



WG2: Post-market Surveillance & Vigilance

Report & Work Plan

(1st AHWP GHTF SG02 joint meeting)



Agenda

- SG02 organization review and key initiatives
- AHWP TC WG02 organization review and key initiatives
- SG02 support to AHWP in implementation of GHTF SG02 guidance documents including the trainings
- AHWP support to SG2 initiatives
- Collaboration programs between SG02 & AHWP TC WG02



Agenda

- Implementation of Adverse Event Reporting system:
 - Manufacturer's report to the Competent Authority;
 - National Competent Authority Report Exchange Programm:
 - Similarities and divergence between SG2 and AHWP WG2 guidance
 - How does SADS and NCAR exchange system compare?
 - Possibility of Sharing of reports among NCAR and SADS participants



WG2 Update

- PMS Survey:
Draft Report on Current Requirements for Post Market Surveillance & Vigilance System is completed
- Review of Implementation of GHTF SG2 Documents status is completed for 7 AHWP economy members
- Safety Alert Dissemination System (SADS) Participating Members: 8,
 - YTD there were 2 cases have been circulated



Collaboration with GHTF SG2

- WG2 Co-Chair participates in the SG2 Meetings in Brussels, Belgium and Toronto, Canada
- WG2 regulators are invited to join SG2
- Joint WG2/SG2 Meeting will be held on 5 November 2009 afternoon
- 3 NCARs training in China, India and Thailand.



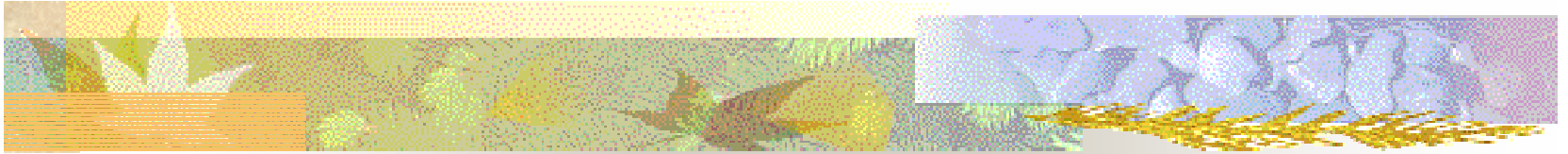
Work Plans

- Finalize the survey report
- Promote SADS/NCAR and education activities
- Propose harmonized requirements for adverse event reporting
- Simplify the SADS Form to encourage reporting
- Study AHWP economy members FSCA definitions
- Study feasibility of providing on-line training through AHWP website



Future Collaboration with GHTF SG2

- Harmonized AE report
- Building regulatory capacity in postmarketing area
- Safety information Handling guidance documents
- Single safety alert system (NCAR)
- Merge NCAR/SADS: Exchange the non-confidential safety information
- Simplify NCAR/SADS forms



THANK YOU!