

The 26th GHWP Annual Meeting Program

Riyadh, Saudi Arabia 13-16 February 2023

DRAFT Program (Version 4E_Public)

			da: 13 February 2023 (Monday) h RDC Hotel & Convention, Riyadh, Saudi Arabia
	5-0900	Registration	
ITEMS	TIME		
1	0900-0910	Welcome Address	Dr. Hisham bin Saad Aljadhey
			Chief Executive Officer
			Saudi Food and Drug Authority, Kingdom of Saudi Arabia
2	0910-0920	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	0920-0930	Remarks by GHWP Vice-Chair (Regulatory Authority)	Mr. Guobiao Gao
			GHWP Vice-Chair
			Secretary of Leading Party Group
			Center for Medical Device Evaluation, NMPA
			People's Republic of China
4	0930-0945	GHWP Strategic Framework (15mins)	Ms. Quan Tran
			GHWP Vice-Chair
			Vice President, QARA, APAC, Baxter Singapore
5	0945-1010	Panel Discussion: GHWP Strategic Framework (20mins) + Q&A (5mins)	To be confirmed
, ,	0945-1010	Parter Discussion. Grow Suategic Framework (20mins) + Qox (5mins)	
6	1010-1015	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
1015-1045			TEA BREAK
		TECHNICAL SESSI	ION - Regulatory Agility and Reliance
7	1045-1105	Regulatory Agility (15mins) + Q&A (5mins)	Ms. Yasha Huang, Head of Regulatory Policy, Roche Asia Pacific
8	1105-1125	Benefits of Regulatory Reliance (15mins) + Q&A (5mins	Dr. Rama, HAS, Singapore
9	1125-1145	Panel Discussion : Expanding Global access to Medical Devices – Reliance (25mins) + Q&A (5mins)	Moderator : Ms. Miang Tanakasemsub
,	1153-1143	n and a second in a constant of the second of the second devices - reliance (2011115) + Q&A (5mins)	Speakers:
			a) Dr. Rama, HSA
			b) Ms. Yasha Huang
			c) TBC
			ncreasing the Opportunities of Digital Health
10	1145-1205		Ith : Innovation and Technology [Industry Perspective]
10	1145-1205	Digital Therapeutics - "Industry Perspective" (15mins) + Q&A (5mins)	Sean (Seong-ji) Kang, MD. MPH. Co-founder, CEO of WELT
11	1205-1230	Digital Twins (15mins) + Q&A (5mins)	Mark Palmer, MD, PhD
			Research Director & Technical Fellow Core Technologies
			Lead Enterprise Modeling & Simulation Working Group
			Medtronic
12	1230-1250	Metaverse using AR/VR/XR (15mins) + Q&A (5mins)	To be confirmed
1250-1400			LUNCH
		TECHNICAL SESSION II : Digital Hea	Ith : Regulatory Approaches [Government perspectives]
13	1400-1420	Digital Health Regulation Development in China (15mins) + Q&A (5mins)	NMPA (TBC)
14	1420-1440	Distant Theorem at the Ultransford Decoderation Deathermore of Distant Theorem at the Ultransford Activity (Activity)	Chung Kang Lan Di D
14	1420-1440	Digital Therapeutics - "Exploring Regulatory Pathways of Digital Therapeutics" (15mins) + Q&A (5mins)	Chung Keun Lee. Ph.D. Assistant Director.
			Digital Health Devices Division, Medical Device Evaluation Department, MFDS, Korea
15	1440-1500	Regulations for Artificial Intelligence (15mins) + Q&A (5mins)	To be confirmed
16	1500 1520	Panal Dissussion, Disital Health, Pagulatan, Anneachas (20mins), 09.4 (5min-1	Te be confirmed
16	1500-1530	Panel Discussion: Digital Health - Regulatory Approaches (25mins) + Q&A (5mins)	To be confirmed
1530-1600			TEA BREAK
			ealthcare Access [Government, Industry, International Org Perspectives]
17	1600-1620	Equitable Access to the Patient and Product / Virtual Hospital / Medical Imaging (15mins) + Q&A (5mins)	
18	1620-1650	Panel Discussion: Digital Transformation and Connected Care in the Hospital (25mins) + Q&A (5mins)	Moderator: Serkan Sezer, Director of QARA, EMEA Baxter
	1000		Panelists: (TBC)
			1) Hospital representative – TBC
			2) Health authority – Dr. Seil Park, MFDS
			3) Notified Body – TBC
			4) Industry Association – TBC CAL SESSION IV : Standards
19	1650-1710	Using Standards for Regulatory Purposes (15mins) + Q&A (5mins)	To be confirmed
	1000.1110	Care (all all all all all all all all all al	
20	1710-1730	Cyber security standard development (15mins) + Q&A (5mins)	To be confirmed
21	1730-1750	Patient data protection regulatory framework development (15mins) + Q&A (5mins)	To be confirmed
22	1750-1755	Closing Remarks for Day 1 (5mins)	Mrs. Salbiah Yaakop
~~	1/30-1/33	Course include to pay 1 (allilla)	GHWP TC Chair
			Director of Policy, International Affairs & Industry Facilitation Division, Medical Device Authority, Ministry of Health,
			Malaysia
L		Adjourn	
23	1755		
23	1755	END OF D	AY 1



	Day 2 Agenda: 14 February 2023 (Tuesday)		
		Venue: Crowne Plaza Riyadh RDC H	lotel & Convention, Riyadh, Saudi Arabia
		TECHNICAL SESSIONS (Cont) - Increasing the Opportunities of Digital Health
ITEMS 1	TIME 0900-0905	Opening Address for DAY 2	Mr. Guobiao Gao
1	0500-0505	Opening Address for DAT 2	Vice-Chair GHWP
			Secretary of Leading Party Group
			Center for Medical Device Evaluation, NMPA
			People's Republic of China
2	0905-0925	TECHNICAL SESSION V : Digital Health : Clinica Improving Healthcare Services (15mins) + Q&A (5mins)	al Applications [Industry, Hospitals and Government Perspectives] Ho Young Lee. M.D.
