Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Day 2 Agenda: 28 Nov 2023			
GHWP Capacity Building on opportunities and challenges of innovative medical devices regulations			
Moderator: Eka			
ITEM	**TIME**		
1	**0900-0910**	Innovative Practices to Promote the Development of the Medical Device Industry in Shanghai Pudong	Jincheng WU Deputy Secretary General/Acting Chief for Pudong District
2	**0910-0920**	GHWP Capacity Building - future ready workforce for innovation	Ms. Quan Tran GHWP Capacity Building Lead Vice President, RAQA, Baxter, APAC
3	**0920-0950**	Panel discussion- Capacity Building Shanghai FDA CB Experience Sharing	Moderator: Mr. Michael Flood Panelists: Dr. Lai XU, Commissioner, Shanghai FDA and others TBC
Risk Management for Innovative Medical Device			
4	**0950-1005**	Roles of standard and Risk management for innovative devices	Dr. YI Tian Global Principal Key Expert, Siemens Healthineers and others TBC
5	**1005-1015**	Change management for innovative devices	Dr. Adelheid Schneider Head of Quality and Regulatory Asia Pacific, Roche Diagnostics Asia Pacific Pte Ltd
6	**1015-1030**	Pre-determined Change Control Plan (PCCP)	Johan Ordish Head of Digital Health and Innovation, Roche and others TBC
1030-1100		**TEA BREAK**	
7	**1100-1115**	Implementation of Medical Devices Vigilance Program (MDVP)	TBC
8	**1115-1125**	Adverse Event Terminology for Medical Device	Dr. Lijia ZHENG CDR of NMPA, China
9	**1125-1135**	Adverse Event Monitoring for Medical Device	Dr. KUSAKABE Tetsuya International Coordination Officer Pharmaceuticals and Medical Devices Agency (PMDA)
10	**1135-1200**	Panel Discussion- Innovative Medical Device Management and Medical Device Adverse Event Mornitoring and Vigilance and change management	Moderator: TBC Panelists: 1) Dr. Pei GAO, Peking University PMDA, local association, Peking University 2) Ms. Salbiah Yaakop, MDA 3) Dr. KUSAKABE Tetsuya, International Coordination Officer Pharmaceuticals and Medical Devices Agency, PMDA, Japan
1200-1400		**LUNCH**	
UDI Application Practices			
11	**1400-1420**	The role of UDI in whole product life cycle management	Xinbing WANG, Regulatory Affairs Director, Mindray Electronics and others TBC
12	**1420-1430**	Good Practice of UDI in Clinical Use	Donglan YU Director of Medical engineering Department, The First Affiliated Hospital of Sun Yat-sen University
13	**1430-1500**	Panel discussion- UDI Application Status and Challenges	Moderator: Dr. Li Yi, CMDSA Panelists: 1) Donglan YU, Director of Medical engineering Department, The First Affiliated Hospital of Sun Yat-sen University 2) Jun CUI, Regulatory Intelligence and Operation Director, GE Healthcare 3) Jiong ZHANG, Assistant GM, Shanghai Pharm 4) Abdullah M. Alghurabi, Director of Regulation and Registration support, SFDA, Saudi Arabia and others TBC
1500-1520		**TEA BREAK**	
Digital Transformation of Medical Device Labelling			
14	**1520-1530**	eIFU - Requirements and best practise	Sharad Mi. Shukla, MedTech Regulatory Affairs, Southeast Asia, J&J Medtech
15	**1530-1540**	Sharing of the Best Practices for elabels	Diana Kanecka, Strategies, Special Projects & International Affairs, MedTechEurope
16	**1540-1550**	Electronic Export Certificate Issuance US FDA	TBC
17	**1550-1620**	Panel Discussion- Pros and cons of digital transformation for medical device supervision	Moderator: Petra Kaars-Wiele, GHWP Adviser Panelists: 1) Ms. Salbiah Yaakop, Director of Policy and Strategic Planning, MDA, Malaysia 2) Sharad Shukla, Regulatory Affairs, Southeast Asia, JnJ Medtech 3) Diana Kanecka, Strategies, Special Projects & International Affairs, Medtech Europe and others TBC
18	**1620-1630**	Summary Day 2	Ms. Miang Tanakasemsub GHWP TC Co-Chair Head or Regulatory Affairs, JnJ Vision
		Adjourn	
END OF DAY 2			