

Day 3 Agenda: 15 February 2023 (Wednesday)		
Venue: Crowne Plaza Rivadh RDC Hotel & Convention, Rivadh, Saudi Arabia		
26th GHWP Technical Committee (GHWP TC) Meeting		
ITEMS	TIME	
1	0900-1045	<p>GHWP TC & WG Leaders Meeting with TC Advisors (1hr45mins) (Closed-Door Meeting)</p> <p>Mr. Ali M. Al-Dalaan (proposed) GHWP Chair Vice Executive President, Medical Devices Sector, Saudi Food and Drug Authority, Kingdom of Saudi Arabia</p> <p>Mr. Guobiao Gao (proposed) GHWP Vice-Chair Secretary of Leading Party Group, Center for Medical Device Evaluation, NMPA, People's Republic of China</p> <p>Ms. Quan Tran (proposed) GHWP Vice-Chair Vice President, QARA, APAC, Baxter, Singapore</p> <p>Mrs. Salbiah Yaakop GHWP TC Chair Director of Policy, International Affairs & Industry Facilitation Division, Medical Device Authority, Ministry of Health, Malaysia</p> <p>Dr Jeong-Rim LEE GHWP TC Co-Chair Ministry of Food and Drug Safety , Republic of Korea</p> <p>Er. Alfred KWEK GHWP TC Co-Chair Director, Public Affairs, Edwards Lifesciences Asia Pte. Ltd.</p> <p>Supported by Ms. Miang TANAKASEMSUB GHWP TC Secretary Head of Regulatory Affairs, Asia Pacific, Johnson & Johnson Vision</p> <p>Ms. Carol Jirui YAN GHWP TC Secretary</p>
1045-1115		TEA BREAK
2	1115-1120	<p>Welcome Speech (5mins)</p> <p>Mr. Ali M. AL-DALAAAN GHWP Chair Vice Executive President, Medical Devices Sector, Saudi Food and Drug Authority, Kingdom of Saudi Arabia</p>
3	1120-1135	<p>Opening of TC Meeting (15mins) -Roll call -Adoption of Agenda -Adoption of 25th GHWP TC Meeting Minutes</p> <p>Mrs. Salbiah Yaakop (Chair) Director of Policy, International Affairs & Industry Facilitation Division Medical Device Authority, Ministry of Health - Malaysia</p> <p>Dr. Jeong-Rim LEE (Co-Chair) Director, Cardiovascular Devices Division Ministry of Food and Drug Safety (MFDS) - Republic of Korea</p> <p>Mr. Alfred KWEK (Co-Chair) Director, Public Affairs Edwards Lifesciences Asia Pte. Ltd. - Lao PDR</p> <p>Supported by TC Secretary Ms. Miang TANAKASEMSUB Head of Regulatory Affairs, Asia Pacific, Johnson & Johnson Vision</p> <p>Mr. Jack WONG Associate Vice President Regulatory Affairs, Asia Pacific, Middle East & Africa, Allergan - Hong Kong SAR, China</p> <p>Ms. Carol YAN Senior Consultant, Founder of Yrsagacity Limited, People's Republic of China</p>
4	1135 – 1245 (5mins + 5mins Q&A each)	<p>Working Group Updates and Next Steps:</p> <p>Work Group 1 (WG1) - Pre-Market Submission and CSDT</p> <p>Work Group 2 (WG2) - Pre-market: IVDD</p> <p>Work Group 3 (WG3) - Pre-market: Software as a Medical Device</p> <p>Work Group 4 (WG4) - Post-Market</p> <p>Work Group 5 (WG5) - Clinical Evidence for Performance and Safety</p> <p>Work Group 6 (WG6) - Quality Management System: Audit & Assessment</p> <p>Work Group 7 (WG7) - Quality Management System: Operation & Implementation</p> <p>Work Group 1 (WG1) Chair - Dr. Seil Park, Ministry of Food and Drug Safety, Republic of Korea Co-Chair - Ms. Mandy Myoung Shim Kim, Johnson & Johnson Medical, Republic of Korea</p> <p>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 SAR, China</p> <p>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 SAR, China</p> <p>Work Group 4 (WG4) Chair - Mr. Yorkie Chow, Department of Health, Hong Kong SAR, China Co-chair - Ms. Kitty MAO, GE Healthcare, Singapore</p> <p>Work Group 5 (WG5) Chair -Mr. Fikriansyah Bin Imran, Ministry of Health, Republic of Indonesia Co-chair - Ms. Sumati Randeo, Danaher Corporation, India</p> <p>Work Group 6 (WG6) Chair - Mr. Abdullah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia</p>

1245-1400		LUNCH / PRAYER TIME	
26th GHWP Technical Committee (GHWP TC) Meeting			
5	1400 -1420 (5mins + 5mins Q&A each)	Working Group Updates and Next Steps (Cont'): Work Group 8 (WG8) - Standards Work Group 9 (WG9) - UDI & Nomenclature	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 Ou, Global Strategic Regulatory Abbott, China
6	1420-1430	TC Advisors Summary Report (10mins)	Representatives of TC Advisory Panel
7	1430-1435	Closing Remarks for Day 3 (5mins)	Mr. Alfred KWEK (GHWP TC Co-Chair) Director, Public Affairs Edwards Lifesciences Asia Pte. Ltd. - Lao PDR
8	1435	Adjourn	
END OF DAY 3			
1435-1515		TEA BREAK	
GHWP Leadership and IMDRF Management Committee Meeting (CLOSED-DOOR) [TBC] (1515-1645)			
GALA DINNER (Dinner starts at 1900)			