

GHWP	lowards	Medical Device Harmonization	
Day 3 Agenda			
11.29 (Wednesday Morning) Closed-door Meeting Venue: Shanghai International Convention Center, Shanghai, China			
27th GHWP Technical Committee (GHWP TC) Meeting Attendees: GHWP LT, TC LT, TC Advisor, TC Secretariat, WG Chair/Vice-chair			
Moderator: Mr. Abdullatif S. Al Watban, PhD			
ITEMS	TIME		
1	0900-1200	GHWP TC & WG Leaders Meeting with TC Advisors (Closed-Door Meeting)	Mr. Abdullatif S. Al Watban, PhD
			GHWP TC Chair
			Executive Director, Medical Device Evaluation, Medical Devices Sector, SFDA, Saudi Arabia
			Ms. Jun Li GHWP TC Co-chair (Regulatory Authority)
			Deputy Director General, Department of Medical Device
			Regulation, NMPA, China
			Ms. Miang Tanakasemsub
			GHWP TC Co-chair (Industry) Head of Regulatory Affairs, Asia Pacific Johnson & Johnson
			Vision, Thailand
11.29 (Wednesday Afternoon) Open Meeting Venue: Shanghai International Convention Center, Shanghai, China			
		venue. Snanghai international convention	
Moderator: Ms. Li Jun			
		tory Authority)	
Deputy Dir	ector General, L	Department of Medical Device Regulation, NMPA, Chin	1
2	1400 1410	Ononing Capacity	Mr. Abdullatif S. Al Watban, PhD GHWP TC Chair
2	1400-1410	Opening Speech	Executive Director, Medical Device Evaluation, Medical Devices Sector, SFDA, Saudi Arabia
3	1410-1420	Roll call Adoption of Agenda	Ms. Jun Li
			GHWP TC Co-chair (Regulatory Authority)
			Deputy Director General, Department of Medical Device Regulation, NMPA, China
4	1420-1425	Adoption of 26th GHWP TC Meeting Minutes	Ms. Miang Tanakasemsub
			GHWP TC Co-chair (Industry) Head of Regulatory Affairs, Asia Pacific Johnson & Johnson
			Vision, Thailand
5		Working Group Updates:	
6	1420-1525 (10mins +	Work Group 1 (WG1) - Pre-Market Submission and CSDT	Work Group 1 (WG1)
7	5mins	Work Group 2 (WG2) - Pre-market: IVDD	Work Group 2 (WG2)
8	Q&A each)	Work Group 3 (WG3) - Pre-market: Software as a Medical Device	Work Group 3 (WG3)
9		Work Group 4 (WG4) - Post-Market	Work Group 4 (WG4)
1525-1540		т	EA BREAK
10		Work Group 5 (WG5) - Clinical Evidence for	Work Group 5 (WG5)
		Performance and Safety Work Group 7 (WG7) - Quality Management System:	
11	1540-1640	Operation & Implementation	Work Group 7 (WG7)
12		Work Group 8 (WG8) – Standards	Work Group 8 (WG8)
13		Work Group 9 (WG9) – UDI & Nomenclature	Work Group 9 (WG9)
14	1640-1655	TC Advisors Summary Report	Representatives of TC Advisory Panel Ms. Jun Li
15	1655-1700	Closing Remarks for Day 3	GHWP TC Co-chair (Regulatory Authority)
			Deputy Director General, Department of Medical Device Regulation, NMPA, China
16	1700	Adjourn	
		END OF DAY 3	L
Dr. Jinghe Xu			
1800		Gala Dinner	GHWP Chair
			Deputy Commissioner NMPA, China