AHWP Work Target (2009-2011) – Draft Proposal

The following should be achieved by the end of 2011

1. Solid experience of pilot implementation of AHWP CSDT, as well as sharing/recognition of pre-market approval among member economies; minimal indicators:
    - A competent authority in a member economy implements CSDT as the pre-market conformity assessment submission document for appropriate class(es) of medical device, one or more manufacturer(s) submit CSDT(s), and the result of conformity assessment of this member is recognized by other members;
    - Technical documents such as QMS auditing report, clinical evidence or type test results are accepted by a competent authority for conformity assessment, and the same documents and results are accepted by the competent authorities of other members.

2. Implementation of Safety Alert Dissemination System (SADS) in all the member economies where the regulatory system is developed and the resource allows; minimal indicator:
    - 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.

3. In coordination with GHTF, an agreement/consensus on a solution is reached toward a single nomenclature system for regulatory purposes; minimal indicator:
    - AHWP jointly with GHTF have decided on agreement with UMDN or GMDN that the nomenclature system is to be applied by members.

4. Establishment of the principles of a rules-based device classification system, as well as the definition of “medical device”, “manufacturer”, “distributor”, “importer” and authorized representative” based on GHTF guidance; minimal indicator:
    - AHWP documents related to principles and definitions are released, and applied in member economy.

5. Establishment of AHWP as a permanent legal entity registered by 2011;
    - AHWP as a nonprofit organization is a registered legal entity in a member economy.

6. Completion of AHWP capacity training by certain number of students enrolled from member economies. And continuation of good cooperation with other international organizations (GHTF, APEC, ASEAN and others) in AHWP workshop/training program; minimal indicator:
    - A certain number of students finish training program successfully and gain the diploma /certificate, and then are active in regulatory capacity development and/or regulatory affairs.
    - AHWP organizes workshop(s) on GHTF documents in member economy, funded by APEC.

7. Completion of AHWP guidance documents for implementing GHTF principles in QMS requirement, QMS auditing and clinical evaluation, minimal indicator:
    - An AHWP guidance document in QMS, auditing and clinical investigation is drafted, commented and then finished.

AHWP Work Intermediate Targets by 2009 – Draft Proposal

1. Meeting on work planning to be held in Dec 2008, Shenzhen
2. New Secretariat set up by the end of 2008
3. Discussion and Setting up AHWP work plan and target (2009-2011) by the end of 2008
4. AHWP TC/WGs develop guidance documents according to work plan and targets
5. TC/WG progress/outcome, report to AHWP Chair quarterly and to 14th AHWP meeting
6. Comparative study and annual summary of regulatory systems in member economies, report to 14th AHWP meeting
7. 14th AHWP Meeting to be held in Oct-Nov Hong Kong
8. Newsletter bimonthly (quarterly?) from Jan to Dec, 2009
9. AHWP Chair and AHWP delegation to attend GHTF if it takes place in 2009
10. TC/WG Chairs to attend GHTF SG if a SG meeting takes place in 2009
11. Passing TOR at 14th AHWP meeting if consensus is reached for any changes or revision