Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

The 26th GHWP Annual Meeting Program

Riyadh, Saudi Arabia
13-16 February 2023

Program (Version 9b_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 (10mins)	Dr. Hisham bin Saad Aljadhey Chief Executive Officer Saudi Food and Drug Authority, Kingdom of Saudi Arabia
2	0910-0920	Opening Address (10mins)	Mr. Ali M. AL-DALAAN GHWP Chair Vice Executive President, Medical Devices Sector, Saudi Food and Drug Authority, Kingdom of Saudi Arabia
3	0920-0935	GHWP Strategic Framework (15mins)	Ms. Quan Tran GHWP Vice-Chair Vice President, QARA, APAC, Baxter Singapore
4	0935-1000	Panel Discussion: GHWP Strategic Framework (20mins) + Q&A (5mins)	Moderator: Prof John Lim, Executive Director, Centre of Regulatory Excellence, Duke-NUS Medical School, Singapore Panelists: a) Mr. Ali M. AL-DALAAN, (GHWP Chair), Vice Executive President, Medical Devices Sector, Saudi Food and Drug Authority, Kingdom of Saudi Arabia b) Mrs. Salbiah Yaakop, (GHWPTC Chair), Director of Policy, International Affairs & Industry Facilitation Division, Medical Device Authority, Ministry of Health, Malaysia c) Dr. Jeong-Rim LEE, (GHWPTC Co-Chair), Director General, Medical Device Evaluation Department, Ministry of Food and Drug Safety, Republic of Korea d) Mr. Alfred KWEK, (GHWPTC Co-Chair), Director, Public Affairs Edwards Lifesciences Asia Pte. Ltd.,Lao PDR e) Ms. Yasha Huang, Head of Regulatory Policy, Roche Asia Pacific
5	1000-1005	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 Hong Kong SAR, China
1005-1040		TEA BREAK	
		TECHNICAL SESSION - Regulatory Agility and Reliance	
6	1040-1100	Regulatory Agility (15mins) + Q&A (5mins)	Ms. Yasha Huang Head of Regulatory Policy, Roche Asia Pacific
7	1100-1120	Benefits of Regulatory Reliance (15mins) + Q&A (5mins)	Dr. Rama Sethuraman Director, Medical Devices, Health Sciences Authority, Singapore
8	1120-1150	Panel Discussion : Expanding Global access to Medical Devices – Reliance (25mins) + Q&A (5mins)	Moderator : Ms. Miang Tanakasemsub Panelists: a) Dr. Rama Sethuraman, Director, Medical Devices, HSA, Singapore b) Ms. Yasha Huang, Head of Regulatory Policy, Roche Asia Pacific c) Dr. Razan Asally, Head of Medical Devices Evaluation Section, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia d) Mr. Varavoot Sermsinsiri, Director, Medical Device Control Division, Food and Drug Administration, Thailand
		TECHNICAL SESSIONS - Increasing the Opportunities of Digital Health	
		TECHNICAL SESSION I : Digital Health : Innovation and Technology [Industry Perspective]	
9	1150-1210	Digital Therapeutics - "Industry Perspective" (15mins) + Q&A (5mins) [ONLINE]	Dr. Sean (Seong-ji) Kang, MD. MPH. Co-founder, CEO of WELT
10	1210-1230	Digital Twins (15mins) + Q&A (5mins) [ONLINE]	Dr. Mark Palmer, MD, PhD Research Director & Technical Fellow | Core Technologies Lead | Enterprise Modeling & Simulation Working Group Medtronic
11	1230-1250	Metaverse using AR/VR/XR (15mins) + Q&A (5mins)	Ms. Joy Sacmar VP Regulatory Affairs, Digital Surgery Johnson & Johnson
1250-1400		LUNCH / PRAYER TIME	
		TECHNICAL SESSION II : Digital Health : Regulatory Approaches [Government perspectives]	
12	1400-1415	Digital Health Regulation Development in China (15mins) [RECORD]	Dr. Guo Zhaojun. MD. Director, MD Evaluation Department II, Center for Medical Device Evaluation, NMPA, People's Republic of China
13	1415-1435	Digital Therapeutics - "Exploring Regulatory Pathways of Digital Therapeutics" (15mins) + Q&A (5mins)	Dr. Chung Keun Lee. Ph.D. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Korea
14	1435-1455	Regulations for Artificial Intelligence (15mins) + Q&A (5mins)	Ms. Melissa Torres Associate Director for International Affairs Center for Devices and Radiological Health USFDA
15	1455-1525	Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins)	Moderator: Mr. Brad Spring, Global Head of Regulatory Policy & Intelligence, Roche Diagnostics Corporation Panelists: 1) Dr. Abdullatif Al Watban, Saudi FDA, Kingdom of Saudi Arabia 2) Dr. Chung Keun Lee. Assistant Director, Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Korea 3) Dr. Feisul Idzwan Bin Mustapha, Deputy Director, Disease Control Division, MOH, Malaysia [ONLINE] 4) Ms. Melissa Torres, Associate Director for International Affairs, Center for Devices and Radiological Health, USFDA
1525-1555		TEA BREAK	
		TECHNICAL SESSION III : Digital Health : Advancing Healthcare Access [Government, Industry, International Org Perspectives]	
16	1555-1615	Equitable Access to the Patient and Product (15mins) + Q&A (5mins)	Dr. Reem A Alnafisah, Innovation and KAIZEN Consultant SEHA Virtual Hospital and Innovation Enablement Center, Kingdom of Saudi Arabia
