Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

Day 1 Agenda: 27 Nov 2023 Venue: Shanghai International Convention Center, Shanghai, China		
GHWP Capacity Building on opportunities and challenges of innovative medical devices regulations		
ITEMS	**TIME**	
1	0900-0905	Opening Speech
2	0905-0920	Keynote Speech
New cutting-edge technologies medical devices		
3	0920-0935	SaMD Industry Showcase
4	0935-0945	SaMD Regulatory Practice
5	0945-1000	AIMD Industry Showcase
6	1000-1015	AIMD-Regulatory Practice
1015-1040		TEA BREAK
7	1040-1055	Robotic - Industry Showcase (Medical devices)
8	1055-1105	Robotic - Regulatory Practice (Medical devices)

9	**1105-1115**	3D Printing Devices - Industry Showcase
10	**1115-1125**	Personalized Medical Device- Industry Showcase
11	**1125-1135**	NGS & Mass Spectroscopy - Industry Showcase
12	**1135-1150**	Medical Device Sterilisation: the need for industrial alternatives to Ethylene Oxide
13	**1150-1210**	Panel Discussion - Innovative technology and regulatory challenges
1210-1330		LUNCH
Regulatory pathways for innovative medical devices		
14	**1330-1340**	Regulatory pathways for innovative medical devices TGA (Ealier access to medical technologies and the MMDR)
15	**1340-1350**	Regulatory pathways for innovative medical devices NMPA (China Green Channel)
16	**1350-1400**	Regulatory pathways for innovative medical devices PMDA (Sakigake)
17	**1400-1410**	Regulatory pathways for innovative medical devices MFDS (An innovative medical device pathway)
18	**1410-1420**	Regulatory pathways for innovative medical devices HSA (Priority Review Scheme)
19	**1420-1430**	Regulatory pathways for innovative medical devices FDA (Breakthrough Devices Program)
20	**1430-1440**	Regulatory pathways for innovative medical devices SFDA
21	**1440-1450**	Innovative Regulatory Pathway for Innovative Products Post Covid

22	**1450-1500**	Q&A: Regulatory pathways for innovative medical devices
1500-1530		TEA BREAK
Regulatory Tools to Foster Innovation		
23	**1530-1550**	Regulatory Sandbox
24	**1550-1610**	RWE
25	**1610-1620**	Medical Devices Pre certification program
26	**1620-1630**	Regulatory convergence & reliance
27	**1630-1655**	Panel Discussion - Best practices and experiences using regulatory tools to foster innovation
28	**1655-1700**	Summary Day 1
		Adjourn
END OF DAY 1		