2	0905-0925	Improving HealthCare Services (15mins) + Q&A (5mins)	Professor. Nuclear Medicine,
			CIO. Digital Medicine & Office of eHealth Research & Business,
			Seoul National University Bundang Hospital, South Korea
3	0925-0945	Decentralized Clinical Trials (15mins) + Q&A (5mins)	To be confirmed
4	0945-1005	New Approaches to Post-market Clinical Follow-Ups (15mins) + Q&A (5mins)	To be confirmed
5	1005-1025	Real World Evidence - Using Real-world Data (15mins) + Q&A (5mins)	To be confirmed
1025-1055			TEA BREAK
			L SESSION VI : New Innovations
6	1055-1115	Post Market Surveillance (15mins) + Q&A (5mins)	To be confirmed
7	1115-1135	Regulatory Framework for Innovative Products (15mins) + Q&A (5mins) Innovations to accelerate	To be confirmed
		access to diagnostics	
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8	1135-1205	Panel : Fit-for-Purpose Change Management (25mins) + Q&A (5mins)	Moderator: Ms. Adelheid Schneider
			Panelists (TBC):
			a) Dr. Rama , HSA, Singapore
			b) Japan MHLW - TBC
			c) Mr. Ali Al-Dalaan, SFDA, Saudi Arabia
			d) Ms. Mariammah Krishnnasamy, Malaysia MOH
			e) USFDA - TBC
9	1205-1225	Biotech applications in Medical Device Industry and the Regulatory Concerns (15mins) + Q&A (5mins)	To be confirmed
1225-1350			LUNCH Capacity Building
10	1350-1410	GHWP Capacity Building Journey and Training Curriculum (15mins) + Q&A (5mins)	Ms. Quan Tran and Ms. Adelheid Schneider
11	1410-1440	Panel Discussion on GHWP Capacity Building (25mins) + Q&A (5mins)	Proposal - Moderator APACMed (TBC)
			Panelists-
			a) NMPA, China -TBC
			b) Prof John Lim
			c) MDA, Malaysia - TBC
			d) Kenya - TBC
12	1440-1500		▼- be see@mood
12	1440-1500	Updates on ISO14155 and ISO20916 (15mins) + Q&A (5mins)	To be confirmed
1500-1530			TEA BREAK
13	1530-1550	UDI (15mins) + Q&A (5mins)	Ms.Victoria Qu
14	1550-1610	IAF CertSearch (15mins) + Q&A (5mins)	Mr. Grant Ramaley and Mr. Nigel Johnston
15	1610-1630	Internet tools kit for medical devices (15mins) + Q&A (5mins)	Mr. Jeff Gren
16	1630-1635	Closing Remarks for Day 2 (5mins)	Dr. Lee, TC Co-Chair, GHWP
	1000-1000		
17	1635	Adjourn	
	1000		
		END OF D.	AY 2



		Day 2	Agenda: 15 February 2023 (Wednesday)
			a Riyadh RDC Hotel & Convention, Riyadh, Saudi Arabia
ITEMS	TIME		W Technical Committee (GHWP TC) Meeting
1	0900-1040	GHWP TC & WG Leaders Meeting with TC Advisors	Mr. Ali M. Al-Dalaan (proposed)
		(Closed Meeting)	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
	ļ		Senior Consultant, Founder of Yrsagacity Limited, People's Republic of China
1040-1110 2	1110-1115	Welcome Speech	TEA BREAK Mr. Ali M. AL-DALAAN
2	1110-1115	weicome speech	MF. Ali M. AL-DALAAN GHWP Chair
			GHWP Chair Vice Executive President, Medical Devices Sector, Saudi Food and Drug Authority, Kingdom of Saudi Arabia
			vice Executive President, Incutor Devices Sector, South POOD and Drug Authonity, Kingdom of Saudi Arabia
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3	1115-1130	Opening of TC Meeting	Mrs. Salbiah Yaakop (Chair)
		-Roll call -Adoption of Agenda	Director of Policy, International Affairs & Industry Facilitation Division Medical Device Authority, Ministry of Health - Malaysia
		-Adoption of Agenda -Adoption of 25th GHWP TC Meeting Minutes	meanar active Authority, Ministry of Hearth - 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 Series Consultant Founder of Verseeits Limited, Beaula's Beaultic of China
			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	1130-1230	Discussion of GHWP STRATEGIC PLANNING TOWARDS HARMONISATION OF MD REGULATORY	Mrs. Salbiah Yaakop (Chair)
		REQUIREMENT	Director of Policy, International Affairs & Industry Facilitation Division
			Medical Device Authority, Ministry of Health - Malaysia
			Dr. Jeong-Rim LEE (Co-Chair)
		- WG Chairs & Co-Chairs	Director, Cardiovascular Devices Division
		- TC Advisors	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
			Supported by IC Secretary Ms. Miang TANAKASEMSUB
			Head of Regulatory Affairs, Asia Pacific, Johnson & Johnson Vision
			Mr. Jack WONG
			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
1230-1345			LUNCH
1250-1545	•		
		26th GHWP Tech	nical Committee (GHWP TC) Meeting
5	1345-1500	26th GHWP Tech Working Group Updates and Next Steps:	nical Committee (GHWP TC) Meeting Work Group 1 (WG1)
5	1345-1500 (10mins +	Working Group Updates and Next Steps:	Work Group 1 (WG1) Chair - Dr. Seil Park, Ministry of Food and Drug Safety, Republic of Korea
5	1345-1500	Working Group Updates and Next Steps: Work Group 1 (WG1)	Work Group 1 (WG1)
