



AHWP WG2: PMS & Vigilance

Report & Work Plan

SG 02 meeting
Nov 2010



Agenda

- AHWP TC WG2 key activities updates
- Collaboration programs between SG2 & AHWP TC WG2
- AHWP TC WG02 work plans



WG2 Update

- Review AHWP TC WG02 membership
 - Nominated AHWP TC WG02 secretariat: Eric Chin, 3M Singapore
 - Propose the house rule for joining AHWP TC WG02
 - Proposed an AHWP TC WG02 registration form
 - Plan to ask all the AHWP TC WG02 members to complete the form again to ensure the most up to date list



WG2 Update

- Improve communication among AHWP TC WG02 members
 - Set up a fix schedule meetings for AHWP TC WG02
 - Meeting face to face with telecon concurrently
 - 1 day prior TC meeting (Attach with TC meeting)
 - 1-2 months prior to the Annual meeting
 - 1 day prior to the Annual meeting (Attach with Annual meeting)
 - Location: Rotating among AHWP economy members



WG2 Update

- 1st face to face meeting in Hong Kong, Oct 27-28
- PMS Survey:
 - Final Report on Current Requirements for Post Market Surveillance & Vigilance System is completed and up on AHWP website
 - No plan to conduct the additional survey
 - Key finding: No harmonization across AHWP economy members



WG2 Update

- Review of Implementation of GHTF SG2 Documents status is completed for 7 AHWP economy members.
 - 2 from 7 economy members fully implemented GHTF SG02 documents
 - 2 from 7 economy members have their own guidelines and implemented GHTF SG2 documents less than 10%
 - Across 7 economy members, the timing of AE reporting guideline is the most adopted
 - Plan to use it as an AHWP TC WG02 dashboard to measure WG02 performance
 - Will follow up the rest economy members to complete the survey



WG2 Update

- Survey of AHWP economy members FSCA definition
 - Have [the previous result](#) from PMS survey: 8 economy members
 - Will obtain more info from the rest and review the definitions with 8 economy members again
- Harmonized AE form across AHWP economy members
 - [Proposed AE form for AHWP approval](#)
 - Post the electronic AE form on the AHWP website



WG2 Update

- Sharing non-confidentiality FSCA among AHWP economy members
 - [Proposed FSCA form for AHWP approval](#)
 - AHWP secretariat will disseminate out [the weekly newsletter from Saudi Arabia](#) to all economy members
 - Required 2 email addresses from all AHWP economy members.
 - In the process of creating AHWP FSCA central email address to communicate FSCA among the AHWP economy members:
SADS@ahwp.info



WG2 Update

- Merge Safety Alert Dissemination System (SADS) and NCAR members
 - 8 AHWP economy members are SADS members
 - 4 AHWP economy members are NCAR members
 - Simplified SADS form (HA need to notify manufacturer prior to dissemination)
 - [Create "SADS Online"](http://www.ahwp.info) under <http://www.ahwp.info>
 - user: sadsonline
 - password : sads123



Collaboration with GHTF SG2

- A representative from WG2 regulators are joined SG2 officially
Essam M.Al-Mohandis
SFDA, Saudi Arabia
- Share the GHTF SG02 training materials on AHWP website
 - SG02 agreed for SG02 guidance documents post on AHWP website
 - Waiting for final approval of Disclaimer from the SG02!



Work Plans

- Training
 - Create the folder under AHWP WG02 & post all the trainings + VDO that need consent form from all the trainers to upload on the folder.
 - Proposed structure the trainings
 - ❖ Basic training
 - SG02 guidance documents
 - Manufacturers Trend Reporting of Adverse Events
 - Guidance of How to handle information concerning Vigilance Reporting Related to Medical Devices
 - FSCA



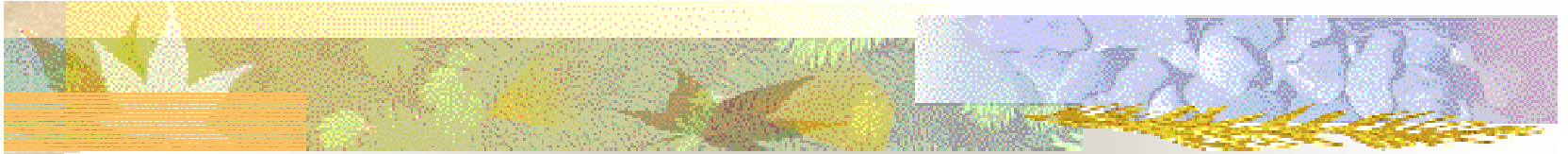
Work Plans

- Training (Cont)
 - ❖ Advance program
 - Mark Bruley (ECRI)_AE investigation program
 - Plan to VDO taping for the whole training
 - After AHWP meeting, plan to provide DVDs to the regulators and industries group for each economy
 - Long term_Propose WG06 to take care all these materials distribution



Future Collaboration with GHTF SG2

- Building regulatory capacity in post-market areas
 - Mentoring programs
 - Risk assessment capability
- Safety information Handling guidance documents for health authorities
- Merge NCAR/SADS: Exchange the non-confidential safety information



THANK YOU!