



Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

AHWP Work Plan & Work Target (2009-2011)

AHWP Secretariat

Hongkong

Nov 06, 2009



AHWP Work Plan (2009-2011)

- **AHWP Terms of Reference & approval process**
- **Establishing E-Newsletter**
- **Renewing AHWP website**
- **Annual summary and comparison study on member's regulatory systems**
- **Promoting the development of AHWP Annual Meeting and workshop reform**
- **Improving work efficiency of TC / WG**
- **Strengthening cooperation with GHTF , APEC & WHO**
- **Setting up permanent Secretariat**



AHWP Terms of Reference & Approval Process

- Complete framework of AHWP /TC
 - Revising Term of Reference
 - Initiative or revision process
 - Voting or Passing process



E-Newsletter Establishment

- On AHWP website or E-mail sending
 - News and activity report
 - Focus discussion or forum
 - AHWP or Member's positions
 - Policy & regulatory report
 - Etc.



Annual Summary and Comparison Study on Member's Regulatory Systems

- Purposes / objectives
- Questionnaire and survey
- Methods and member investigators
- Result illustration
- Deviation of harmonization from GHTF principles
- Analysis and recommendations
- Future trend



Renewing AHWP website

- New website: www.AHWP.info
- Managed by HKPC at present.
- Managed by AHWP permanent Secretariat in the future.
- New business operations.
- Serve for AHWP future development.



Promoting the development of AHWP Annual Meeting and workshop reform

- Establish organizing committee & core team to guarantee the Annual meeting.
- Encourage member economies' participation and express their viewpoints.
- Hold hot topic discussion.
- Centralize views of different member economies.
- Cooperate with other international organizations to ensure that the global in same step.
- Form conference resolution.



Improving work efficiency of TC / WG

- Next 3 years work plans of TC and WGs as part of AHWP work plan.
- Perioddly hold Tele-con by TC and WGs Chair.
- Publish progress/outcome/objective or roadmap.
- Develop pilot experience in member economies.
- Achieve substantive results in some area.
- Frequently contact with GHTF Study Group and attend GHTF SGs meeting.



Strengthening cooperation with GHTF , APEC & WHO

- Regularly communication between AHWP Chair and GHTF Chair.
- AHWP and GHTF Participating each annual meeting and present progress of each organization.
- Regular cooperation training with APEC/WHO.
- Funding of seminars / trainings.



Setting up permanent Secretariat

- AHWP as a nonprofit organization needs to registered a legal entity.
- Set up AHWP ltd. in Hongkong.
- Finance management for AHWP activities.
- Fix office location of permanent secretariat in Hongkong.





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AHWP Work Targets (2009-2011)



Accumulate experiences of pilot implementation of AHWP CSDT

- Accumulate experiences of pilot implementation of AHWP CSDT among member economies.
- A competent authority in a member economy implements CSDT as the pre-market conformity assessment submission document for appropriate class(es) of medical device.
- Technical documents such as QMS auditing report or clinical evidence or type test results are shared by different competent authorities for conformity assessment



Implementation of Safety Alert Dissemination System (SADS)

- Implementation of Safety Alert Dissemination System (SADS) in member economies where the regulatory system is developed and the resource allows.
- An adverse event report, a recall, a warning known or issued by a competent authority is provided from this authority to the sharing system for other member economies.
- All participating competent authorities have been trained in SADS requirements and operation.



Manage to reach a single nomenclature system and UDI system in the world

- Manage to reach an agreement or consensus on a solution toward a single nomenclature system and UDI system for regulatory purposes in coordination with GHTF.
- AHWP jointly with GHTF will train member economies on the nomenclature system and UDI system.



Establishment of the principles of a rules-based device classification system

- The definition of “medical device”, “manufacturer”, “distributor”, “importer” and authorized representative” based on GHTF guidance.
- AHWP documents related to principles and definitions are released, and applied in member economy.



Enlarge AHWP training capacity

- Completion of AHWP capacity training by certain number of students enrolled from member economies.
- Continue good cooperation with other international organizations (GHTF, APEC, ASEAN and others) in AHWP workshop/training program
- AHWP organizes workshop(s) on GHTF documents in member economy funded by APEC.



Draft AHWP guidance documents for implementing GHTF principles in QMS requirement

- Mainly in QMS auditing and clinical evaluation.
- An AHWP guidance document in QMS, auditing and clinical investigation is drafted, commented and then finished.



Thank you !