5	1345-1500 (10mins + 5mins Q&A	Working Group Updates and Next Steps: Work Group 1 (WG1) - Pre-Market Submission and CSDT	Work Group 1 (WG1) Chair - Or, 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)
5	1345-1500 (10mins + 5mins Q&A	Working Group Updates and Next Steps: Work Group 1 (WG1) - Pre-Market Submission and CSDT Work Group 2 (WG2)	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
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5	1345-1500 (10mins + 5mins Q&A	Working Group Updates and Next Steps: Work Group 1 (WG1) - Pre-Market Submission and CSDT Work Group 2 (WG2) - Pre-market: IVDD	Work Group 1 (WG1) Chair - Or. 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. Men-wei TSAI, Food and Drug Administration, Chinese Taipei Co-Chair - Ir. Porf. Albert K.F. Poon, Hong Kong Polytechnic University, Hong Kong Work Group 3 (WG3) Chair - Mr. Abdullatif Al Watban, Saudi FDA, Kingdom of Saudi Arabia
5	1345-1500 (10mins + 5mins Q&A	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 1 (WG1) Chair - Or. Sell 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. Ford. Albert K.F. Poon, Hong Kong Polytechnic University, Hong Kong Work Group 3 (WG3)
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5	1345-1500 (10mins + 5mins Q&A	Working Group Updates and Next Steps: Work Group 1 (WG1) - Pre-Market Submission and CSDT Work Group 2 (WG2) - Pre-market: SUPD Work Group 4 (WG4) - Post-Market	Work Group 1 (WG1) Chair - Or, Sell 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. Ford. Albert K.F. Poon, Hong Kong Polytechnic University, Hong Kong Work Group 3 (WG3) Chair - Mr. Abullatif Al Watban, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Tony Yip, APAC Grifols (HK) Limited, Hong Kong Work Group 4 (WG4)
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	1345-1500 (10mins + 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)	Work Group 1 (WG1) Chair - Or. 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. Shar, Kord and Drug Administration, Chinese Taipei Co-Chair - Ir. Prof. Albert K.F. Poon, Hong Kong Polytechnic University, Hong Kong Work Group 3 (WG3) Chair - Mr. Abdullatif Al Watban, Saudi FDA, Kingdom of Saudi Arabia Co-Chair - Mr. Abdullatif Al Watban, Saudi FDA, Kingdom of Saudi Arabia Co-Chair - Mr. Tony Yip, APAC Grifols (HK) Limited, Hong Kong Work Group 4 (WG4) Chair - Mr. Tony Kitty MAO, GE Healthcare, Singapore Work Group 5 (WG5) Chair - Mr. Fikriansyah Bin Inran, Ministry of Health, Republic of Indonesia Co-Chair - Ms. Sumati Randeo, Danaher Corporation, India
1500-1530	1345-1500 (10mins + 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 4 (WG4) - Post-Market Work Group 5 (WG5) - Clinical Evidence for Performance and Safety	Work Group 1 (WG1) Chair - Or. Sell 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. Work Weit TSAI, Foon, Hong Kong Polytechnic University, Hong Kong Work Group 3 (WG3) Chair - Mr. Abdut K.F. Poon, Hong Kong Polytechnic University, Hong Kong Work Group 4 (WG4) Chair - Mr. Torkle Chow, Department of Health, Hong Kong Work Group 4 (WG4) Chair - Ms. Kitty MAO, GE Healthcare, Singapore Work Group 4 (WG5) Chair - Ms. Fitriansyah Bin Imran, Ministry of Health, Republic of Indonesia Co-chair - Ms. Sumati Randeo, Danaher Corporation, India
	1345-1500 (10mins + 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 4 (WG4) - Post-Market Work Group 5 (WG5) - Clinical Evidence for Performance and Safety Work Group 6 (WG6)	Work Group 1 (WG1) Chair - Or, 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 Talpei Co-chair - Ir. Prof. Albert K.F. Poon, Hong Kong Polytechnic University, Hong Kong Work Group 3 (WG3) Chair - Mr. Tony Yip, APAC Grifols (HK) Limited, Hong Kong Work Group 4 (WG4) Chair - Mr. Tony Yip, APAC Grifols (HK) Limited, Hong Kong 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 TEA BREAK Work Group 6 (WG6)
1500-1530	1345-1500 (10mins + 5mins Q&A each) 1530-1630 (10mins + 5mins Q&A	Working Group Updates and Next Steps: Work Group 1 (WG1) - Pre-Market Submission and CSDT Work Group 2 (WG2) - Pre-market: IVDD 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 1 (WG1) Chair - Or. Sell 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. Work wei TSAI, Foon, Hong Kong Polytechnic University, Hong Kong Co-Chair - I. Ford. Albert K.F. Poon, Hong Kong Polytechnic University, Hong Kong Work Group 3 (WG3) Chair - Mr. Abdullatif Al Watban, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Tory Yip, APAC Grifols (HK) Limited, Hong Kong Work Group 4 (WG4) Chair - Ms. Titty MAO, GE Healthcare, Singapore Work Group 4 (WG5) Chair - Ms. Fitriansyah Bin Imran, Ministry of Health, Republic of Indonesia Co-chair - Ms. Sumati Randeo, Danaher Corporation, India
