14th Asian Harmonization Working Party Technical Committee

Report/Overview of the Seoul Meeting

July 2011

8 November 2011
Bali, Republic of Indonesia
Hyatt Hotel

ASIAN HARMONIZATION WORKING PARTY

14th AHWP TC Meeting – Bali
Agenda

- **Review of 13th AHWP TC Meeting (Seoul)**
- Announcement of the Election Arrangement for Office Bearers of: AHWP and AHWP TC Officers
- Adoption of TC Meeting Agenda
- Progress Report from
  - WG 1, 2, 3, 4, 5 and 6
  - STG (Legal Entity) and STG (Nomenclature)
- Report on the formation of AHWP Administration Services Limited
- Briefing on TC Office Bearer Election

ASIAN HARMONIZATION WORKING PARTY

Review of 13th AHWP TC Meeting

- AHWP TC Meeting (6 – 7 July 2011)
- Working Items:
  - Progress Report from
    - WG 1, 2, 3, 4, 5 and 6
    - STG (Legal Entity) and STG (Nomenclature)
  - Discussion on nomination procedure and positions for AHWP elections
  - Training

WG1 – Premarket Submission & CSDT

Chair: BAI Huifen Co-Chair: Daphne YEH

Sub-group 1: STED and CSDT

- Completed mapping of CSDT and STED
- To project AHWP as a good reference source for CSDT

Sub-group 2: Definition of Manufacturer

- Proposal for Definition of a Manufacturer

Sub-group 3: Labelling requirement

- e-labeling : comply with local regulatory requirements including requirements for local IFU

Sub-group 4: Classification

- Survey done & results gathered. To consult with member economy representatives on the classifications of medical devices before making any recommendations.

Sub-group 5: Combination products

- Report on a baseline study of GHTF Founding Members and **survey the experience of 3 AHWP member economies** (Chinese Taipei, SFDA, Singapore) that have implemented registration of combination products.

WG1a – IVD Subgroup

Chair: Essam Al MOHANDIS Co-Chair: Jeffrey CHERN

- Completed gap analysis of IVD medical devices regulations in member economies

- Liaising with GHTF in developing Guidance documents for IVDs on Essential principles, labeling and on Clinical evidence

- Completing feasibility study on the adoption of the IVD STED, definition and concepts on clinical evidence of IVD proposed by GHTF

Possible update in the agenda today.

WG2 – Post-market Surveillance & Vigilance

Chair: Yorkie CHOW Co-Chair: Miang TANAKASEMSUB

1. SADS Update

- 15 AHWP member economy members joined SADS
- WG2 disseminates safety alerts information on weekly basis (contribution from Saudi FDA)
- Trial run of SADS online on AHWP website

2. Harmonized AE and FSCA forms across AHWP member economies

- Proposed AE and FSCA forms for AHWP approval
- Post the electronic AE and FSCA forms on the AHWP website

(Proposed Forms in alignment with forms for ASEAN post-market?)

3. Review of implementation of GHTF SG2 documents status

- Completed for 7 AHWP member economies

4. Training

- To disseminate SG2 and other training materials on website
- WG6 to coordinate the training on long term basis with support from WG2

WG3 – Quality Management Systems

Chair: Ali M AL-DALAAN Co-Chair: Ronald GOON

1. Collaboration with GHTF

- Involved in development of guidances N17, N18 and to participate in development of N19 with GHTF SG3
- Participation with GHTFSG3, ISOTC210 in revision of ISO 13485

2. Adoption of GHTF Guidance documents

- Adopted the N17 (Guidance on the control of product and services obtained from suppliers)
- To circulate the N18 document (CAPA) for review by AHWP member economies and industry – **Feedback from member economies**

3. ISO 13485 Revision User Requirements Survey – online survey to be submitted directly to ISO agency

Complete the QMS survey based on responses from AHWP member economies

WG4 – Quality System Audit

Chair: Moloy MITRA Co-Chair: Eun Hee CHO

GHTF Guidance documents

- On-going review and consideration of all five parts of SG4 guidance on auditing and discuss among work group members
- To present the key aspects of the GHTF guidances in the agenda item today for TC consideration of adopting the guidances in full or with amendments

WG5 – Clinical Safety/Performance*

Chair: Jie GAO Co-Chair: Quan TRAN

1. Comparative study of clinical trials regulations & related guidances on clinical safety/performance in AHWP member economies

- Survey Form circulated to member economies
- Analyzed the development of clinical trial regulations in member economies

Analysis of survey performed to be presented in the update report later.

2. Review GHTF SG5 documents & feasibility study to adopt the GHTF SG5 documents by AHWP member economies

- Study and review of the GHTF SG5 documents completed within WG5
- Based on the outcome of clinical trials regulation survey, to make recommendations on feasibilities of adoption

Feasibility study report to be presented in the update report later.

WG6 – Regulatory Training*

Chair: Sanjay S KUMAR Co-Chair: Jack Wong

1. To explore and leverage on APEC AHC framework for regulatory convergence for training.

- Additional topics of interest include: - combination products, clinical evaluation and post-market training programs

2. To consolidate training info by each WG and post the info on AHWP website for visibility.

3. To present strategic training roadmap for consideration during Bali meeting.

Notation: Each WG may continue to conduct training.

Amend AHWP Website details for WG6

STG – Legal Entity

Chair: Althea LAU Co-Chair: Jack Wong

1. Establishment of AHWP ASL

- Business Registration obtained in April 2011
- Bank Account to be set up by September 2011
- Founding Members
  - Regulatory members and Industry members (have voting rights)
  - Associate members

2. Objective of AHWP ASL

- To provide administrative service and execute legal mandate to help achieve the goals and mission of AHWP

→ Complete information available in “Memorandum and articles of association of AHWP ASL”

(available on the AHWP website)

STG – Medical Device Nomenclature

Chair: Lianchun YANG Co-Chair: Lindsay TAO

1. **Joined GHTF efforts on GMDN governance reform** – participation in GMDN management as part of Policy Advisory Group (PAG) and Board of Trustees (BOT)

→ Priority work items at GMDN
- Funding and Business model of GMDN
- Free access to regulators
- Development of GMDN SOP including scope, transparency, procedure on development of new terms, obsolete terms, translation etc..
- Finalize document on "Regulatory Use of GMDN"

2. **Participated in WHO efforts on single nomenclature**

→ Agreed on mapping of GMDN and UMDNS

3. Participated in development of draft GHTF document on UDI as joint efforts between AHWP and GHTF
(document published for comments in Nov 2010)

4. To explore possibilities for training on UDI for AHWP member economies

Others

1. Proposed Project workgroup on Membership: (Temporary)

- To update the list of member economies and include the details of all country representatives (primary and secondary) for both AHWP and AHWPTC
  (Acting Chair – Ee bin)
  Project closed.

2. Recommendation to update records on name of WG5

- Correct name: Clinical Safety/Performance*

3. Website update to include hyperlinks to regulatory requirements of various AHWP member economies

- Jack and the Secretariat to work on this task
- To mention that AHWP is not responsible for the contents and information in the links

Updates will be reported in upcoming presentation.

THANK YOU