

Day 1 Agenda: 27 Nov 2023			
GHWP Capacity Building on opportunities and challenges of innovative medical devices regulations			
Moderator: Ms. EunHee Cho			
ITEMS	TIME		
1	0900-0905	Opening Speech	Dr. Jinghe Xu GHWP Chair Deputy Commissioner NMPA, China
2	0905-0920	Keynote Speech	TBC
New cutting-edge technologies medical devices			
3	0920-0935	SaMD Industry Showcase	1) Johan Ordish Head of Digital Health and Innovation Policy Roche Diagnostics Corporation 2) Xu Qiang Software R&D Director, GE Healthcare 3) Weiwei DAI IT Solution Business Director, Mindray Biomedical Electronics
4	0935-0945	Regulatory Progress of Digital Health in China	Mr. Pengfei YANG Deputy Division Director CMDE, China
5	0945-1000	Artificial Intelligence Medical Device - Industry Showcase	1) Professor Selwa Al-Hazzaa, MD, FRCS, MMM CEO and Founder at SDM, Saudi Arabia 2) Dr. Yaozong GAO 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)	Dr. Wenbo LIU CEO, Sino Vision Medtech and others TBC
8	1055-1105	Medical Robotic Industry Development and Best Practice in Supervision	Shuting GUO Vice Commissioner, SH FDA, China
9	1105-1115	3D Printing Devices - Industry Showcase	Dr. Ming LU Wego Holding
10	1115-1125	Personalized Medical Device- Industry Showcase	TBC
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: Ms. Miang Tanakasemsub Panelists: 1) Muqing LIN, Mindray Biomedical Electronics and others TBC
1210-1330 LUNCH			
Regulatory pathways for innovative medical devices			
14	1330-1340	Regulatory pathways for innovative medical devices NMPA (China Green Channel)	Dr. Jianxiong JIA Division Director, CMDE
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)	TBC
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 FDA (Breakthrough Devices Program)	TBC
19	1420-1430	Regulatory pathways for innovative medical devices SFDA	Dr Razan Asaly IVD section head SFDA, Saudi Arabia
20	1430-1440	Innovative Regulatory Pathway for Innovative Products Post Covid	Philip AUCLAIR TC Advisor
21	1440-1450	Q&A: Regulatory pathways for innovative medical devices	Moderator: Cindy Pelou, Director, APACMed Panelists: TBC
1450-1520 TEA BREAK			
Regulatory Tools to Foster Innovation			
22	1520-1540	Utilizing the Regulatory Sandbox to Facilitate Innovation	Nicole Taylor Smith VP, Regulatory Science & Policy, Patient Safety & Quality, Philip and others TBC
23	1540-1600	RWE - tools to support innovation	1) Dr. Yinghui LIU Division Director, CMDE, China 2) Mr. Colvin Heather JnJ Medtech
24	1600-1610	Medical Devices Pre certification program	TBC
25	1610-1620	Regulatory convergence & reliance	Yasha Huang Head of Regulatory Policy Asia Pacific Roche Diagnostics Asia Pacific Pte Ltd
26	1620-1645	Panel Discussion - Best practices and experiences using regulatory tools to foster innovation	Moderator: TBC Panelists: TBC
27	1645-1650	Summary Day 1	Dr. Abdullatif S. AlWatban GHWP TC Chair Executive Director, Medical Devices Evaluation, SFDA, Saudi Arabia
Adjourn			
END OF DAY 1			