Asian Harmonization Working Party
Technical Committee
WG update

30 Nov 2010, Riyadh, Kingdom of Saudi Arabia

Asian Harmonization Working Party
Technical Committee
WG 1

Accomplishments

- STED - CSDT Comparison Data
- AHWP CSDT-STED Mapping Document

Next Action Steps

- Recommendations on Labelling Requirements
- Definition of Manufacturer, Authorisation Representatives etc.
- Survey on the adoption of STED or CSDT

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Technical Committee
WG 1a

2010-2011 Work Plan

Work Item	Deadline
Gap analysis of IVD medical devices regulations in member economies Feasibility study on adoption of the classification and conformity assessment of IVD medical devices proposed by GHTF	Mar 28, 2010 (Extended to Jul 31, 2010)
Liaise to GHTF in developing related documents on clinical evidence for IVD medical devices	Jul 31, 2010 (Extended to Sep ,2010)
Liaise to GHTF in developing related documents on the Essential Principles and labeling of IVD medical devices	Dec 31, 2010
Holding workshop on GHTF documents on IVD medical devices regulations	During 15th AHWP- 12th TC meeting Sunday 28th Nov 2010 by:Dr.Petra Wiele
Feasibility study on the adoption of the IVD STED, definition and concepts on clinical evidence of IVD medical devices proposed by GHTF	Sep, 2011

Ever since the foundation of this subgroup, we have been working closely with GHTF in the harmonization of IVD medical devices regulations

Achievements

- AHWP-WG01a has been cooperating with GHTF-SG01a to review or draft the following documents:
  - SG1-N45:2008 Principles of In Vitro Diagnostic (IVD) Medical Devices Classification
  - SG1-N46:2008 Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices
  - SG1(PD)/N063 “Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices”
  - “Clinical Evidence for IVD medical devices–Key Definitions and Concepts” (Draft)
  - ”Clinical Evidence for IVD medical devices–Clinical utility and performance evaluation” (Draft)

The documents were subject to the review of WG01a and comments were consolidated and reflected in GHTF SG1 IVD Subgroup working meetings.

Progress (1)

Work Item	Deadline	Status
●Gap analysis of IVD medical devices regulation within AHWP member economies ●Feasibility study on adoption of the classification and conformity assessment of IVD medical devices proposed by GHTF	Mar 28, 2010 (Extended to Jul 31, 2010)	Inputs from 5 member economies have been consolidated.

Progress (2)

Work Item	Deadline	Status
Liaise to GHTF in developing the following documents: ●"Clinical Evidence for IVD medical devices– Key Definitions and Concepts" (Draft) ●"Clinical Evidence for IVD medical devices– Clinical utility and performance evaluation" (Draft)	Jul 31, 2010 (Postponed to Nov 30, 2010)	**Underway** : collecting comments & will be discuss during 6-10 Dec 2010 Ca-meeting.

Both draft guidance are available upon request. (For internal circulation only.)

Progress (3)

Work Item	Deadline	Status
Liaise to GHTF in developing documents on the following topics : ●Essential principles for demonstrating the safety and performance of IVD medical devices ●Labeling of IVD medical devices (including graphical symbols)	Dec 31, 2010	Underway: □ Conducting exercises on the EP for IVD medical devices □collected comments will be discussed during Dec, CA-meeting

Progress (4)

Work Item	Deadline	Status
Holding workshop on STED for IVD medical devices and various related topics	(28th Nov 2010)	the presenter: Dr. Petra Carls Wiele

2011 Work Plan

Work Item	Deadline
• Feasibility study on the adoption of the IVD STED, definition and concepts on clinical evidence of IVD medical devices proposed by GHTF. • Proposing the training for IVDMD capacity building needs	Sep, 2011

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WG 2

WG2 Key achievements

- Dissemination of Saudi's NCMDR on weekly basis

(To become effective shortly)

- SADS ON-Line Reporting (Trial website available)
- Training Material Folder under AHWP Website

(Posted already)

- Draft Adverse Event Report Form (For comments)
- Draft FSCA Report Form (For comments)

Work Plans

- Training
  - Create the folder under AHWP WG02 & post all the trainings + VDO that need consent form from all the trainers to upload on the folder.

  - Proposed structure the trainings
    - Basic training
      - SG02 guidance documents
      - Manufacturers Trend Reporting of Adverse Events
      - Guidance of How to handle information concerning Vigilance Reporting Related to Medical Devices
      - FSCA

Work Plans

- Training (Cont)
  - Advance program
    - Mark Bruley (ECRI)_AE investigation program
      - Plan to VDO taping for the whole training
      - After AHWP meeting, plan to provide DVDs to the regulators and industries group for each economy
      - Long term_Propose WG06 to take care all these materials distribution

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WG 3

Achievements

- Worked with GHTF SG3 to actively developed N17 (Guidance on the control of product and services obtained from suppliers) and N18 (Guidance on corrective action and preventive action).
- Reviews by WG3 and AHWP member economies of N17 did not raise any issues that required modification of the document for use by AHWP. As such, WG3 recommends that document be adopted by AHWP with no changes.
- Initiated survey on the QMS requirements in AHWP member economies and analyzed data from responses received to date.
- Initiated development of N19 (Criteria for characterizing the significance of QMS deficiencies) with GHTF SG3

Next Steps

- Complete QMS survey by obtaining responses from remaining AHWP member economies and analyzing data
- Complete development of N19 with GHTF SG3
- Review comments and feedback from AHWP on N18 and evaluate for adoption by AHWP
- Work with GHTF SG3 and ISO TC210 to evaluate need for revision of ISO 13485 and, if applicable, to work on follow-up activities

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WG 4

- Action items for WG4 had unclear objectives or guidelines.
- working group members proposed to survey the demands of each member economy for auditing.

