



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



27 <sup>th</sup> Nov (Sat)		28 <sup>th</sup> Nov (Sun)		29 <sup>th</sup> Nov (Mon)	30 <sup>th</sup> Nov (Tue)		1 <sup>st</sup> Dec (Wed)	
12 <sup>th</sup> AHWP TC Meeting		Workgroup Training & Visit		Member Update	15 <sup>th</sup> AHWP Meeting		15 <sup>th</sup> AHWP Meeting	
<b>Registration</b>								
08:00	<b>AHWP TC Meeting</b>	<b>WG Training (A)</b>	<b>WG Training (B)</b>	<b>Member Update</b>	<b>Opening Ceremony</b>		<b>Workshops</b>	
	8:30 – 8:35 Welcome speech by host – Saudi FDA (5 min) – Dr. Salleh, Vice President, Medical Devices Sector, Saudi FDA.	<b>Room A</b> 8:30 – 9:30 Topic: ISO 14155 Ms. Daniell Giroud (GHTF SGS)	<b>Room B</b> 8:30 – 9:30 Topic: IVD Dr. Petra Wiele (Abbott GmbH & Co KG)	Chair: Mr. Ali Co-Chair: Daphne	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			8:30 – 8:50 - Speaker 1: Mr. Chris Jepson ( Global Manager- Medical Device Certification, SGS) Topic: <b>Conformity Assessment</b>
08:30	8:35 – 8:40 Opening by AHWP's Chair – Mr. Wang Bao Ting (10 min)	<b>Room A: 9:30 – 10:00</b> Topic: <b>Clinical Trial</b>  Prof. Mi Xianqiang University of Shanghai for Science and Technology)  <b>10:00 – 10:30</b> Topic: <b>Clinical Trials Regulations development in India</b>  Sumati Randeo	<b>Room B:</b>  <b>9:30 – 10:30</b> Topic: <b>Adverse Incident Investigation</b> Mr. Mark Bruley ( Vice President, ECRI)	8:30 – 9:30 ISO Quality Management Update (Speaker: Mr Eamonn Hoxey) Chair, ISO TC 210	10:30 – 11:00 Tea Break			8:50 – 9:10 - Speaker 2: Mr. Jan van Lochem (BSI) Topic: <b>Notified Body Harmonization Effort in Europe</b>
	8:40 – 9:00 Report/Overview of the Taipei meeting Ms. Joanna Koh (20 min)			9:30 – 10:00 Saudi Arabia 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)			9:10 – 9:30 - Speaker 3: Mr. Michael Flood (ex-TGA) Topic: <b>Practising GHTF Recommendations in Regulatory Systems</b>
	9:00 – 9:30 WG1 Pre-market Submission & CSDT Jacqueline Monteiro, Daphne Yeh, Meshal A. Al-Amri (30 min)			Moderator of Meeting: TC Chair) -Confirmation of Minutes of the 14 <sup>th</sup> 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)			9:30 – 9:50 - Speaker 4: Mr. Vincent Lam (TUV SUD) Topic: <b>Good Distribution Practise</b>
	9:30 – 10:00 WG1A Pre-market Submission IVD Essam, Jeffrey Chern (30 min)				10:00 – 10:30 Chile Update			9:50 – 10:10 - Speaker 5: Mr. Michael Cheng (Sympatico) Topic: <b>Shared responsibility in medical device regulations</b>
	10:00 – 10:30 WG2 Post-market Surveillance & Vigilance Mark Lau, Chadaporn Thanakasemsub (30 min)	TEA BREAK		12:00 Praying and Lunch Break		10:10 – 10:40 Tea Break		
10:40	<b>AHWP TC Meeting</b>	<b>Main Conference Room</b> Moderator: Miang		<b>Member Update</b>	<b>13:00 – 15:00 Report by Working Groups</b>		<b>Update (Session 1)</b>	
	11:00 – 11:30 WG3 Quality Management System Ali M. Al Dalaan (30 min)	11:00 – 11:55 Topic: FSCA Ms. Isabella Demade (EU Commission)		11:00 – 11:30 Chinese Taipei Update	- 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	11:30 – 11:50 WG4 Quality System Audit Eun Hee Cho, Al Rasheed (20 min)	11:55 – 12:50 Mr Philippe Auclair ( Senior Director, Regulatory Strategy and Advocacy, Abbott)		11:30 – 12:00 India Update				11:00 -11:20 Collaboration between AHWP and APEC (Speaker: Mr Jeffrey Green)
	11:50 – 12:20 WG5 Clinical Evidence Requirements Tran Quan (30 min)			12:00 – 12:30 Pakistan Update				11:20 -11:40 Collaboration between AHWP and LSIF (Speaker: Ms Lindsay Tao)
	12:20 – 12:40 WG6 Capacity Bldg & Regulatory Training Jack Wong (20 min)			12:30 – 13:30 PM Praying and Lunch Break				11:40 -12:00 Collaboration between AHWP and GHTF (Speaker: Mr Jean-Yves Carentz)
12:50	PRAYING AND LUNCH BREAK				12:20 Praying and Lunch Break		12:00 -12:20 Update by GHTF Study Groups - SG1 (Speaker: Mr Kentaro Azuma)	
14:00	<b>AHWP TC Meeting</b>	<b>Main Conference Room</b> 14:00 – 15:00 Update on Replacing Mercury Containing Medical Devices (Speaker: Datuk Dr MS Pillay)		13:30 – 14:00 Singapore 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		<b>Update (Session 2)</b>	
	14:00 – 14:20 STG(LE) Legal Entity Mark Lau (20 min)			14:00 – 14:30 Hong Kong Update				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 – 14:40 STG (N) Nomenclature Lindsay Tao (20 min)			14:30 – 15:00 Indonesia Update				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 <sup>th</sup> AHWP Meeting Meeting Closing Remarks
	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)	15:00 – 16:00 <b>Main Conference Room</b> Panel Discussion (All Speakers) Moderator – Ms. Tran Quan		15:00 – 15:30 Thailand Update				
	15:40 – 16:20 Any Other Business (40 min)	Visit						
19:00	Dinner	Dinner			Gala Dinner			