AHWP TC Meeting Venue: Al Faisaliah Hotel, Riyadh
Nov 27, 2010 (Sat) 8:30 – 17:00

Welcome speech by AHWP Chair (10 min) (Mr. Wang Bao Ting)
Welcome speech by Saudi FDA (5 min) (Mr. Wang Bao Ting)
Opening speech by AHWP TC Chair (5 min) (Joanna Koh)

Reports on AHWP TC meeting in Chinese Taipei (20 min) (Joanna Koh)

WG1 Pre- market Requirements (30 min) (Jacqueline Monteiro, Daphne Yeh, Meshal A. Al-Amri)

1. Report on Comparison of STED and CSDT
2. Proposals from WG01
3. Update on the GHTF SG1 Meeting in Oct 2010
4. Next step

WG1a Pre-market Requirement for IVD (30 min) (Essam M. Al Mohandis)

1. Report on the GHTF Guidance document on IVDs
2. Next step

WG2 Post-market Requirements (30 min) (Mark Lau, Chadaporn Thanakasemsub)

1. Progressive report on post market surveillance action plan
- Harmonized AE report
- Building regulatory capacity in post-market areas
- Sharing of non-confidential information
- Merge NCAR/SADS: Exchange the non-confidential safety information

2. Next step

10:40-11:00 Tea Break

WG3 Quality Management System Requirements (30 min) (Ali M. Al Dalaan)

1. Update on GHTF QMS Document xxx and proposal for AHWP for adoption
2. Update on GHTF CAPA document and proposal for AHWP for discussion
3. Next step

WG4 Auditing (20 min) (E H Cho)

1. Progressive report on WG4 Survey on the "Country auditing requirements"
2. Next Step

WG5 Clinical Evidence Requirements (30 min) (Tran Quan)

Progressive report on:

1) The comparative study of Clinical Trials regulations & related guidance on Clinical Safety/Performance in AHWP member economies
2) Training initiatives
3) Development of SG5 guidance documents
4) GHTF SG5 collaboration & support to develop Advisory & Expert Panel