1500-1530	1345-1500 (10mins + 5mins Q&A each) 1530-1630 (10mins +	Working Group Updates and Next Steps: Work Group 1 (WG1) - Pre-Market Submission and CSDT Work Group 2 (WG2) - Pre-market: IVDD 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)	Work Group 1 (WG1) Chair - Or. Sell 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 - In: Porl. Albert K.F. Poon, Hong Kong Polytechnic University, Hong Kong 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 Work Group 4 (WG4) Chair - Mr. Yorkie Chow, Department of Health, Hong Kong Co-chair - Mr. Sitty MAO, GE Healthcare, Singapore Work Group 5 (WG5) Chair - Mr. Fixiansyah Bin Imran, Ministry of Health, Republic of Indonesia Co-chair - Ms. Sumati Randeo, Danaher Corporation, India TEA BREAK 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
1500-1530	1345-1500 (10mins + 5mins Q&A each) 1530-1630 (10mins + 5mins Q&A	Working Group Updates and Next Steps: Work Group 1 (WG1) - Pre-Market Submission and CSDT Work Group 2 (WG2) - Pre-market: IVDD 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 1 (WG1) Chair - OF. Sell 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. Ford. Albert K.F. Poon, Hong Kong Polytechnic University, Hong Kong Work Group 3 (WG3) Chair - Mr. Challent K.F. Poon, Hong Kong Polytechnic University, Hong Kong Work Group 3 (WG3) Chair - Mr. Tony Yip, APAC Grifols (HK) Umited, Hong Kong Co-Chair - Mr. Tony Yip, APAC Grifols (HK) Umited, Hong Kong Co-Chair - Mr. Yorkie Chow, Department of Health, Hong Kong Co-Chair - Ms. Kitty MAO, GE Healthcare, Singapore Work Group 5 (WG5) Chair - Mr. Firiansyah Bin Inran, Ministry of Health, Republic of Indonesia Co-Chair - Ms. Sumati Randeo, Danaher Corporation, India <u>TEA BREAK</u> Work Group 6 (WG6) Chair - Mr. Abduliah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-Chair - Mr. Abduliah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-Chair - Mr. Abduliah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-Chair - Mr. Abduliah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-Chair - Mr. Sumati Randeo, Danaher Corporation, India
1500-1530	1345-1500 (10mins + 5mins Q&A each) 1530-1630 (10mins + 5mins Q&A	Working Group Updates and Next Steps: Work Group 1 (WG1) - Pre-Market Submission and CSDT Work Group 2 (WG2) - Pre-market: YDD Work Group 4 (WG4) - Post-Market Work Group 5 (WG5) - Clinical Evidence for Performance and Safety Work Group 5 (WG5) - Quality Management System: Audit & Assessment Work Group 7 (WG7) - Quality Management System: Operation & Implementation Work Group 8 (WG8)	Work Group 1 (WG1) Chair - Or. Sell 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 - In: Porl. Albert K.F. Poon, Hong Kong Polytechnic University, Hong Kong 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 Work Group 4 (WG4) Chair - Mr. Yorkie Chow, Department of Health, Hong Kong Co-chair - Mr. Sitty MAO, GE Healthcare, Singapore Work Group 5 (WG5) Chair - Mr. Fixiansyah Bin Imran, Ministry of Health, Republic of Indonesia Co-chair - Ms. Sumati Randeo, Danaher Corporation, India TEA BREAK 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
1500-1530	1345-1500 (10mins + 5mins Q&A each) 1530-1630 (10mins + 5mins Q&A	Workfing Group Updates and Next Steps: Work Group 1 (WG1) - Pre-Market Submission and CSDT Work Group 2 (WG2) - Pre-market: IVDD 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 - OF, Sell Park, Ministry of Food and Drug Safety, Republic of Korea Co-Chair - Ms. Mandy Myoung Shim Kim, Johnson & Johnson Medical, Republic of Korea Co-Chair - Ms. Mandy Myoung Shim Kim, Johnson & Johnson Medical, Republic of Korea Work Group 2 (WG2) Chair - Mr. Wen-wei TSAJ, Food and Drug Administration, Chinese Taipei Co-chair - Ir. Prof. Albert K.F. Poon, Hong Kong Polytechnic University, Hong Kong Work Group 3 (WG3) Chair - Mr. Tony Yip, APAC Grifols (HK) Limited, Hong Kong Work Group 4 (WG4) Chair - Mr. Tony Yip, APAC Grifols (HK) Limited, Hong Kong Co-chair - Ms. Kitty MAO, GE Healthcare, Singapore Work Group 5 (WG5) Chair - Mr. Tony Kie Chow, Department of Health, Hong Kong Co-chair - Ms. Kitty MAO, GE Healthcare, Singapore Work Group 5 (WG5) Chair - Mr. Tomati Randeo, Danaher Corporation, India TEA BREAK Work Group 6 (WG6) Chair - Mr. Abullah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. National Medical Products Administration, China Co-chair - Mr. National Medical Products Administration, China Co-chair - Mr. Elei Liew, Access-2-Healthcare, Singapore
