

The 26th GHWP Annual Meeting and 26th TC Meeting Program

Riyadh, Saudi Arabia
13-16 February 2023

Program (Version 9a)

		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, (GHWPPTC Chair), Director of Policy, International Affairs & Industry Facilitation Division, Medical Device Authority, Ministry of Health, Malaysia c) Dr. Jeong-Rim LEE, (GHWPPTC Co-Chair), Director General, Medical Device Evaluation Department, Ministry of Food and Drug Safety, Republic of Korea d) Mr. Alfred KWEK, (GHWPPTC 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
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
21	1730	Adjourn	
END OF DAY 1			