Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Day 1 Agenda: 27 Nov 2023			
GHWP Capacity Building on opportunities and challenges of innovative medical devices regulations			
Moderator: Ms. EunHee Cho (GHWP Cochair, RA Director, Abbott Medical Korea, Republic of Korea)			
ITEMS	**TIME**		
1	**0900-0905**	**Opening Speech**	Dr. XU Jinghe GHWP Chair Deputy Commissioner NMPA, China
2	**0905-0920**	**GHWP Strategic Framework - Keeping in pace with Innovation**	Ms. Quan Tran GHWP Capacity Building Lead Vice President, RAQA, Baxter, APAC
New cutting-edge technologies medical devices			
3	**0920-0935**	SaMD Industry Showcase	1) Mr. Johan Ordish Head of Digital Health and Innovation Policy Roche Diagnostics Corporation 2) Mr. XU Qiang Software R&D Director, GE Healthcare 3) Mr. DAI Weiwei IT Solution Business Director, Mindray Biomedical Electronics
4	**0935-0945**	Regulatory Progress of Digital Health in CHINA	Dr. YANG Pengfei Director, Division of Evaluation I, Center for Medical Device Evaluation (CMDE), NMPA
5	**0945-1000**	Artificial Intelligence Medical Device - Industry Showcase	1) Professor Selwa Al-Hazzaa, MD, FRCS, MMM CEO and Founder at SDM, Saudi Abrabia 2) Dr. GAO Yaozong PhD, Chief Scientist, United Imaging Healthcare
6	**1000-1015**	Artificial Intelligence Medical Device -Regulatory Practice	1) Dr. Hala Alhodaib Senior Chief Scientific Evaluation Expert Medical Devices Sector Saudi Food and Drug Authority 2) Dr. Young Woo BAE Assistant Director, MFDS
1015-1040		**TEA BREAK**	
7	**1040-1055**	Robotic - Industry Showcase (Medical devices)	1) Dr. LIU Wenbo CEO, Sino Vision Medtech 2) Mr. Christopher HACK Sr. Director, Digital Robotics Global Policy, Johnson and Johnson Medtech
8	**1055-1105**	Medical Robotic Industry Development and Best Practrice in Supervision	Ms. GUO Shuting Deputy Commissioner, Shanghai MPA, China
9	**1105-1115**	3D Printing Devices - Industry Showcase	Dr. LU Ming Wego Holding
10	**1115-1125**	Global personalised devices regulatory development	Ms. Belinda Dowsett Associate Director, Medical Devices / IVD, PharmaLex Pty Ltd (Sydney)Australia
11	**1125-1135**	NGS & Mass Spectroscopy - Industry Showcase	Mr. 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) Mr. Lambert Byron Research Fellow, Abbott Medical 2) Mr. 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: Ms. Miang Tanakasemsub Panellists: 1) Mr. LIN Muqing, Mindray Biomedical Electronics 2) Mr. Brad Spring, Global Head of Regulatory Policy & Intelligence Roche Diagnostics Corporation 3) Mr. Lambert Byron, Research Fellow, Abbott Medical 4) Mr. 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**	Regulatory pathways for innovative medical devices NMPA (China Green Channel)	Mr. JIA Jianxiong Director of Integrated Affairs Division, Center for Medical Device Evaluation (CMDE), NMPA
15	**1340-1350**	Regulatory pathways for innovative medical devices PMDA (Sakigake)	Mr. 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)	Dr. 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)	Ms. Lailing LIEW Acting Deputy Director, Diagnostic Devices Branch, Medical Devices Cluster, HSA, Singapore
18	**1410-1420**	Regulatory pathways for innovative medical devices SFDA	Dr. Razan Asaly IVD section head SFDA, Saudi Arabia
19	**1420-1430**	USFDA Breakthrough designation pathway introduction	Ms. Victoria Brennand, Global Regulatory Affairs Director, Vision Care, Johnson and Johnson
20	**1430-1440**	Innovative Regulatory Pathway for Innovative Products Post Covid	Dr. Philip AUCLAIR, TC Advisor
21	**1440-1450**	Q&A: Regulatory pathways for innovative medical devices	Moderator: Ms. Cindy Pelou, Director, APACMed Panelists: TBC
1450-1520		**TEA BREAK**	
Regulatory Tools to Foster Innovation			
22	**1520-1540**	Utilizaing the Regulatory Sandbox to Facilitate Innovation	Ms. Nicole Taylor Smith VP, Regulatory Science & Policy, Patient Safety & Quality, Philips
23	**1540-1600**	RWE - tools to support innovation	1) Dr. LIU Yinghui Director of Clinical and Biostatistics Evaluation Division I, Center for Medical Device Evaluation (CMDE), NMPA 2) Ms. Heather M. Colvin, Director of Evidence & Outcomes Policy, Johnson and Johnson Medtech
24	**1600-1610**	Regulatory convergence & reliance	Ms. HUANG Yasha Head of Regulatory Policy Asia Pacific Roche Diagnostics Asia Pacific Pte Ltd
25	**1610-1635**	Panel Discussion - Best practices and experiences using regulatory tools to foster innovation	Moderator: Ms. Nicole Talor Smith Panelists: 1) Ms. HUANG Yasha, Head of Regulatory Policy Asia Pacific, Roche Diagnostics Asia Pacific Pte Ltd 2) Ms. Heather M. Colvin, Director of Evidence & Outcomes Policy, Johnson and Johnson Medtech 3) Ms. Salbiah BT Yaakop, Director of Policy, International Affairs & Industry, Facilitation Division, Medical Device Authority Ministry of Health, Malaysia
26	**1635-1640**	Summary Day 1	Dr. Abdullatif S. AlWatban GHWP TC Chair Executive Director, Medical Devices Evaluation, SFDA, Saudi Arabia
		Adjourn	
END OF DAY 1			