1500-1530	1345-1500 (10mins + 5mins Q&A each) 1530-1630 (10mins + 5mins Q&A	Working Group Updates and Next Steps: Work Group 1 (WG1) - Pre-Market Submission and CSDT Work Group 2 (WG2) - Pre-market: TODD Work Group 4 (WG4) - Post-Market Work Group 5 (WG5) - Clinical Evidence for Performance and Safety Work Group 5 (WG5) - Quality Management System: Audit & Assessment Work Group 7 (WG7) - Quality Management System: Operation & Implementation Work Group 8 (WG8) - Standards	Work Group 1 (WG1) Chair - Or. Sell 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. York. Albert K.F. Poon, Hong Kong Polytechnic University, Hong Kong 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 Work Group 5 (WG4) Chair - Ms. Kitty MAO, GE Healthcare, Singapore Work Group 5 (WG5) Chair - Ms. Sumati Randeo, Danaher Corporation, India TEA BREAK Work Group 5 (WG6) Chair - Ms. Kuty MAO, Danaher Corporation, India Co-chair - Ms. Kuty MAO, Danaher Corporation, India Co-chair - Ms. Kuty MAO, National Medical Products Administration, China Co-chair - Mr. Yoncen Chee-Choong Lam, TUV SUD Product Service, Malaysia Work Group 7 (WG7) Chair - Mr. Xutional Medical Products Administration, China Co-chair - Mr. Sutonal Medical Pro
1500-1530	1345-1500 (10mins + 5mins Q&A each) 1530-1630 (10mins + 5mins Q&A	Working Group Updates and Next Steps: Work Group 1 (WG1) - Pre-Market Submission and CSDT Work Group 2 (WG2) - Pre-market: YDD Work Group 4 (WG4) - Post-Market Work Group 5 (WG5) - Clinical Evidence for Performance and Safety Work Group 5 (WG5) - Quality Management System: Audit & Assessment Work Group 7 (WG7) - Quality Management System: Operation & Implementation Work Group 8 (WG8)	Work Group 1 (WG1) Chair - OF, Sell Park, Ministry of Food and Drug Safety, Republic of Korea Co-Chair - Ms. Mandy Myoung Shim Kim, Johnson & Johnson Medical, Republic of Korea Co-Chair - Ms. Mandy Myoung Shim Kim, Johnson & Johnson Medical, Republic of Korea Work Group 2 (WG2) Chair - Mr. Wen-wei TSAJ, Food and Drug Administration, Chinese Taipei Co-chair - Ir. Prof. Albert K.F. Poon, Hong Kong Polytechnic University, Hong Kong Work Group 3 (WG3) Chair - Mr. Tony Yip, APAC Grifols (HK) Limited, Hong Kong Work Group 4 (WG4) Chair - Mr. Tony Yip, APAC Grifols (HK) Limited, Hong Kong Co-chair - Ms. Kitty MAO, GE Healthcare, Singapore Work Group 5 (WG5) Chair - Mr. Tony Kie Chow, Department of Health, Hong Kong Co-chair - Ms. Kitty MAO, GE Healthcare, Singapore Work Group 5 (WG5) Chair - Mr. Tomati Randeo, Danaher Corporation, India TEA BREAK Work Group 6 (WG6) Chair - Mr. Abullah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. National Medical Products Administration, China Co-chair - Mr. National Medical Products Administration, China Co-chair - Mr. Elei Liew, Access-2-Healthcare, Singapore
1500-1530	1345-1500 (10mins + 5mins Q&A each) 1530-1630 (10mins + 5mins Q&A	Work Group 1 (WG1) - Pre-Market Submission and CSDT Work Group 2 (WG2) - Pre-market: IVDD Work Group 4 (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 5 (WG6) - Quality Management System: Audit & Assessment Work Group 7 (WG7) - Quality Management System: Operation & Implementation Work Group 8 (WG8) - Standards Work Group 9 (WG9)	Work Group 1 (WG1) Chair - OF. Sell 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. York - Albert K.F. Poon, Hong Kong Polytechnic University, Hong Kong Work Group 3 (WG3) Chair - Mr. Chalbert K.F. Poon, Hong Kong Polytechnic University, Hong Kong Work Group 3 (WG3) Chair - Mr. Abdullatif Al Watban, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Tony Yip, APAC Grifols (HK) Umited, Hong Kong Co-chair - Mr. Yorkie Chow, Department of Health, Hong Kong Co-chair - Mr. Yorkie Chow, Department of Health, Hong Kong Co-chair - Mr. Kitty MAO, GE Healthcare, Singapore Work Group 5 (WG5) Chair - Mr. Sumati Randeo, Danaher Corporation, India <u>TEA BREAK</u> Work Group 6 (WG6) Chair - Mr. Abdullah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. National Medical Products Administration, China Co-chair - Mr. Sutional Medical Products Administration, China Co-chair - Mr. Sutional Medical Products Administration, China Co-chair - Mr. Sutional Medical Products Administration, China Co-chair - Mr. Susional Yaakoop, Ministry of Health, Malaysia Co-chair - Mr. Tory Licey, Commissioning Agents International, Malaysia