17	1615-1645	Panel Discussion: Digital Transformation and Connected Care in the Hospital (25mins) + Q&A (5mins)	Moderator: Mr. Serkan Sezer, Director of QARA, EMEA Baxter Panelists: 1) Ms. Layla Sulaiman Alsalehi, Director, Digital Services Activation, Ministry of Health, Kingdom of Saudi Arabia 2) Dr. Reem A Alnafisah, Innovation and KAIZEN Consultant SEHA Virtual Hospital and Innovation Enablement Center, Kingdom of Saudi Arabia 3) Dr. Seil Park, Ministry of Food and Drug Safety, Republic of Korea 4) Mr. Michael Bothe, Head of Notified body, DQS Medizinprodukte GmbH 5) Ms Alicia Chang, Country Lead, APACMed China
		TECHNICAL SESSION IV : Standards	
18	1645-1705	Using Standards for Regulatory Purposes (15mins) + Q&A (5mins)	Mr. Scott Colburn Director, CDRH Standards & Conformity Assessment Program / S-CAP, USFDA
19	1705-1725	Cyber Security standard development	Mr. Michael Bothe, Head of Notified body, DQS Medizinprodukte GmbH
20	1725-1730	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
21	1730	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	0900-0910	Opening Address for Day 2 (10mins)	Mr. Guobiao Gao GHWP Vice Chair Secretary of Leading Party Group, Center for Medical Device Evaluation, National Medical Products Administration People's Republic of China
		TECHNICAL SESSION V : Digital Health : Clinical Applications [Industry, Hospitals and Government Perspectives]	
2	0910-0930	Improving Healthcare Services (15mins) + Q&A (5mins) [ONLINE]	Dr. Ho Young Lee. M.D. Professor. Nuclear Medicine, CIO. Digital Medicine & Office of eHealth Research & Business, Seoul National University Bundang Hospital, South Korea
3	0930-0950	Artificial Intelligence Clinical Application in Hospital (15mins) + Q&A (5mins) [Online]	Dr. Chong Jai KiM, MD Professor of Pathology Asan Medical Center Seoul, Korea
4	0950-1010	New Approaches to Post-market Clinical Follow-Ups (15mins) + Q&A (5mins) [Online]	Ms. Heather M. Colvin Director, MD Regulatory Affairs Evidence & Outcomes Policy Global Regulatory Affairs Policy Johnson and Johnson Medtech
5	1010-1030	Real World Evidence - Using Real-world Data (15mins) + Q&A (5mins)	Mr. Kenneth Cavanaugh Deputy Director, Officer of Cardiovascular Devices, USFDA Center for Devices and Radiological Health
1030-1100		TEA BREAK	
		TECHNICAL SESSION VI : New Innovations	
6	1100-1120	Post Market Surveillance (15mins) + Q&A (5mins)	Mr. Mohd Zul hisham Junaidi, Post Market & Enforcement Division, Medical Device Authority, Malaysia
7	1120-1140	Regulatory Pathways for Innovative Products (15mins) + Q&A (5mins)	Mr. Kenneth Cavanaugh Deputy Director, Officer of Cardiovascular Devices, USFDA Center for Devices and Radiological Health
8	1140-1210	Panel : Fit-for-Purpose Change Management (25mins) + Q&A (5mins)	Moderator: Ms. Adelheid Schneider Panelists: a) Dr. Rama Sethuraman, Director, Medical Devices, Health Sciences Authority, Singapore b) Dr. KUSAKABE Tetsuya, PhD, MPH, Director, Office of Manufacturing Quality and Vigilance for Medical Devices, International Coordination Officer, Pharmaceuticals and Medical Devices Agency (PMDA), Japan c) Mr. Ali Al-Dalaan, Vice Executive President, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia d) Ms. Mariammah Krishnnasamy, Malaysia MOH e) Mr. Kenneth Cavanaugh, Deputy Director, Officer of Cardiovascular Devices, Center for Devices and Radiological Health, USFDA
9	1210-1230	Biotech Applications in Medical Device from the Authority Perspective (15mins) + Q&A (5mins)	Dr. Razan Asally, Head of Medical Devices Evaluation Section, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia
1230-1345		LUNCH / PRAYER TIME	
		Capacity Building	
10	1345-1405	GHWP Capacity Building Journey and Training Curriculum (15mins) + Q&A (5mins)	Ms. Quan Tran Vice President, QARA, APAC, Baxter Singapore Dr. Praveen Kumar Manager, Regulatory Affairs, APACMed
11	1405-1435	Panel Discussion on GHWP Capacity Building (25mins) + Q&A (5mins)	Moderator: Mr. Anirudh Sen, APACMed Panelists- a) Prof John Lim, Executive Director, Centre of Regulatory Excellence, Duke-NUS Medical School, Singapore b) Mrs. Salbiah Yaakop, Director of Policy, International Affairs & Industry Facilitation Division, Medical Device Authority, Ministry of Health, Malaysia c) Dr. Razan Asally, Head of Medical Devices Evaluation Section, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia d) Mr. Yiting Cai, Chair, Capacity Building Working Group, APACMed; Regional Regulatory Affairs Director, Alcon, Singapore
12	1435-1455	MDSAP Updates (15mins) + Q&A (5mins)	Ms. Michelle Noonan International Policy Analyst Center for Devices and Radiological Health U.S. Food and Drug Administration
13	1455-1515	UDI (15mins) + Q&A (5mins)	Ms. Victoria Qu, Director, Quality and Regulatory Affairs, Asia Pacific, Cordis
1515-1545		TEA BREAK	
14	1545-1605	IAF CertSearch (15mins) + Q&A (5mins)	Mr. Grant Ramaley and Mr. Nigel Johnston, IAF
15	1605-1625	Internet tools kit for medical devices (15mins) + Q&A (5mins) [ONLINE]	Mr. Jeff Gren & Ms. Miang TANAKASEMSUB
16	1625-1630	Closing Remarks for Day 2 (5mins)	Dr. Jeong-Rim LEE (GHWPTC Co-Chair) Director General, Medical Device Evaluation Department Ministry of Food and Drug Safety (MFDS) Republic of Korea
17	1630	Adjourn	
		END OF DAY 2	

