

الهيئة الحامة للضخاء والحواء Saudi Food & Drug Authority

The 26<sup>th</sup> GHWP Annual Meeting Program <sub>Biyadh, Saudi Arabia</sub> 13-16 February 2023

## DRAFT Program (Version 9b public)

			Agenda: 13 February 2023 (Monday) Riyadh RDC Hotel & Convention, Riyadh, Saudi Arabia
	815-0900	Registration	kiyaan KDC Hotel & Convention, kiyaan, saual Arabia
ITEMS 1	TIME 0900-0910	Welcome Address (10mins)	Dr. Hisham bin Saad Aljadhey
-	0,00 0,10		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
4	0935-1000	Panel Discussion: GHWP Strategic Framework (20mins) + Q&A (5mins)	Singapore Moderator: Prof John Lim, Executive Director, Centre of Regulatory Excellence, Duke-NUS Medical School,
~	0555 1000		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
5	1000-1005	Grwe Secretariat Announcement (Smins)	GHWP Executive Secretary General
			CYH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong Hong Kong SAR, China
			Tong Kong Skit, cilina
1005-1040		тесника	TEA BREAK SESSION - Regulatory Agility and Reliance
6	1040-1100	Regulatory Agility (15mins) + Q&A (5mins)	Ms. Yasha Huang
	1100 4	Parafile of Populatons Dellor (45-1-1-) - 00.5 (5-1-1-)	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	Moderator : Ms. Miang Tanakasemsub
		(25mins) + Q&A (5mins)	Panelists: a) Dr. Rama Sethuraman, Director, Medical Devices, HSA, Singapore
			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 SESSIO	INS - Increasing the Opportunities of Digital Health al Health : Innovation and Technology [Industry Perspective]
9	1150-1210	Digital Therapeutics - "Industry Perspective" (15mins) + Q&A (5mins)	Dr. Sean (Seong-ji) Kang, MD. MPH.
		[ONLINE]	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 al Health : Regulatory Approaches [Government perspectives]
		TECHNICAL SESSION II : Digit	
12	1400-1415	TECHNICAL SESSION II : Digit Digital Health Regulation Development in China (15mins) [RECORD]	Dr. Guo Zhaojun. MD.
12			Dr. Guo Zhaojun. MD. Director, MD Evaluation Department II, Center for Medical Device Evaluation, NMPA, People's Republic of China
12		Digital Health Regulation Development in China (15mins) [RECORD] Digital Therapeutics - "Exploring Regulatory Pathways of Digital	Director, MD Evaluation Department II, Center for Medical Device Evaluation,
	1400-1415	Digital Health Regulation Development in China (15mins) [RECORD]	Director, MD Evaluation Department II, Center for Medical Device Evaluation, NMPA, People's Republic of China Dr. Chung Keun Lee, Ph.D. Assistant Director,
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	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 1	TIME 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) [ONUNE]	Dr. Ho Young Lee. M.D. Professor. Nuclear Medicine, Clo. 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 Directory, 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
6	1100-1120	TECH Post Market Surveillance (15mins) + Q&A (5mins)	NICAL SESSION VI : New Innovations Mr. Mohd Zul hisham Junaidi. Post Market & Enforcement Division. Medical Device Authority. Malavsia
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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
		Panel : Fit-for-Purpose Change Management (25mins) + Q&A (5mins)	Panelists: a) Dr. Rama Schuraman, 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-Dalan, Vice Executive Prevident, Medical Devices Sector, SFDA, Kingdom of Saudi Arabia d) Ms. Marianmah 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)	
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. Sabiah Yaakop, Director of Policy, International Affairs & Industry Facilitation Division, Medical Device Authority, Ministry of Health, Malaysia c) Dr. Razan Asally, Head of Medical Devices Statuation 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 14	1545-1605	IAF CertSearch (15mins) + Q&A (5mins)	TEA BREAK 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 (Smins)	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 C	F DAY 2
	END OF DAY 2		