1500-1530	1345-1500 (10mins + 5mins Q&A each) 1530-1630 (10mins + 5mins Q&A	Work Group 1 (WG1) - Pre-Market Submission and CSDT Work Group 2 (WG2) - Pre-market: IVDD Work Group 4 (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 5 (WG6) - Quality Management System: Audit & Assessment Work Group 7 (WG7) - Quality Management System: Operation & Implementation Work Group 8 (WG8) - Standards Work Group 9 (WG9)	Work Group 1 (WG1) Chair - Or. Sell 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. York Jabert K Poon, Hong Kong Polytechnic University, Hong Kong Work Group 3 (WG3) Chair - Mr. Abdullatif Al Watban, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Tory Yip, APAC Grifols (HK) Limited, Hong Kong Work Group 4 (WG4) Chair - Ms. Kitty MAO, GE Healthcare, Singapore Work Group 5 (WG5) Chair - Ms. Kitty MAO, GE Healthcare, Singapore Work Group 5 (WG5) Chair - Ms. Skitty MAO, GE Healthcare, Singapore Work Group 5 (WG5) Chair - Ms. Shuthal Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Ms. Nabullah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Yorkie Chow, Danaher Corporation, India TEA BREAK Work Group 7 (WG5) Chair - Mr. Shudilah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Vincent Chee-Choong Lam, TUV SUD Product Service, Malaysia Work Group 7 (WG5) Chair - Mr. Shudilah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Shudilah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Shudilah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Shudilah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Shudilah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Shudilah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Shudilah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Subilah Yakop, Ministry of Health, Malaysia Co-chair - Mr. Salbaih Yakop, Ministry of Health, Malaysia Co-chair - Mr. Salbaih Yakop, Ministry of Health, Malaysia Work Group 9 (WG9)
1500-1530	1345-1500 (10mins + 5mins Q&A each) 1530-1630 (10mins + 5mins Q&A	Work Group 1 (WG1) - Pre-Market Submission and CSDT Work Group 2 (WG2) - Pre-market: IVDD Work Group 4 (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 5 (WG6) - Quality Management System: Audit & Assessment Work Group 7 (WG7) - Quality Management System: Operation & Implementation Work Group 8 (WG8) - Standards Work Group 9 (WG9)	Work Group 1 (WG1) Chair - OF. Sell 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. York - Albert K.F. Poon, Hong Kong Polytechnic University, Hong Kong Work Group 3 (WG3) Chair - Mr. Chalbert K.F. Poon, Hong Kong Polytechnic University, Hong Kong Work Group 3 (WG3) Chair - Mr. Abdullatif Al Watban, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Tony Yip, APAC Grifols (HK) Umited, Hong Kong Co-chair - Mr. Yorkie Chow, Department of Health, Hong Kong Co-chair - Mr. Yorkie Chow, Department of Health, Hong Kong Co-chair - Mr. Kitty MAO, GE Healthcare, Singapore Work Group 5 (WG5) Chair - Mr. Sumati Randeo, Danaher Corporation, India <u>TEA BREAK</u> Work Group 6 (WG6) Chair - Mr. Abdullah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. National Medical Products Administration, China Co-chair - Mr. Sutional Medical Products Administration, China Co-chair - Mr. Sutional Medical Products Administration, China Co-chair - Mr. Sutional Medical Products Administration, China Co-chair - Mr. Susional Yaakoop, Ministry of Health, Malaysia Co-chair - Mr. Tory Licey, Commissioning Agents International, Malaysia
<u>1500-1530</u> 6	1345-1500 (10mins + Smins Q&A each) 1530-1630 (10mins + Smins Q&A each)	Working Group Updates and Next Steps: Work Group 1 (WG1) - Pre-Market Submission and CSDT Work Group 2 (WG3) - Pre-market: IODD Work Group 4 (WG4) - Post-Market Work Group 5 (WG5) - Clinical Evidence for Performance and Safety Work Group 5 (WG5) - Quality Management System: Audit & Assessment Work Group 7 (WG7) - Quality Management System: Operation & Implementation Work Group 8 (WG8) - Standards Work Group 9 (WG9) - JUDI & Nomenclature	Work Group 1 (WG1) Chair - Or. Sell 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. York - Albert K.F. Poon, Hong Kong Polytechnic University, Hong Kong Work Group 3 (WG3) Chair - Mr. Challent K.F. Poon, Hong Kong Polytechnic University, Hong Kong 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 Work Group 4 (WG4) Chair - Mr. Yorkic Chow, Department of Health, Hong Kong Co-Chair - Ms. Kitty MAQ, GE Healthcare, Singapore Work Group 5 (WG5) Chair - Mr. Sumati Randeo, Danaher Corporation, India <u>TEA BREAK</u> Work Group F (WG6) Chair - Mr. Notional Medical Products Administration, China Co-chair - Mr. Sutional Medical Products Administration, China Co-chair - Mr. Sutional Medical Products Administration, China Co-chair - Mr. Sutional Medical Products Administration, China Co-chair - Mr. Tony Low, Commissioning Agents International, Malaysia Work Group 9 (WG8) Chair - Mr. Sutional Medical Products Administration, China Co-chair - Mr. Tony Low, Commissioning Agents International, Malaysia Work Group 9 (WG8)
