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: Ms. Eka Purnamasari (GHWP Cochair, Director for Medical Devices Control, Ministry of Health, Indonesia)			
ITEM	**TIME**		
1	**0900-0910**	Innovative Practices to Promote the Development of the Medical Device Industry in Shanghai Pudong	Mr. WU Jincheng 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…it's not just a one time thing	Moderator: Mr. Michael Flood Panelists: 1) Dr. Lai XU, Commissioner, Shanghai MPA 2) Dr. Razan Asaly, IVD section head, SFDA, Saudi Arabia 3) Ms Salbiah Yaakop, Director of Policy and Strategic Planning, MDA, Malaysia, 4) Mr Tony Low, Director of Human Performance and Medical Device RA/QA 5) APACMed
Risk Management for Innovative Medical Device			
4	**0950-1005**	The roles of standards for innovative medical device	Dr. Ir Peter W. J. Linders, TC Advisor
5	**1005-1020**	Standardization drives innovation in medical devices	Dr. TIAN Yi Global Principal Key Expert, Siemens Healthineers
6	**1020-1030**	Change management for innovative devices	Dr. Adelheid Schneider Head of Quality and Regulatory Asia Pacific, Roche Diagnostics Asia Pacific Pte Ltd
7	**1030-1045**	Pre-determined Change Control Plan (PCCP)	1) Mr. Johan Ordish Head of Digital Health and Innovation, Roche 2) Ms. April Veoukas RA Director, Abbott
1045-1105		**TEA BREAK**	
8	**1105-1120**	Post-market Vigilance and Adverse Event Monitoring for Medical Device	Dr. KUSAKABE Tetsuya International Coordination Officer Pharmaceuticals and Medical Devices Agency (PMDA)
9	**1120-1130**	Adverse Event Terminology for Medical Device	Mr. ZHENG Lijia CDR of NMPA, China
10	**1130-1140**	Hybrid Registry and EHR based Active Surveillance System Design for Medical Device	Dr. GAO Pei, Professor, Director of Center of Clinical Evaluation and RWE Evaluation of Peking University
11	**1140-1210**	Panel discussion- Innovative Medical Device Management and Medical Device Adverse Event Mornitoring and Vigilance and change management	Moderator: Ms. Kitty Mao Yiqing Panelists: 1) Dr. GAO Pei, Professor, Director of Center of Clinical Evaluation and RWE Evaluation of Peking University 2) Ms. Salbiah Yaakop, MDA 3) Dr. KUSAKABE Tetsuya, International Coordination Officer Pharmaceuticals and Medical Devices Agency, PMDA, Japan 4) Ms. SHANG Wei, Director of Regulatory Affairs, JAPAC, Allergan Aesthetics
1210-1400		**LUNCH**	
UDI Application Practices			
11	**1400-1430**	The role of UDI in whole product life cycle management	1) Mr. WANG Xinbing, Regulatory Affairs Director, Mindray Electronics 2) Mr. Jay Cowely, VP of Medical Device Solutions and Services, USDM
12	**1430-1445**	Good Practice of UDI in Clinical Use	Ms. YU Donglan Director of Medical engineering Department, The First Affiliated Hospital of Sun Yat-sen University
13	**1445-1515**	Panel discussion- UDI Application Status and Challenges	Moderator: Dr. YI Li, CMDSA Panelists: 1) Mr. Abdullah M. Alghurabi, Director of Regulation and Registration support, SFDA, Saudi Arabia 2) Ms. YU Donglan, Director of Medical engineering Department, The First Affiliated Hospital of Sun Yat-sen University 3) Mr. Alex Budiman, VP of Regulatory Affairs, Greater Asia, BD 4) Mr. Edi Rahman, RA/GA manager, Mindray Indonesia 5) Mr. CUI Jun, Regulatory Intelligence and Operation Director, GE Healthcare 6) Mr. ZHANG Jiong, Assistant GM, Shanghai Pharm
1515-1545		**TEA BREAK**	
Digital Transformation of Medical Device Labelling			
14	**1545-1600**	eIFU - Requirements and best practise	Mr. Sharad Mi. Shukla, MedTech Regulatory Affairs, Southeast Asia, J&J Medtech
15	**1600-1615**	Sharing of the Best Practices for elabels	Ms. Diana Kanecka, Strategies, Special Projects & International Affairs, MedTechEurope
16	**1615-1645**	Panel Discussion- Pros and cons of digital transformation for medical device supervision	Moderator: Dr. Petra Kaars-Wiele, GHWP Adviser Panelists: 1) Ms. Salbiah Yaakop, Director of Policy and Strategic Planning, MDA, Malaysia 2) Mr. Sharad Shukla, Regulatory Affairs, Southeast Asia, JnJ Medtech 3) Ms. Diana Kanecka, Strategies, Special Projects & International Affairs, Medtech Europe 4) Mr. Ed WOO, Advisor, Philips
17	**1645-1650**	Summary Day 2	Ms. Miang Tanakasemsub GHWP TC Co-Chair Head or Regulatory Affairs, JnJ Vision
		Adjourn	
END OF DAY 2			