17th Asian Harmonization Working Party Meeting

Report on the 16th AHWP TC Meeting (Technical work items only)

5 November 2012

Joanna Koh

Chair, AHWP Technical Committee

Working Group Update Reports

WG1 : Pre-Market Submission and CSDT

Chair: Hui Fen BAI, Regulator, HSA, Singapore
Co-chair: Alfred KWEK, Industry, Singapore

Key Achievements:

1. Mapping of CSDT to STED complete and document published on website
2. Introduced Software overview in Manila meeting and catered for training on software in this meeting.

Next Steps:

1. New GHTF Definition for Medical Device – To review and analyze the impact of the changes to the definition
2.To continue ongoing work on medical device software.

Working Group Update Reports

WG 1a: IVDD

Chair: Li-Ling LIU, Regulator, Chinese Taipei
Co-chair: Jeffrey CHERN, Industry, Chinese Taipei

Key Achievements:

1. Active participation and inputs on GHTF guidance documents on IVD clinical evidence - finalized and completed – To be endorsed by AHWP
2. Conferences organized on regulatory convergence for IVDs

Next Steps:

1. Training for AHWP member economies including developing training materials
2. To keep abreast of upcoming challenges generated from new clinical applications and technology innovation in IVDs.
3. To work with other workgroups in TC (e.g. clinical investigation – WG5, Quality systems – WG3) to enable a life cycle approach for regulation of IVDs.

Working Group Update Reports

WG2: Post-Market Surveillance and Vigilance

Chair: Yorkie CHOW, Regulator, DOH, Hong Kong SAR
Co-chair: SAINI Kulwant, Industry, India

Key Achievements:

1. Developed common AE and FSCA forms for use across AHWP economy members
2. Document on website for comments – AE report form and Definition and classification Field corrective actions.

Next Steps:

1. Secure SADS system
2. Review other GHTF guidance documents and consider training/ adoption
3. Set up SADS secretariat

Working Group Update Reports

WG3: Quality Management System

Chair: Ali AL-DALAAN, Regulator, Saudi FDA, Saudi Arabia
Co-chair: Ee Bin LIEW, Industry, Singapore

Key Achievements:

1. Completed QMS survey and analysis
2. GHTF N17 and N18 documents endorsed by AHWP, to consider for implementation
2. Liaison Member with ISO TC210 – provided comments for ISO 13485 through TC210 on behalf of AHWP.

Next Steps:

1. Elements of QMS for import and distribution of medical devices
2.Develop awareness for the need to have QMS requirement and share best practice among members.

Working Group Update Reports

WG4: Quality System Audit

Chair: Abdullah AL RASHEED, Regulator, Saudi FDA, Saudi Arabia
Co-chair: E H CHO, Industry, Korea

Key Achievements:

1. Completion of the review of the GHTF guidance and reformat for AHWP
2. Developed new work item for the auditing of importers and distributors.

Next Steps:

1. Development of new guidance for auditing for importers and wholesalers
2. Development of training program on auditing for member economies.

Working Group Update Reports

WG5: Clinical Safety/Performance

Co-chair: SUMATI Randeo, Industry, India

Key Achievements:

1. Mapped the differences between old and new versions of ISO 14155.
2. Provided consolidated comments on New GHTF guidance documents on clinical evidence for IVDs.

Next Steps:

1. Guidance on determining Risk/Benefit analysis in pre and post market scenarios
2. Clinical and nonclinical evaluation of nano particles
3. To coordinate training for member economies with WG6.

Working Group Update Reports

WG6: Capacity Building and Regulatory Training

Chair: Rama SETHURAMAN, Regulator, HSA, Singapore
Co-chair: Jack WONG, Industry, Singapore

Key Achievements:

1. Training needs of TC workgroups collated, prioritized and some topics covered in current AHWP meeting.
2. Links to external training platforms for members' review on AHWP website.

Next Steps:

1. Setting up of a post-training feedback system
2. Explore other training platforms and collaboration partners (e.g. WMDO, RAPS)

Working Group Update Reports

STG(N): Medical Device Nomenclature

Chair: YANG Lian chuan, Regulator, SFDA, China
Co-chair: Carol YAN, Industry, China

Key Achievements:

1. Member recruitment and membership list update
2. Collaboration and connection with GMDN – training on UDI conducted
3. Pilot study on UDI implementation in China

Next Steps:

1. Continue study on GMDN feasibility and provide recommendations
2. Work with AHWP economies for nomination of regulators and obtain access to GMDN database
3.Follow up closely with IMDRF UDI working group

Secretariat Updates – Summary

ASIAN HARMONIZATION WORKING PARTY

Working Group Update Reports

Secretariat Update – Upcoming Endorsements on 5th Nov2012

Amendment 2 to AHWP & AHWPTC Terms of Reference (TOR)

-To eliminate conflicting/ambiguous terms and elements

- Clauses edited
  - 1.2 Membership
  - 1.3 Leadership
  - 1.5 Relationship with other parites
  - 2.2 AHWPTC membership
- Posted on website for comments
- To be endorsed in main meeting on 5th Nov 2012

Amendment 1 to AHWP House Rules

- Clauses edited
  - 3 Nominations and Elections of the AHWP Chair/co-chairs
  - 9 Appointments of AHWP and AHWPTC Representatives
- Addition of Clause 17
- Posted on website for comments
- To be endorsed in main meeting on 5th Nov 2012

ASIAN HARMONIZATION WORKING PARTY

Working Group Update Reports

Advisory Panel for AHWP Technical Committee

1. A panel of advisors to be appointed for the Technical Committee.

2. Propose that Members' approve to pass the resolution –
   Addition of Clause 17 for appointment of Advisors to AHWPTC

3. If resolution is passed,

   - The 1st meeting of the Advisory Panel with the TC Leaders is proposed to be in **March / April 2013**.

   - **Purpose**: To facilitate interaction of advisors with WGs and chart the way forward to meet the goals of AHWP and AHWPTC

THANK YOU