

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

GHWP TC Chair

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)				
	Venue: Shanghai International Convention Center, Shanghai, China					
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2	1400-1410	Opening Speech	Mr. Abdullatif S. Al Watban, PhD GHWP TC Chair 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		TEA BREAK				

9		Work Group 4 (WG4) - Fost-Warket	work group 4 (wg4)		
1525-1540		TEA BREAK			
10		Work Group 5 (WG5) - Clinical Evidence for Performance and Safety	Work Group 5 (WG5)		
11	1540-1640	Work Group 7 (WG7) - Quality Management System: 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		
15	1655-1700	Closing Remarks for Day 3	Ms. Jun Li GHWP TC Co-chair (Regulatory Authority) Deputy Director General, Department of Medical Device Regulation, NMPA, China		
16	1700	Adjourn			
END OF DAY 2					

		Dr. Jinghe Xu			
1800	Gala Dinner	GHWP Chair			
		Deputy Commissioner NMPA, China			