Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Asian Harmonization Working Party Technical Committee

Work Plan Meeting

20 Dec 2008

Wu Zhou Guest House
Shenzhen, China

Scope

- Key Deliverables of AHWP Technical Committee
- Work Items for Workgroups:-
  - WG01, WG01a
  - WG02
  - WG03
  - WG04
  - WG05
  - WG06
  - STG GMDN
  - STG AHWP Legal Entity
- Discussion on foreseeable problems / implementation difficulties, etc

Technical Committee's Guiding Principles

- Implementation – Without experience of implementation, there is no momentum and confidence with guidances
- Project professionalism and technical competencies of Technical Committee
- Commitment, especially from Committee Members, to implementation of harmonisation

Technical Committee's Key Deliverables

- Study and publication of guidances OR adoption of GHTF guidances – XX from each WG
- Implementation of guidances by member economies – Committee members' commitment to implementation
- Targeted training seminars, to be organized by each WG – specific topics of interest for harmonization of medical device regulations; XX from each WG

AHWP WG01 Work Items

1. Finalize and propose adoption AHWP CSDT document
2. Prepare comparison of GHTF STED and AHWP CSDT
3. Prepare and finalize guidance on AHWP CSDT
4. Implement pilot trial on AHWP CSDT in AHWP member economies
5. Finalize the principles and elements of conformity assessment for medical devices
6. Conduct survey on medical device registration requirements in AHWP member economies
7. Study the definition of manufacturer
8. Special import process (scope to be clarified in t-con)

AHWP WG01a Work Items

1. Study and report on the definition of IVD in AHWP member economies
2. Study and report to member economies on the feasibility of adopting GHTF IVD classification rules
3. Prepare and finalize guidance on AHWP CSDT for IVD
4. Implement pilot trial on AHWP IVD CSDT in AHWP member economies
5. ……
6. ……

AHWP WG02 Work Items

1. Improvement to Safety Alerts Dissemination System – e.g. sharing of assessment results, etc.
2. WG Chair / Co Chair will elaborate

AHWP WG03 Work Items

1. Promote the use of ISO 13485 as one of the cornerstone of conformity assessment
2. Explore and liaise with GHTF and International Accreditation Forum (IAF) on accreditation for ISO 13485
3. Increase adoption and use of ISO 13485 in AHWP member economies
4. Propose adopt and use: SG3, Quality management system – Medical Devices – Guidance on the control of product and services obtained from suppliers. Submitted to steering committee for final approval,
5. Propose adopt and use: SG3,Quality management system – Medical Devices – Guidance on corrective action and preventive action (Under development)

AHWP WG04 Work Items

1. Study and report to member economies on the feasibility of adopting GHTF WG04 guidance documents
2. Study and report to member economies on the feasibility of implementing GHTF WG04 guidance documents e.g. standard format for preparing audit reports
3. ……..
4. ……..

AHWP WG05 Work Items

1. Study and report to member economies on the feasibility of adopting GHTF SG5 guidances
2. Study and report to member economies on the similarity and difference between EU MedDev 2.7.1 guidance document on evaluation of clinical data and SG5's
3. Liaise and propose recommendations to WG01 regarding CSDT's section on clinical evidence
4. Promote Helsinki's Declaration on ethics governing clinical investigations
5. WG Chair / Co Chair will elaborate

AHWP WG06 Work Items

1. Commitment to drafting of training materials for each member economy – e.g. Industry committee members collaborate with regulators to draft and finalize training materials
2. Solicit firm commitment from member economies on completion date for training materials
3. Publicize training and commence enrollment (with definite timeline e.g. through adoption of an (AHWP – X) formula in order not to delay implementation)
4. All TC representatives will be trainers and lecturers of the program as agreed. Eric will provide the training template and sample with deadline to secretariat, and secretariat will follow up all TC representatives
5. Target launch date is 30 Mar 09 (or latest 15 May 09)

AHWP STG GMDN Work Items

1. Urgent: GHTF moving forward fast
2. Monitor progress and provide periodic update to AHWP regarding the implementation of GMDN corporate governance and fee payment system
3. Liaise and propose recommendations to WG02 regarding application of GMDN to SADS

AHWP Legal Entity Work Items

1. Urgent: Setting up of AHWP as a legal entity
2. Corporate governance structure to manage funds

Recommendations

- Implementation
  - To speed up implementation and gather momentum, propose using the (AHWP – X) formula for implementation
  - Celebrate success stories
- Project Professionalism of Technical Committee
  - Public consultation on all guidance documents
  - Seek approval from AHWP member economies to finalize guidance documents
  - Populate website with finalized documents in order to project AHWP website as a resource of choice on Asian regulations
- Commitment to implementation
  - Participation in meetings is no longer enough; expect TC members to implement and harmonize

Discussion from Teleconference

- Accreditation of 3rd party conformity assessment bodies

- Certificate of Free Sales
  - Accept that use of FSC is inevitable in the interim
  - Guidance on what is in that FSC issued by that exporting country; aims to clarify doubts and constraints of that FSC

Discussion

- foreseeable problems / implementation difficulties, etc

Thank You

China SFDA, SZ FDA

CAMDI

Asian Harmonization Working Party
Technical Committee

20 Dec 2008