Global Harmonization Working Party
Towards Medical Device Harmonization

Day 1 Agenda: 27 Nov 2023 Venue: Shanghai International Convention Center, Shanghai, China				
GHWP Capacity Building on opportunities and challenges of innovative medical devices regulations				
Moderator: EunHee Cho (GHWP Cochair, RA Director, Abbott Medical Korea, Republic of Korea)				
ITEMS	TIME			
1	0900-0905	**Opening Speech**	XU Jinghe GHWP Chair Deputy Commissioner NMPA, People's Republic of China	
2	0905-0920	**GHWP Strategic Framework - Keeping in pace with Innovation**	Quan Tran GHWP Capacity Building Lead Vice President, RAQA, Baxter, APAC	
New cutting-edge technologies medical devices				
3	0920-0935	SaMD Industry Showcase	1) Asmaa Awad Regulatory Policy Lead, EEMEA, Roche Diagnostics 2) XU Qiang Software R&D Director, GE Healthcare 3) DAI Weiwei IT Solution Business Director, Mindray Biomedical Electronics	
4	0935-0945	Regulatory Progress of Digital Health in CHINA	YANG Pengfei Director, Division of Evaluation I, Center for Medical Device Evaluation (CMDE), NMPA, People's Republic of China	
5	0945-1000	Artificial Intelligence Medical Device - Industry Showcase	1) Selwa Al-Hazzaa, MD, FRCS, MMM CEO and Founder at SDM, Kingdom of Saudi Arabia 2) GAO Yaozong PhD, Chief Scientist, United Imaging Healthcare	
6	1000-1015	Artificial Intelligence Medical Device -Regulatory Practice	1) Hala Alhodaib Senior Chief Scientific Evaluation Expert Medical Devices Sector, SFDA, Kingdom of Saudi Arabia 2) Young Woo BAE Assistant Director, MFDS	
1015-1040		**TEA BREAK**		
7	1040-1055	Robotic - Industry Showcase (Medical devices)	1）LIU Wenbo CEO, Sino Vision Medtech 2）Christopher HACK Sr. Director, Digital Robotics Global Policy, Johnson and Johnson Medtech	(VIDEO)
8	1055-1105	Medical Robotic Industry Development and Best Practice in Supervision	GUO Shuting Deputy Commissioner, Shanghai MPA, People's Republic of China	
9	1105-1115	3D Printing Devices - Industry Showcase	LU Ming Wego Holding	
10	1115-1125	Global personalised devices regulatory development	Belinda Dowsett Associate Director, Medical Devices / IVD, PharmaLex Pty Ltd (Sydney) Australia	(VIDEO)
11	1125-1135	NGS & Mass Spectroscopy - Industry Showcase	Brad Spring Global Head of Regulatory Policy & Intelligence Roche Diagnostics Corporation	
12	1135-1150	Medical Device Sterilisation: the need for industrial alternatives to Ethylene Oxide	1) Lambert Byron Research Fellow, Abbott Medical 2) Miguel Ávila Vice President, Global Quality, Regulatory, Medical and Clinical Affairs, Cordis U.S. Corp	
13	1150-1210	Panel Discussion - Innovative technology and regulatory challenges	Moderator: Miang Tanakasemsub Panellists: 1) LIN Muqing, Mindray Biomedical Electronics 2) Brad Spring Global Head of Regulatory Policy & Intelligence Roche Diagnostics Corporation 3) Lambert Byron Research Fellow, Abbott Medical 4) Miguel Ávila Vice President, Global Quality, Regulatory, Medical and Clinical Affairs, Cordis U.S. Corp	
1210-1330		**LUNCH**		
Regulatory pathways for innovative medical devices				
14	1330-1340	Introduction of Innovative Medical Devices Review in CHINA	JIA Jianxiong Director of Integrated Affairs Division, Center for Medical Device Evaluation (CMDE), NMPA, People's Republic of China	
15	1340-1350	Regulatory pathways for innovative medical devices PMDA (Sakigake)	MIYASAKA Tomoyuki Deputy Director Medical Devices Evaluation Division, MHLW, Japan	
16	1350-1400	Regulatory pathways for innovative medical devices MFDS (An innovative medical device pathway)	Seil Park Assistant Director Division of High-Tech Medical Devices Ministry of Food and Drug Safety, Republic of Korea	
17	1400-1410	Regulatory pathways for innovative medical devices HSA (Priority Review Scheme)	Lailing LIEW Acting Deputy Director, Diagnostic Devices Branch, Medical Devices Cluster, HSA, Singapore	
18	1410-1420	Regulatory pathways for innovative medical devices SFDA	Razan Asaly IVD section head SFDA, Kingdom of Saudi Arabia	
19	1420-1430	Innovative Regulatory Pathway for Innovative Products Post Covid	Philip AUCLAIR TC Advisor, Director of Abbott	
20	1430-1450	Q&A: Regulatory pathways for innovative medical devices	Moderator: Cindy Pelou Lead for Regulatory Affairs, APACMed	
1450-1520		**TEA BREAK**		
Regulatory Tools to Foster Innovation				
21	1520-1540	Utilizaing the Regulatory Sandbox to Facilitate Innovation	Nicole Taylor Smith VP, Regulatory Science & Policy, Patient Safety & Quality, Philips	
22	1540-1600	RWE - tools to support innovation	1) LIU Yinghui Director of Clinical and Biostatistics Evaluation Division I, Center for Medical Device Evaluation (CMDE), NMPA, People's Republic of China 2) Heather M. Colvin Director of Evidence & Outcomes Policy, Johnson and Johnson Medtech	
23	1600-1610	Regulatory convergence & reliance	HUANG Yasha Head of Regulatory Policy Asia Pacific Roche Diagnostics Asia Pacific Pte Ltd	
24	1610-1635	Panel Discussion - Best practices and experiences using regulatory tools to foster innovation	Moderator: Nicole Talor Smith Panelists: 1) HUANG Yasha Head of Regulatory Policy Asia Pacific, Roche Diagnostics Asia Pacific Pte Ltd 2)Heather M. Colvin Director of Evidence & Outcomes Policy, Johnson and Johnson Medtech 3)Salbiah BT Yaakop Director of Policy, International Affairs & Industry, Facilitation Division, Medical Device Authority Ministry of Health, Malaysia	
25	1635-1640	Summary Day 1	Abdullatif S. AlWatban GHWP TC Chair Executive Director, Medical Devices Evaluation, SFDA, Kingdom of Saudi Arabia	
		Adjourn		
END OF DAY 1				