (EUIF)" b) WGS "Guidance for Additional Considerations to Support Conformity Assessment of In vitro Companion Diagnostic Medical Devices" c) WGS "Best Market Resource Center" d) WGS "Guidance document on the risk-based approach to quality management system aspects: ISO13485:2016" e) WGS "Guidance for Auditing Supplier to Medical Device Manufacturers" f) WGS "A Guide to Understanding Presently Available Audit Duration Determination Systems" g) WGS "A Guide to Understanding Best Practices in Audit Life Cycle Management" h) WGS "Onepart ISO 13485" 3. Endorsement of New Members, followed by short speeches a) Egypt [Speech by Ramia Soliman, General Manager, Of General Administration Of Medical Devices Marketing authorities, Egyptian Drug Authority, Egypt] b) Cuba [Speech by Yadir Alvarez Rodriguez, Specialist of Medical Devices Department, CECMED, Cuba]	Xu Jinghe GHWP Chair Deputy Commissioner, NMFA, People's Republic of China Bryan SO GHWP Executive Secretary General Managing Director, Multi-Scale Medical Robotics Center, The Chinese University of Hong Kong, Hong Kong SAR, China
1545-1610: TEA BREAK		
1610-1625	Presentation of Certificates of Appointment to the Members of GHWP Strategic Advisory Board (SAB) (15mins)	Xu Jinghe GHWP Chair Deputy Commissioner, NMFA, People's Republic of China Bryan SO GHWP Executive Secretary General Managing Director, Multi-Scale Medical Robotics Center, The Chinese University of Hong Kong, Hong Kong SAR, China
1625-1640	Presentation of Bronze Plaque to GHWP (Guangzhou) Academy and Short Presentation (15mins)	Xu Jinghe GHWP Chair Deputy Commissioner, NMFA, People's Republic of China Yong XU Vice President of South China University of Technology People's Republic of China Bryan SO GHWP Executive Secretary General Managing Director, Multi-Scale Medical Robotics Center, The Chinese University of Hong Kong, Hong Kong SAR, China
1640-1645	Ceremony on Strategic Cooperation between GHWP and Reed Sinopharm Exhibitors on CMEF (5mins)	Lumbee Cho GHWP Vice-Chair (Industry) Regulatory Affairs Director, Abbott Medical Korea, Republic of Korea Li Zhao Managing Director, Reed Sinopharm Exhibitions Bryan SO GHWP Executive Secretary General Managing Director, Multi-Scale Medical Robotics Center, The Chinese University of Hong Kong, Hong Kong SAR, China
1645-1700	Presentation of Souvenirs to Company Sponsors (15mins)	Xu Jinghe GHWP Chair Deputy Commissioner, NMFA, People's Republic of China Eka Nurmanandani Director for Medical Devices Control, Ministry of Health, Indonesia GHWP Vice-Chair (Regulatory Authority) Bryan SO GHWP Executive Secretary General Managing Director, Multi-Scale Medical Robotics Center, The Chinese University of Hong Kong, Hong Kong SAR, China
1700-1705	Announcement of the next GHWP Annual Meeting Host & Short Speech (5mins)	Xu Jinghe GHWP Chair Deputy Commissioner, NMFA, People's Republic of China Bryan SO GHWP Executive Secretary General Managing Director, Multi-Scale Medical Robotics Center, The Chinese University of Hong Kong, Hong Kong SAR, China
1705-1710	Closing Remarks (5mins)	Xu Jinghe GHWP Chair Deputy Commissioner, NMFA, People's Republic of China
1710	Adjourn	END OF DAY 4