Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Day 2 Agenda: 28 Nov 2023 Venue: Shanghai International Convention Center, Shanghai, China			
GHWP Capacity Building on opportunities and challenges of innovative medical devices regulations			
Moderator: 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	Lyu Xuecheng Deputy District Mayor of Shanghai Pudong New Area, People's Republic of China
2	**0910-0920**	GHWP Capacity Building - future ready workforce for innovation	Quan Tran GHWP Capacity Building Lead Vice President, RAQA, Baxter, APAC
3	**0920-0930**	Shanghai MPA Capacity Building Experience	XU Lai Commissioner, Shanghai MPA, People's Republic of China
4	**0930-1000**	Panel discussion- Capacity Building...it's not just a one time thing	Moderator: Michael Flood Panelists: 1)Razan Asaly IVD section head, SFDA, Kingdom of Saudi Arabia 2)Salbiah Yaakop Director of Policy and Strategic Planning, MDA, Malaysia 3) APACMed
Risk Management for Innovative Medical Device			
5	**1000-1015**	The roles of standards for innovative medical device	Ir Peter W. J. Linders TC Advisor, Philips
6	**1015-1025**	Standardization drives innovation in medical devices	TIAN Yi Global Principal Key Expert, Siemens Healthineers
7	**1025-1035**	Sharing Best Practices on Innovative Pathways for Changes	Adelheid Schneider Head of Quality and Regulatory Asia Pacific, Roche Diagnostics Asia Pacific Pte Ltd
8	**1035-1050**	Pre-determined Change Control Plan (PCCP)	1)Brad Spring Global Head of Regulatory Policy & Intelligence Roche Diagnostics Corporation 2)April Veoukas RA Director, Abbott
1050-1110		**TEA BREAK**	
9	**1110-1120**	Post-market Vigilance and Adverse Event Monitoring for Medical Device	KUSAKABE Tetsuya International Coordination Officer Pharmaceuticals and Medical Devices Agency (PMDA), Japan
10	**1120-1130**	Medical Device Adverse Event Terminology	ZHENG Lijia Engineer, Center for Drug Reevaluation, NMPA, People's Republic of China
11	**1130-1140**	Hybrid Registry and EHR based Active Surveillance System Design for Medical Device	GAO Pei, Professor Director of Center of Clinical Evaluation and RWE Evaluation of Peking University, People's Republic of China
12	**1140-1210**	Panel Discussion- Innovative Medical Device Management and Medical Device Adverse Event Mornitoring and Vigilance and change management	Moderator: Kitty Mao Yiqing Panelists: 1) GAO Pei Professor, Director of Center of Clinical Evaluation and RWE Evaluation of Peking University, People's Republic of China 2) Salbiah Yaakop MDA, Malaysia 3) KUSAKABE Tetsuya International Coordination Officer Pharmaceuticals and Medical Devices Agency, PMDA, Japan 4) SHANG Wei Director of Regulatory Affairs, JAPAC, Allergan Aesthetics
1210-1400		**LUNCH**	
UDI Application Practices			
13	**1400-1430**	The role of UDI in whole product life cycle management	1) WANG Xinbing Regulatory Affairs Director, Mindray Electronics 2) Jay Crowley VP of Medical Device Solutions and Services, USDM (VIDEO)
14	**1430-1445**	Good Practice of UDI in Clinical Use	YU Donglan Director of Medical engineering Department, The First Affiliated Hospital of Sun Yat-sen University, People's Republic of China
15	**1445-1515**	Panel discussion- UDI Application Status and Challenges	Moderator: YI Li Center for Medical Device Standardization Administration, NMPA, People's Republic of China Panelists: 1) Abdullah M. Alghurabi Director of Regulation and Registration support, SFDA, Kingdom of Saudi Arabia 2) YU Donglan Director of Medical engineering Department, The First Affiliated Hospital of Sun Yat-sen University, People's Republic of China 3) Alexander Budiman VP of Regulatory Affairs, Greater Asia, BD 4) Edi Rahman RA/GA manager, Mindray, Indonesia 5) CUI Jun Regulatory Intelligence and Operation Director, GE Healthcare 6) ZHANG Jiong Assistant GM, Shanghai Pharm
1515-1545		**TEA BREAK**	
Digital Transformation of Medical Device Labelling			
16	**1545-1600**	eIFU - Requirements and best practise	Sharad Mi. Shukla, Director, Regulatory Affairs, Southeast Asia, Johnson and Johnson Medtech
17	**1600-1615**	Sharing of the Best Practices for elabels	Diana Kanecka Strategies, Special Projects & International Affairs, MedTech Europe
18	**1615-1645**	Panel Discussion- Pros and cons of digital transformation for medical device supervision	Moderator: Petra Kaars-Wiele GHWP Adviser Panelists: 1) Salbiah Yaakop Director of Policy and Strategic Planning, MDA, Malaysia 2) Sharad Mi. Shukla, Director, Regulatory Affairs, Southeast Asia, Johnson and Johnson Medtech 3) Diana Kanecka, Strategies, Special Projects & International Affairs, Medtech Europe 4) Ed WOO, Advisor, Philips
19	**1645-1650**	Summary Day 2	Miang Tanakasemsub GHWP TC Co-Chair Head or Regulatory Affairs, Johnson & Johnson Vision
		Adjourn	
END OF DAY 2			