		Day 3 A	sgenda: 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)	Mr. Ali M. Al-Dalaan (proposed)
		(Closed-Door 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
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			Er. Alfred KWEK GMWP 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 2	1115-1120	Welcome Speech (5mins)	TEA BREAK 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)	Mrs. Salbiah Yaakop (Chair)
		-Roll call -Adoption of Agenda	Director of Policy, International Affairs & Industry Facilitation Division
		-Adoption of Agenda -Adoption of 25th GHWP TC Meeting Minutes	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 Pacífic, 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. Adeiheid Schneider Head of Quality and Regulatory Affairs Asia Pacific Roche Diagnostics Asia Pacific, Singapore
4	1135 - 1245	Working Group Updates and Next Steps:	Work Group 1 (WG1)
	(5mins + 5mins Q&A each)	Work Group 1 (WG1) - Pre-Market Submission and CSDT	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) - Pre-market: IVDD	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) - Pre-market: Software as a Medical Device	Work Group 3 (WG3) Chair - Mr. Abdullatif Al Watban, Saudi FDA, Kingdom of Saudi Arabia
		Work Group 4 (WG4)	Co-chair - Mr. Tony Yip, APAC Grifols (HK) Limited, Hong Kong SAR, China
		- Post-Market	Work Group 4 (WG4)
		Work Group 5 (WG5) - Clinical Evidence for Performance and Safety	Chair - Mr. Yorkie Chow, Department of Health, Hong Kong SAR, China Co-chair - Ms. Kitty MAO, GE Healthcare, Singapore
			Work Group 5 (WG5)
		Work Group 6 (WG6) - Quality Management System: Audit & Assessment	Chair - Mr. Fikriansyah Bin Imran, Ministry of Health, Republic of Indonesia Co-chair - Ms. Sumati Randeo, Danaher Corporation, India
		Work Group 7 (WG7) - Quality Management System: Operation & Implementation	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
5	1400 -1420	26th GHWF Working Group Updates and Next Steps (Cont'):	P Technical Committee (GHWP TC) Meeting
	(5mins + 5mins Q&A each)		Work Group 8 (WG8)
		Work Group 8 (WG8) - Standards	Chair - Mrs. Salbiah Yaakop, Ministry of Health, Malaysia Co-chair - Mr. Tony Low, Commissioning Agents International, Malaysia
		Work Group 9 (WG9) - UDI & Nomenclature	Work Group 9 (WG9) Chair - Ms. Jun Li, National Medical Products Administration, China
6	1420-1430	TC Advisors Summary Report (10mins)	Co-chair - Ms. Victoria Qu, Global Strategic Regulatory Abbott, China Representatives of TC Advisory Panel
7	1420-1430	Closing Remarks for Day 3 (5mins)	Representatives of IC Advisory Panel Mr. Alfred KWEK (GHWPTC Co-Chair)
			Mr. Altrea KWEK (GHWPI / C.OChair) Director, Public Affairs Edwards Lifesciences Asia Pte. Ltd Lao PDR
8	1435	Adjourn END C	DF DAY 3
1435-1515	i		TEA BREAK
			nt Committee Meeting (CLOSED-DOOR) [TBC] 5-1645)
		GALA	DINNER
		(Dinner st	arts at 1900)





	Day 4 Agenda: 16 February 2023 (Thursday)	
TIME	26 <sup>th</sup> GHWP Annual Meeting (Main Meeting)	
0855-0900	Announcement by MC (SFDA) (5mins)	Master of Ceremony (MC) by Saudi FDA Announcement
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-
		Mr. Ali M. AL-DALAAN
		GHWP Chair
		Vice Executive President, Medical Devices Sector
		Saudi Food and Drug Authority, Kingdom of Saudi Arabia
0930-0940	Main Meeting	Mr. Ali M. AL-DALAAN
	- Roll Call (8mins)	GHWP Chair
	- Adoption of Agenda (1min)	Vice Executive President, Medical Devices Sector
	- Adoption of 25th GHWP Annual Meeting Minutes (1min)	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
	0855-0900 0900-0930	Title         path           0955-900         Opening Ceremony (30mins)           0900-0930         Opening Ceremony (30mins)           - Opening address (7mins)         - Opening address (7mins)           - Group Photo (16mins)         - Group Photo (16mins)           0930-0940         Main Meeting           - Roll (all (8mins)           - Adoption of Agenda (1min)