1500-1530	1345-1500 (10mins + 5mins Q&A each) 1530-1630 (10mins + 5mins Q&A each)	Work Group 1 (WG1) - Pre-Market Submission and CSDT Work Group 2 (WG2) - Pre-market: IVDD Work Group 4 (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 5 (WG6) - Quality Management System: Audit & Assessment Work Group 7 (WG7) - Quality Management System: Operation & Implementation Work Group 8 (WG8) - Standards Work Group 9 (WG9)	Work Group 1 (WG1) Chair - Or. Sell 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. Ford. Albert K.F. Poon, Hong Kong Polytechnic University, Hong Kong 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 Work Group 4 (WG4) Chair - Mr. Yorkie Chow, Department of Health, Hong Kong Co-Chair - Ms. Kitty MAO, GE Healthcare, Singapore Work Group 5 (WG5) Chair - Mr. Sumati Randeo, Danaher Corporation, India TEA BREAK Work Group F (WG6) Chair - Mr. National Medical Products Administration, China Co-chair - Mr. Sutional Medical Products Administration, China Co-chair - Mr. Sutional Medical Products Administration, China Co-chair - Mr. Sutional Medical Products Administration, China
1500-1530 6 7	1345-1500 (10mins + 5mins Q&A each) 1530-1630 (10mins + 5mins Q&A each) 1630-1715 (3mins 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 4 (WG3) - Pre-market: Software as a Medical Device Work Group 4 (WG4) - Post-Market Work Group 5 (WG5) - Quality Management System: Audit & Assessment Work Group 7 (WG7) - Quality Management System: Operation & Implementation Work Group 9 (WG8) - Standards Work Group 9 (WG8) - Standards Work Group 9 (WG9) - UDI & Nomendature Introduction by Candidates for Election of GHWPTC Chair & Co-chairs, WGs Chairs & Co-chairs	Work Group 1 (WG1) Chair - Ors. Sell Park, Ministry of Food and Drug Safety, Republic of Korea Co-Chair - Ms. Mandy Myoung Shim Kim, Johnson & Johnson Medical, Republic of Korea Co-Chair - Ms. Mandy Myoung Shim Kim, Johnson & Johnson Medical, Republic of Korea Work Group 2 (WG2) Chair - Mr. York. Jabert K Poon, Hong Kong Polytechnic University, Hong Kong Co-chair - Mr. Abdullatif Al Watban, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Tony Yip, APAC Grifols (HK) Limited, Hong Kong Work Group 3 (WG3) Chair - Mr. Tony Yip, APAC Grifols (HK) Limited, Hong Kong Co-chair - Mr. Tony Yip, APAC Grifols (HK) Limited, Hong Kong Co-chair - Ms. Kitty MAO, GE Healthcare, Singapore Work Group 5 (WG5) Chair - Mr. Shirt, Shirt of Health, Hong Kong Co-chair - Ms. Sunati Randeo, Danaher Corporation, India TEA BREAK Work Group 5 (WG5) Chair - Mr. Nabullah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Nabullah 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 - Mr. Shullah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Shullah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Shullah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Shullah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Shullah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Shullah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Shullah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Shullah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Shullah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Shullah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Shullah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Shullah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Shullah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co-chair - Mr. Shullah Al Rasheed, Saudi FDA, Kingdom of Saudi Arabia Co
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			da: 16 February 2023 (Thursday)
ITEMS	TIME	venue: crowne Piaza Riyao	h RDC Hotel & Convention, Riyadh, Saudi Arabia
1	0855-0900	Announcement by MC (SFDA) (5mins)	Master of Ceremony (MC) by Saudi FDA Announcement
2	0900-0930	Opening Ceremony (30mins)	Welcome Address-
_		- Welcome Address (7mins)	Dr. Hisham bin Saad Aljadhey
		- Opening address (7mins)	Chief Executive Officer, Saudi Food and Drug Authority
		- Group Photo (16mins)	Kingdom of Saudi Arabia
			Opening Address
			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	Mr. Ali M. AL-DALAAN
		- Roll Call (8mins)	GHWP Chair
		- Adoption of Agenda (1min)	Vice Executive President, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia
		- Adoption of 25th GHWP Annual Meeting Minutes (1min)	The Executive President, include Denies Sector, Stadi PSA, Angabin O Stadi Plasta
		Adoption of 25th of the Annual Meeting minutes (2000)	Supported by
			Ir. Bryan SO
			GHWP Executive Secretary General
			CYH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong
