



UPDATED Agenda for AHWP KSA, Riyadh Meeting (27 Nov - 1 Dec 2010)



	27 th Nov (Sat)	28 th Nov (Sun)	29 th Nov (Mon)	30 th Nov (Tue)	1 st Dec (Wed)
	12 th AHWP TC Meeting	Workgroup Training & Visit	Member Update	15 th AHWP Meeting	15 th AHWP Meeting
08:00	Registration				
	AHWP TC Meeting 8:30 – 8:35 Welcome speech by host – Saudi FDA (5 min) – Dr. Salleh, Vice President, Medical Devices Sector, Saudi FDA.	WG Training (A) Room A 8:30 – 9:30 Topic: ISO 14155 Ms. Daniell Giroud (GHTF SGS)	WG Training (B) Room B 8:30 – 9:30 Topic: IVD Dr. Petra Wiele (Abbott GmbH & Co KG)	Member Update Chair: Mr. Ali Co-Chair: Daphne	Opening Ceremony 8:30 – 8:45 Welcome Speech by Host Dr. Salleh 8:45 – 8:55 Congratulation Speech by China SFDA (by Ms Xu Youjun) 8:55 – 9:15 Opening Speech by Chair Mr. Wong Bao Ting 9:15 – 9:30 Keynote Speech by Datuk Dr MS Pillay 9:30 – 9:40 Sponsor Speech Dr. Mohd Al Kanhal 9:40 – 10:00 Souvenirs to Host, Keynote Speakers and Diamond sponsor (by Chair) 10:00 – 10:30 Photo Taking 10:30 – 11:00 Tea Break
08:30	8:35 – 8:40 Opening by AHWP's Chair – Mr. Wang Bao Ting (10 min) 8:40 – 9:00 Report/Overview of the Taipei meeting Ms. Joanna Koh (20 min) 9:00 – 9:30 WG1 Pre-market Submission & CSDT Jacqueline Monteiro, Daphne Yeh, Meshal A. Al-Amri (30 min) 9:30 – 10:00 WG1A Pre-market Submission IVD Essam, Jeffrey Chern (30 min) 10:00 – 10:30 WG2 Post-market Surveillance & Vigilance Mark Lau, Chadaporn Thanakasemsub (30 min)	Room A: 9:30 – 10:00 Topic: Clinical Trial Prof. Mi Xianqiang University of Shanghai for Science and Technology) 10:00 – 10:30 Topic: Clinical Trials Regulations development in India Sumati Randeo	Room B: 9:30 – 10:30 Topic: Adverse Incident Investigation Mr. Mark Bruley (Vice President, ECRI)	8:30 – 9:30 ISO Quality Management Update (Speaker: Mr Eamonn Hoxey) Chair, ISO TC 210 9:30 – 10:00 Saudi Arabia Update 10:00 – 10:30 Chile Update	11:00 – 11:15 Adoption of Agenda (Mr Wang Baoting) -Admission of New AHWP Members (Mr Wang Baoting) -Roll Call (Only Official Members) (Mr Wang Baoting) (Moderator of Meeting: TC Chair) -Confirmation of Minutes of the 14 th AHWP Meeting 11:15 – 11:30 Report by Secretariat -2009/10 Report of HK Secretariat Branch (Mr Mark Lau) 11:30 – 11:40 -2009/10 Financial Statement and 2010/11 Budget (Mr Bryan So) 11:40 – 12:00 Report by AHWP TC Chair (Joanna)
10:40	AHWP TC Meeting 11:00 – 11:30 WG3 Quality Management System Ali M. Al Dalaan (30 min) 11:30 – 11:50 WG4 Quality System Audit Eun Hee Cho, Al Rasheed (20 min) 11:50 – 12:20 WG5 Clinical Evidence Requirements Tran Quan (30 min) 12:20 – 12:40 WG6 Capacity Bldg & Regulatory Training Jack Wong (20 min)	TEA BREAK Main Conference Room Moderator: Miang 11:00 – 11:55 Topic: FSCA Ms. Isabella Demade (EU Commission) 11:55 – 12:50 Mr Philippe Auclair (Senior Director, Regulatory Strategy and Advocacy, Abbott)	Member Update 11:00 – 11:30 Chinese Taipei Update 11:30 – 12:00 India Update 12:00 – 12:30 Pakistan Update 12:30 – 13:30 PM Praying and Lunch Break	12:00 Praying and Lunch Break 13:00 – 15:00 Report by Working Groups - WG1- Jacqueline Monteiro, Daphne Yeh, Meshal A. Al-Amri -WG1A – Essam, Jeffrey Chern WG2 –Mark Lau, Chadaporn Thanakasemsub -WG3 – Ali M. Al Dalaan -WG4 – Al Rasheed - WG5 – Tran Quan -WG6 – Jack Wong -STG(LE) – Mark Lau -STG(N) – Lindsay Tao	10:40 -11:00 Collaboration between AHWP and WHO (Speaker: Ms Adriana Velazquez) 11:00 -11:20 Collaboration between AHWP and APEC (Speaker: Mr Jeffrey Green) 11:20 -11:40 Collaboration between AHWP and LSIF (Speaker: Ms Lindsay Tao) 11:40 -12:00 Collaboration between AHWP and GHTF (Speaker: Mr Jean-Yves Carentz) 12:00 -12:20 Update by GHTF Study Groups - SG1 (Speaker: Mr Kentaro Azuma)
12:50	PRAYING AND LUNCH BREAK				
14:00	AHWP TC Meeting 14:00 – 14:20 STG(LE) Legal Entity Mark Lau (20 min) 14:20 – 14:40 STG (N) Nomenclature Lindsay Tao (20 min) 14:40 – 15:40 Discussion on Terms of Reference for Bearers of AHWP TC: -Proposal on the refinement of TOR -Resolution to form a consistent structure of Office Bearers in both AHWP & AHWP TC Joanna (60 min) 15:40 – 16:20 Any Other Business (40 min)	Main Conference Room 14:00 – 15:00 Update on Replacing Mercury Containing Medical Devices (Speaker: Datuk Dr MS Pillay) 15:00 – 16:00 Main Conference Room Panel Discussion (All Speakers) Moderator – Ms. Tran Quan Visit	13:30 – 14:00 Singapore Update 14:00 – 14:30 Hong Kong Update 14:30 – 15:00 Indonesia Update 15:00 – 15:30 Thailand Update	15:00 – 16:00 -Resolution 1: Adoption of the Proposed AHWP House Rules – Mark Lau -Resolution 2: Adoption of the Proposed Amendment 1 to the AHWP Terms of Reference - Mark Lau	Update (Session 1) 13:20 – 14:20 (15 min each) Update by GHTF Study Groups - SG2 (Speaker: Ms Isabelle Demade) - SG3 (Speaker: Dr Dirk Wetzel) - SG4 (Speaker: Mr Tim Missios) - SG5 (Speaker: Mr Greg LeBlanc) 14:20 – 16:20 Panel Discussion: The Possibility of AHWP Joining GHTF Steering Committee (by TC Chair, TC Co-chairs, member economies, guests from GHTF Steering Committee) Confirmation of Host of the 16 th AHWP Meeting Meeting Closing Remarks
19:00	Dinner	Dinner		Gala Dinner	