Action Plan in 2010

- WG4 members proposed a survey in June.
- Developing Questionnaires in July.
- Questionnaires review meeting via Telcon in August.
- Finalizing and deploy the Questionnaires in September.
- Gathering answers from both Industries and Regulators during Oct.– Nov.

Survey Results

- 7 member economies(China, Chinese Taipei, India, Korea, Malaysia, Saudi Arabia, Singapore) out of 9 have audits and audit regulations.
- Improvement areas that member economies see;
  - Auditors' qualification and training
  - Audit guidance to be consistent.
  - Standardized audit report.

- **Some opinions look too subjective to represent member economies.**
- **Limited to 9 member economies only.**
- **Expectations are various based on regulations developmental status.**

Some Questions

- Do we need more feedbacks to have a full picture of audit status of AHWP member economies ?
- Do we have to go for ISO standard first or GHTF guidance for auditing for AHWP member economies ?

Plan for 2011

- Feedback on survey results in Dec 2010.
- Identify & prioritize key action items for WG4 to focus on in Jan.
- Review of ISO or GHTF guidance in Jan – March.
- Top priority project kick-off in April.
- Progress update on AHWP TC meeting
- Delivery the outcome in 16th. AHWP meeting

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WG 5

WG5 - Progress Report

1. Comparative study of Clinical Trials Regulations & related guidances on Clinical Safety/Performance in AHWP member economies

➢ Review Clinical Trials Regulations or its developments in China, **India**, Korea, Singapore, Chinese Taipei &Thailand

2. Training Initiatives

➢ **Workshop at 10th AHWP TC meeting, Singapore, May 2010**

- Painting the Clinical Picture: Clinical Evaluation & Clinical Evidence by Mr. Greg LeBlance, Vice Chair GHTF SG5

➢ **Workshop at 15th AHWP annual meeting, Saudi Arabia, Nov 2010**

- **ISO14155** by Ms. Danielle Giroud, Convenor TC 194 WG4

3. Review GHTF SG5 Document & make recommendations to AHWP member economies on the feasibilities of adoption

➢ **Completed studying and reviewing 5 GHTF SG5 documents (incl. 1 in draft)**

4. Set up Advisory Expert Panels of GHTF SG5 members

➢ **6 members** incl. Chair & Vice Chair; 2 Japan, PMDA officers; 2 Industry experts (EU & Australia)

Presented by Gao Jie/Tran Quan (Chair/Co-Chair AHWP WG5)

Reaching 2011 Milestones - Strategies & Plans

1. Leveraging on the Advisory Panel of SG5 experts for training & advice on GHTF SG5 documents review & adoption
   - March / April 2011 – Review of **Clinical Evidence, Key Definitions & Concepts** (SG5/N1R8:2007) & **Clinical Evaluation** (SG5/N2R8:2007)
   - May/June 2011 –**Face to face working session** (SG5-WG5)
     - **Review AHWP guidance document on adoption of GHTF SG5 GN**
     - **Discuss at least one GHTF GN on feasibility of adoption in AHWP member economies**
   - June-Sept 2011 – Seek preliminary input from member economies on draft GN
   - Oct 2011 – **Follow up to finalize recommendations for AHWP Annual meeting '11**
2. Comparative study of Clinical Trials Regulations & related guidances on Clinical Safety/Performance in AHWP member economies
   - **Deep dive into member economies regulations**
   - **Update survey with new questions**
3. Training Initiatives
   - **Organize experts to speak on GCP & Declaration of Helsinki at AHWP conferences**
   - Invite **Regulators from Member Economies to discuss Clinical Trial Regulations development & directions**
4. Greater collaborations with other international organizations / Work Groups
   - E.g. **APEC Harmonization Centre** & **Harmonization By Doing (USFDA & MHLW, Japan)**

Presented by Gao Jie/Tran Quan (Chair/Co-Chair AHWP WG5)

Asian Harmonization Working Party
Technical Committee
WG 6

ASIAN HARMONIZATION
WORKING PARTY

STG Nomenclature

Lindsay Tao, Co Chair
15th AHWP Annual Conference,
Riyadh, Saudi Arabia

Achievements

- Nomination of two representatives to Board of Trustee of GMDN
  - China SFDA, Mr. Chang Yongheng
  - Singapore HSA, Mrs. Christina Lim
- Nomination of new Chair of AHWP STG nomenclature
  - China SFDA, Mr. Yang Lianchun

Next Step

- Nomination of 5 PARTICIPANTS from AHWP to be Policy Advisory Group at GMDN
  - 1 from each of the following members - CHINA, MALAYSIA,SAUDI ARABIA,SINGAPORE,SOUTH KOREA
- Join WHO special work task force on nomenclature
- Work with WHO, GMDN and other stakeholders on a single nomenclature system for medical device
- Working on issues on governance, charging fee transparency, communication and response mechanism of nomenclature system

AHWP


Break for
Questions ??
James Nedock / The Monitor