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4	0940-1010	GHWP Status Reports	Mr. Ali M. AL-DALAAN
		- GHWP Overall Status Report (10mins + 5mins Q&A)	GHWP Chair
			Vice Executive President, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia
			Mrs. Salbiah Yaakop
	1	- GHWPTC Status Report (10mins + 5mins Q&A)	GHWPTC Chair
	1	Sinti is status report (tornins + sinins Quey	Director of Policy, International Affairs & Industry Facilitation Division
			Medical Device Authority, Ministry of Health - Malaysia
1010-1040	0		TEA BREAK
5	1040-1055	IMDRF Status Updates by IMDRF Chair (10mins+5mins)	To be confirmed
6	1055-1155	International Organizations & Harmonization Efforts (10mins+5mins Q&A each)	
		- APEC	- APEC (TBC)
	1	- APEC	- ASEAN (TBC)
		- EU Commission (MDR)	
			- EU Commission (TBC)
		- US FDA (Medical Device Single Audit Program (MDSAP))	- US FDA (TBC)
7	1155-1255	GHWP Liaison Member Updates (5mins + 5mins Q&A each)	- APACMed (TBC)
1	1100-1200		
		- APACMed Update	- DITTA (TBC)
		- DITTA Update	- GS1 (TBC)
		- GS1 Update	- GMDN Agency (TBC)
		- GMDN Agency Update	- GMTA (TBC)
	1	- GMTA Update	- IACRC (TBC)
		- IACRC Update	
4355 4 440			
1255-1410		Country/Region Updates (5mins+5mins Q&A each)	LUNCH To be confirmed (All)
8	1410-1530		
		- China	- China NMPA
		- Philippines	- Philippines DOH
		- Saudi Arabia	- Saudi FDA
		- South Korea	- South Korea MFDS
		- Thai	- Thai FDA
		- USA	- US FDA
		- Japan (new member to be endorsed)	- Japan MHLW
		- Australia	- Australia TGA
1530-1600			TEA BREAK
9	1600-1615	Introduction by Candidates for Election of GHWP Chair and Vice-chairs (5mins each)	To be confirmed
10	1616 1620	Resolution and Endorsement (15mins)	Mr. Ali M. AL-DALAAN
10	1615-1630	1. Resolutions	GHWP Chair
		- Amendment 8 to House Rules on SAB	Vice Executive President, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia
		- Amendment & to house rules on SAB	Vice Executive President, Intellical Devices Sector, Sadur PDA, Kingdom of Sadur Arabia
		2. Endorsement of White Paper on	Supported by
		- Capacity Building Training Curriculum for Regulatory Authorities	Ir. Bryan SO
			GHWP Executive Secretary General
		3. Endorsement of Guidance Documents from WG	CYH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong
		- TBC	
	1	4. Endorsement of New Member(s)	
11	1630-1640	Short Speech by New Member(s) (5mins x 2)	To be confirmed
			Mr. Ali M. AL-DALAAN
12	1640-1705	Election and Endorsement of GHWP Office Bearers (25mins)	Mr. Ali M. AL-DALAAN GHWP Chair
	1	- Briefing on Election and Endorsement Procedures	
		Election of CHIMD Chair and Vice Chairs	
		- Election of GHWP Chair and Vice Chairs	Vice Executive President, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia
		- Election of GHWPTC Chair and Co-Chairs	Vice Executive President, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia
			Vice Executive President, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia Supported by
		- Election of GHWPTC Chair and Co-Chairs	Vice Executive President, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia Supported by Ir. Bryan SO
		- Election of GHWPTC Chair and Co-Chairs	Vice Executive President, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia Supported by Ir. Bryan SO GHWP Executive Secretary General
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	1705-1715	- Election of GHWPTC Chair and Co-Chairs - Election of Working Groups Chairs and Co-Chairs	Vice Executive President, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia Supported by Ir. Bryan SO GHWP Executive Secretary General CYH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong
13	1705-1715	- Election of GHWPTC Chair and Co-Chairs	Vice Executive President, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia Supported by Ir. Bryan SO GHWP Executive Secretary General
13		- Election of GHWPTC Chair and Co-Chairs - Election of Working Groups Chairs and Co-Chairs Speech by Newly Elected GHWP Chair (10mins - including any translation)	Vice Executive President, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia Supported by Ir. Bryan SO GHWP Executive Secretary General CYH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong To be confirmed
	1705-1715 1715-1735	- Election of GHWPTC Chair and Co-Chairs - Election of Working Groups Chairs and Co-Chairs	Vice Executive President, Medical Devices Sector, Saudi FDA, Kingdom of Saudi Arabia Supported by Ir. Bryan SO GHWP Executive Secretary General CYH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong To be confirmed Mr. Ali M. AL-DALAAN
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