	Day 3 Agenda: 15 February 2023 (Wednesday) Venue: Crowne Plaza Riyadh RDC Hotel & Convention, Riyadh, Saudi Arabia		
ITEMS	TIME	26th GHWP Technical Committee (GHWP TC) Meeting	
1	0900-1045	GHWP TC & WG Leaders Meeting with TC Advisors (1hr45mins) (Closed-Door 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 KWEK 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
1045-1115		TEA BREAK	
2	1115-1120	Welcome Speech (5mins)	Mr. Ali M. AL-DALAAN GHWP Chair Vice Executive President, Medical Devices Sector, Saudi Food and Drug Authority, Kingdom of Saudi Arabia
3	1120-1135	Opening of TC Meeting (15mins) -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 *Supported by TC Secretary* 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	1135 – 1245 (5mins + 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 6 (WG6) - Quality Management System: Audit & Assessment Work Group 7 (WG7) - Quality Management System: Operation & Implementation	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 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 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 Work Group 4 (WG4) Chair - Mr. Yorkie Chow, Department of Health, Hong Kong SAR, China 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 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
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 Qu, 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 (GHWPTC 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)			

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

		Day 4 Agenda: 16 February 2023 (Thursday)	
ITEMS	TIME	26th 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)	Welcome Address- Dr. Hisham bin Saad Aljadhey Chief Executive Officer, Saudi Food and Drug Authority Kingdom of Saudi Arabia Opening Address- 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 Health , Malaysia, ASEAN
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 Alkhayat, Policy Officer, Directorate-General for Health and Food Safety (DG SANTE) European Commission
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 Comissioner, 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 Sermsinsiri, 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) - WG1,WG2&WG3 - Categorisation of Changes to a Registered Medical Device - WG8 - Medical Gas System – Essential Principles of Safety and Performance – Standards for Demonstrating Compliance 5. Endorsement of New Member - Japan	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 Regnerative Medicines Products Evaluation Ministry of Health, Labour and Welfare (MHLW) Japan
12	1550-1645	Election and Endorsement of GHWP Office Bearers (55mins) *[including 1minute self-introduction by each candidate before election and endorsement (25mins)]* - 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 and 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 and 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)			