AHWP WG5

- Progress Report

AHWP Meeting, Saudi Arabia

Presented by Gao Jie/Tran Quan,
WG 5 Chair/Co-Chair

27 November 2010

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

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WG5 MEMBER LIST - Update

Last Name	First Name	Regulator/Industry	Organization/Company	Economies
Gao	Jie	Regulator	SFDA	China
Tran	Quan	Industry	GE Healthcare	Singapore
Huang	Hsiau-Wen	Regulator	TFDA	Chinese, Taipei
Thangavelu	Sasikala	Regulator	Medical Devices Control Division	Malaysia
Feng	Yan	Industry	Philips Healthcare	China
Guo	Ye	Industry	Johnson & Johnson	China
HAN	Rena	Industry	Boston Scientific	China
Han	Davey	Industry	BrightStars Hitech Development Co. Ltd	China
Huang	Jin	Industry	Shenzhen Association of Medical Devices	China
Lee	Peter	Industry	Straumann	Korea
Lv	Fang	Industry	Synthes	China
Mi	Xianqiang	Industry (Academia)	USST	China
Peterson	Katy	Industry (Advisor)	Boston Scientific	USA
Randeo	Sumati	Industry	Abbott Vascular	India
SU	JING	Industry	SYSMEX	China
wong	Woei Jiuang	Industry	Ciba Vision	Singapore
Wang	Amber	Industry	Medtronic	China
Yan	Carol	Industry	Johnson & Johnson	China

TOTAL : 18

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- **3 Regulators, 1 Academia**
- **Membership covers 6 member economies**

Work Plan 2009-2011

1. Start up WG05 & finalize work plan - Completed
2. Establish WG05 representation at GHTF SG5 (Completed) & participate in the development of SG5 guidance documents (Ongoing)
* 3. Comparative study of Clinical Trials regulations & related guidances on Clinical Safety/Performance in AHWP member economies – Ongoing
* 4. Review SG5 & other relevant guidance documents and make recommendations to AHWP member economies on the feasibility of adoption - Ongoing
* 5. Training to promote Good Clinical Practice, Declaration of Helsinki & ISO 14155 governing clinical investigations - Ongoing
6. Partner with other TC Work Groups' initiatives to provide expertise & input relating to clinical safety/performance eg. WG01 regarding CSDT's section on clinical evidence - TBD

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
   - Training Workshop at 10th AHWP TC meeting, Singapore
     - **Topic: Painting the Clinical Picture – Clinical Evaluation & Clinical Evidence**
     - **Speaker: Mr. Greg LeBlance, Vice Chair GHTF SG5**
     - **Time: May 2010**
   - Training Workshop at 15th AHWP annual meeting, Saudi Arabia
     - **Topic: ISO14155**
     - **Speaker: Ms. Danielle Giroud, Convenor TC 194 WG4**
     - **Time: Nov 2010**

Progress Report – cont'd

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

   - Completed studying and reviewing the GHTF SG5 documents within WG5

   - AE reporting during clinical investigation (GHTF SG2-SG5)
   - Post-market Clinical Follow-up Studies (GHTF/SG5/N4:2010)
   - Clinical Investigations (GHTF/SG5/N3:2010)
   - Clinical Evidence - Key Definitions & Concepts (SG5/N1R8:2007)
   - Clinical Evaluation (SG5/N2R8:2007)

4. Set up Advisory Expert Panels of GHTF SG5 members

   - **6 members**
     - Chair (MHRA, UK) & Vice Chair (Industry, Canada)
     - 2 Japan, PMDA officers;
     - 2 Industry experts (EU & Australia)

Reaching 2011 Milestones

Strategies & Plans

1. Leveraging on the Advisory Panel of SG5 experts for training & advice on GHTF SG5 documents review & adoption
   - March 2011 – Teleconference review of Clinical Evidence, Key Definitions & Concepts (SG5/N1R8:2007) led by Advisory Panel
   - April 2011 – Teleconference review of Clinical Evaluation (SG5/N2R8:2007)
   - May/June 2011 –Face to face working session (SG5-WG5)
     - Review AHWP guidance document on adoption of GHTF SG5 guidance documents (prior draft to be developed by WG5)
     - Discuss at least one GHTF guidance document on feasibility of adoption in AHWP member economies (flushing out issues & focus on practical applications)
   - June-Sept 2011 – Seeking preliminary input & comments from member economies on draft guidance/s
   - Oct 2011 – Teleconference follow up to finalize recommendations