4			
	0940-1010	GHWP Status Reports - GHWP Overall 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
		- GHWPTC Status Report (10mins + 5mins Q&A)	Mrs. Salbiah Yaakop GHWPTC Chair Director of Policy, International Affairs & Industry Facilitation Division Medical Device Authority, Ministry of Health , Malaysia
<u>1010-1040</u> 5	1040-1055	IMDRF Status Updates (10mins+Smins )	TEA BREAK Dr. Andrzej Rys MIDRF 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. Salbah Vaako, Director O 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. Denit 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 Ligis Gonzalez, Executive Secretary, Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector (IACRC)
8	1225-1245	Country/Region Updates (Smins+Smins 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	4400	Country Declary Hadress (Country Francis	LUNCH / PRAYER TIME
9	1400-1500	Country/Region Updates (Cont') (Smins+Smins 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 (PMOA), Japan d) Eng. Abdulha 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 1) 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
		Resolution and Endorsement (15mins)	
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, WG28WG3 - Categorisation of Changes to a Registered Medical Device - WG8 - Medical Gas System - Essentia Principles of Safety and Performance	Mr. Ali M. AL-DALAAN GMWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia Ir. Bryan SO GMWP Executive Secretary General CYH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong Hong Kong SAR, China
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10		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)     - WG3. Mc28WG3 - Categorisation of Changes to a Registered Medical Device     - WG4. Mc28WG3 - Categorisation of Changes to a Registered Medical Device     - Standards for Demonstraing Compliance     S. Endorsement of New Member     - Japan	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 Mr. TAKAHATA Masahiro Director, Office of Regererative Medicines Products Evaluation Ministry of Health, Jabour and Weffare (MHUW)
10	1545-1550 1550-1645		GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia Ir. Bryan SO GHWP Executive Secretary General (VH Technology Center for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong Hong Kong SAR, China Mr. TAKAHATA Masahiro Director, Office of Regnerative Medicines Products Evaluation Ministry of Health, Labour and Welfare (MHLW) Japan Mr. Ali M. AL-DALAN GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia Ir. Bryan SO GHWP Chair Crim Evanology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong Kong Hong Kong SAR, China
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10	1545-1550 1550-1645 1645-1655	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  Short Speech by New Member (Smins)  Election and Endorsement Procedures  - Election of GHWP Chair and Vice Chairs  - Election of GHWP Chair and Vice Chairs  - Election of WHWP Chair and Vice Chairs  Speech by GHWP Chair-Elect (10mins - including any translation)	GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia Ir. Bryan SO GHWP Executive Secretary General CVH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong Hong Kong SAR, China Mr. TAKAHATA Masahiro Director, Office of Regnerative Medicines Products Evaluation Ministry of Health, Labour and Welfare (MHLW) Japan Mr. All M.A.LOALAN GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia Ir. Bryan SO GHWP Executive Secretary General CVH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong Hong Kong SAR, China GHWP Chair-Elect Mr. All M.A.LOALAN GHWP Chair-Elect Mr. All M.A.LOALAN
10 10 11 12 13 14 15 16	1545-1550 1550-1645 1645-1655 1655-1715 1715-1720 1720-1725	1. Resolutions  - Amendment B 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  - WG3, Medical Gas System – Essential Principles of Safety and Performance  - Standards for Demonstrating Compliance  S. Endorsement of New Member  - Japan  Short Speech by New Member (Smins)  Election and Endorsement Procedures  - Election of GHWP Office Bearers (S5mins) [Including Iminute self-introduction by each condidate before election and endorsement (Z5mins)] - Election of GHWP Chair and Vice Chairs  - Election of GHWP Chair and Vice Chairs  - Election of GHWP Chairs and Co-Chairs  Speech by GHWP Chair-Elect (10mins - including any translation)  Presentation of Certificates and Recognition Award on Stage (20mins)  Announcement of next GHWP Annual Meeting Host & Short Speech (5mins)  Closing Remarks (5mins)	GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia Ir. Bryan SO GHWP Executive Secretary General (VH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong Hong Kong SAR, China Mr. TAKAHATA Masahiro Director, Office of Regnerative Medicines Products Evaluation Ministry of Health, Labour and Welfare (MHLW) 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 Exist Vice Executive Secretary General CYH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong GHWP Chair GHWP Chair-Elect Mr. Ali M. AL-DALAAN GHWP Chair GHWP Chair Liett Mr. Ali M. AL-DALAAN GHWP Chair Liett Mr. Ali M. AL-DALAAN GHWP Chair Elect Mr. Ali M. AL-DALAAN GHWP Chair Elect Mr. Ali M. AL-DALAAN GHWP Chair Elect
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10 10 11 11 12 12 14 14 15	1545-1550 1550-1645 1645-1655 1655-1715 1715-1720 1720-1725	1. Resolutions     - Amendment B to the Global Harmonization Working Party House Rules on GHWP Strategic Advisory Board (SAB)      2. Endorsement of Strategic Framework     - Global Harmonization Working Party Stategic 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     - WG3, Medical Gas System – Essential Principles of Safety and Performance     - Standards for Demonstraing Compliance     S. Endorsement of New Member     - Japan     Short Speech by New Member (Smins)     [Including Iminute self-introduction by each condidate before election and     endorsement (ZSmins)]     [Including Iminute self-introduction by each condidate before election and     endorsement (ZSmins)]     Election of GHWP Onlice Bearers (SSmins)     [Including Iminute self-introduction by each condidate before election and     endorsement (ZSmins)]     Foreiting on Election and Andorsement Procedures     - Election of GHWP Chair and Vice Chairs     Speech by GHWP Chair-Elect (10mins - including any translation)     Presentation of Certificates and Recognition Award on Stage (20mins)     Announcement of next GHWP Annual Meeting Host & Short Speech (Smins)     Closing Remarks (Smins)	GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia Ir. Bryan SO GHWP Executive Secretary General (VH Technology Centre for Innovative Medicine, Faculty of Medicine, The Chinese University of Hong Kong Hong Kong SAR, China Mr. TAKAHATA Masahiro Director, Office of Regnerative Medicines Products Evaluation Ministry of Health, Labour and Weffare (MHLW) 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 GHWP Chair-Elect Mr. Ali M. AL-DALAAN GHWP Chair-Cleck Mr. Ali M. AL-DALAAN GHWP Chair-Elect Mr. Ali M. AL-DALAAN GHWP Chair-Cleck 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 Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia and GHWP Chair Vice Executive President, Medical Devices Sector Saudi Food and Drug Authority, Kingdom of Saudi Arabia