Reaching 2011 Milestones

2. Deep dive into member economies regulations

Update Survey

- Member economies with Clinical Trial Regulations
- Local Trials required for premarket registration or foreign clinical data acceptable
- Any member economies adopted/interested to adopt GHTF SG 5 guidance documents

New questions

- Regulatory agency approval required for clinical trials? Pre & Post market
- Ethics Committee approval required?
- Informed Consent required?
- GCP or ISO 14155?
- Type testing required?
- Clinical Trial Audit conducted by regulatory agencies
- Adverse Event Reporting

Reaching 2011 Milestones

3. Training Initiatives
   - Organize experts to speak on GCP & Declaration of Helsinki at AHWP & AHWP TC conferences
   - Regulators from Member Economies to discuss the Clinical Trial Regulations development & directions

4. Greater collaborations with other international organizations / Work Groups
   - eg. APEC Harmonization Centre & Harmonization By Doing (USFDA & MHLW, Japan)

SG5 Update – Meeting Sept 2010

Key Focus

1. 1) Update on work of joint subcommittee with SG2 – Adverse Event Reporting during Clinical Investigations – and discussion of current draft
2. - Latest draft of the document reviewed by the membership of SG5 with comments noted for discussion within the task force.
3. - Anticipated that once the comments coming out of the SG5 and forthcoming SG2 meeting are consolidated, the document will be ready to be presented to the Steering Committee for posting on the GHTF website as a draft for public comment.
    1.
4. 2. Discussion of SG1 IVD Subgroup work on Clinical Evaluation for IVDs document and Key Definitions and Concepts document
5. - The group received an update on the work on these two documents that is currently underway within the IVD Subgroup of SG1 from two members of SG5 that are participating, Benny Ons and Maria Carballo.
6. - Latest drafts of the documents were discussed by the members of SG5 and comments were provided. Mr. Ons and Ms. Carballo agreed to bring these comments back to the IVD Subgroup for discussion and action at the IVD Subgroup's next meeting.

SG5 Update – Meeting Sept 2010

Key Focus

1.
2. 3. AHWP update
3. - Quan Tran provided an update on the activities of AHWP and its Working Group 5 via dial-in.
4. - WG5 is currently at the stage of its life cycle where it is undertaking a review of the documents produced by GHTF SG5. The goal of this review is to determine the suitability of the documents for adoption in AHWP Member Economies and provide recommendations in this regard.
5. - Quan Tran indicated that close liaison with SG5 was necessary to achieve this goal and asked for a group of SG5 members to help advise WG5 on their activities. Several volunteers were identified

6. 4. ISO 14155 update
7. - Brief discussion of the status of the latest revisions to the ISO 14155 standard was conducted.
8. - Agreed that the latest draft appeared to offer many positive developments. The group was informed that the draft was in its final editorial stage and no substantial changes were envisioned at this point

Appendix

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WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

GHTF SG5 Guidance Document
SG5/N1R8:2007 (final)
Clinical Evidence: Key Definitions & Concepts

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Introduction

- Goal of Study Group 5
  - Promote convergence of regulatory requirements for generation and presentation of evidence of the clinical safety and performance of medical devices’

Scope

- Introduce the concepts of clinical evaluation and clinical evidence
- Examine the relationship between clinical investigation, clinical data, clinical evaluation and clinical evidence
- Serve as guidance to all those involved in the generation, compilation and review of clinical evidence sufficient to support the marketing of medical devices (regulatory authorities, conformity assessment bodies, manufacturers of medical devices and their associated industry groups).

Definitions and Concepts

- Clinical investigation
- Clinical data
- Clinical evaluation
- Clinical evidence

Clinical Investigation

Definition :

Any systematic investigation or study in or on one or more human subjects, undertaken to assess the safety and/or performance of a medical device.

Clinical investigation

Examples:

Feasibility study, regulatory study, premarket study, postmarket study.

Other terms : ‘clinical trial’, ‘clinical study’

Clinical Data

Definition

Safety and/or performance information that are generated from the clinical use of a medical device

Clinical Data

Examples:

- Results of pre- and postmarket clinical investigations of the device
- Results of pre- and postmarket clincial investigations or other studies reported in the scientific literature of a justifiably comparable device
- Published and/or unpublished reports on other clinical experience of either the device in question or a justifiably comparable device

Clinical Evaluation

Definition

- Process undertaken to help establish compliance with the relevant Essential Principles for safety and performance
- A report is generated after the evaluation
- An on-going process
- Input are primarily clinical data

Clinical Evidence

Definition

The clinical data and clinical evaluation report pertaining to a medical device

AHWP

THANK YOU !

Working Towards
Medical Device
Harmonization
in Asia

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