AHWP WG5

- Progress Report

AHWP Meeting, Hong Kong

Gao Jie/ Tran Quan

6th November 2009

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Contents

- WG 5 Member List
- Work Plan 2009-2011
- Progress update – Accomplishments
- Future Direction and Plans

WG5 MEMBER LIST

	Surname	First Name	Regulator/Industry	Organization/company	Economies
1	Gao	Jie	Regulator-Chair	SFDA	China
2	Tran	Quan	Industry-Co chair	GE	Singapore
3	Guo	Ye	Industry-Secretary	Johnson & Johnson	China
4	Feng	Yan	Industry-Secretary	Philips	China
5	Tseng	Hsiu-Ting	Regulator	DOH	Chinese Taipei
6	Poon	Raymond	Regulator	DH	Hongkong SAR, China
7	Sasikala	Thangavelu	Regulator	MD Bureau of MOH	Malaysia
8	Yan	Jirui - Carol	Industry	JNJ	China
9	Lin	Linda	Industry	Boston Scientific	China
10	Han	De Hui	Industry	Siemens	China
11	Huang	Jin	Industry	OrbusNeich	China
12	Lv	Fang -Louisa	Industry	Synthes	China
13	Wang	Yuhong -Amber	Industry	Medtronic	China
14	Sun	Honglei	Industry	Medtronic	China
15	Wong	Woei Jiuang	Industry	CIBA Vision	Singapore
16	Mi	Xianqiang	University	University of Shanghai for Science & Technology	China
17	Vu Thi	Loi	Industry	Johnson & Johnson	Vietnam
18	Randeo	Sumati	Industry	Abbott Vascular	India
19	Su	Jing	Industry	Sysmex	China
20	Peterson	Katy	Industry- Advisor	Boston Scientific	U.S.A
21	Yang	Emily	Industry	Vision Care-JNJ	Chinese Taipei
22	Tang	Rachel	Industry	Synthes	China

TOTAL : 22

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Work Plan 2009-2011

1. Start up WG05 & finalize work plan - Q2 '09
2. Comparative study of Clinical Trials regulations & related guidances on Clinical Safety/Performance in AHWP member economies – '09
3. Establish WG05 representation at GHTF SG5 (Q1 '09) & participate in the development of SG5 guidance documents
4. Review SG5 & other relevant guidance documents and make recommendations to AHWP member economies on the feasibility of adoption
5. Training to promote Good Clinical Practice, Declaration of Helsinki & ISO 14155 governing clinical investigations
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

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Progress Report – Accomplishments

- Set up WG5 in Q1 '09
  - Current total membership: 22 (incl. 4 regulators, 1 Academia, 1 Advisor)
  - Covers 7 member economies
    - China, Singapore, Hong Kong, Chinese Taipei, Malaysia, Vietnam, India
  - Potentially participation from other regulators
- 2 Tcons to date
- 1 face to face meeting (participated by 13 members & supported by SG5 ViceChair)

Progress Report – Accomplishments

- **3 subgroups focus**
  - 1: Comparative Study; 2: SG5 Doc. Review & Adoption; 3: Training
- **Regulation survey to all AHWP economies – Phase I**
  - 10 responded (China, Hong Kong, Singapore, Saudi Arabia, South Africa, Korea, Chinese Taipei, Malaysia, Thailand, Philippines)
- **SG5 document review**
  - AE reporting during clinical investigation (GHTF SG2-SG5)
    - Post-market Clinical Follow-up Studies (GHTF SG5(PD)N4R7)
    - Clinical Investigations (GHTF SG5 (PD)N3R7)

Comparative study of Clinical Evaluation of Medical Devices in AHWP Member Economies

	1. Does your economy have any established regulation on clinical evaluation specifically	2. Does your economy require local clinical trial for pre-market approval?	3. Does your economy accept GHTF guidance documents on Clinical Safety/Performance by SG5?	4. Is your authority interested in adoption of GHTF guidance documents on Clinical Safety/ Performance by SG5?	5. Is your authority interested in AHWP guideline on Clinical Safety/Performance ?	6. Which topic your authority would be interested in regarding to clinical training organized by AHWP?
China	Jan. 17, 2004 Rules on Medical Device Clinical Trial	for most class 2&3 domestic products, part of imported class 3 implantable products and all class 2& 3 IVD products. The guideline to define if the clinical trial is needed or not is instructed in SFDA order 16,"Medical Device Registration Regulation", appendix 12. The link is here: http://www.sfda.gov.cn/WS01/CL0053/25844.html	not yet	yes	yes	yes
HongKong	No. 2010	Clinical Evaluation or Investigation conducted or Bibliography of references from the Index Medicus concerning the device	yes	yes	yes	yes
Singapore	No, currently no plan	For higher risk devices, clinical data is required as part of pre-market application submission.	yes	yes	yes	yes
Saudi Arabia	No, currently no plan	As required in any of the GHTF country members	yes	yes	yes	yes
South Africa	No, currently no plan	No clinical evaluation of medical devices currently in South Africa.	NA	NA	NA	NA
Korea	July 14, 2005 Medical Device Clinical Study Implementation standard	local clinical trial is not required, foreign clinical data needed	yes	yes	yes	yes
Chinese TaiPei	May 30, 2007 Guidelines for Medical Device Good Clinical Practice	1. Clinical data will be required depending on the type of device. 2. If it is required, oreign data may be accepted.	will consider the SG5 documents when they are finalized	Yes	/	yes
Malaysia	Yes, but no time line for issue	We will adopt the GHTF concept, ie clinical trial is required to provide the data not available through other sources (such as literature or preclinical testing) to demonstrate compliance with the relevant Essential Principles	no	yes	yes	yes
Thailand	Yes, but no time line for issue	Local clinical trial is required for some products.	no	/	yes	yes

Comparative study of Clinical Evaluation of Medical Devices in AHWP member economies - Analysis

1) Does your economy have any established regulation on clinical evaluation specifically

Yes. Please provide details:

a) Publication date:_____

Administrative regulation

Industry guidance document

b) Document name: _____

c) Website link (if have) : _____

No. Does your authority have the plan to issue one in the future?

Yes： When _____

Currently no plan.

- Only China and Korea have published administrative regulation on medical device clinical evaluation. Chinese Taipei has guidance document.
- Hong Kong has the plan to publish in 2010
- Malaysia and Thailand has plan to publish but no timeline provided
- Singapore, Saudi Arabia, South Africa currently no plan

Comparative study of Clinical Evaluation of Medical Devices in AHWP member economies

2) **Does your country (region) require local clinical trial for pre-market approval?**

Yes. Is there any guideline or criteria to define if the clinical trial is needed or not?

No. If local clinical trial is not required, are foreign clinical data needed?

- If local trial is required, only for selected products, depends on device classification
- Usually foreign data, literature accepted
- China require clinical trial for domestic class II & III products, part of class III implantable products, class II & III IVD products. Accepts foreign data for non-local trial required products.

Comparative study of Clinical Evaluation of Medical Devices in AHWP member economies

3) Does your country (region) accept GHTF guidance documents on Clinical Safety/Performance by SG5?
Yes/No/Not yet.

- China, Malaysia, Thailand do not accept GHTF guidance doc, but showed interested except Thailand (Q#4)
- Hong Kong, Singapore, Saudi Arabia, Korea accepts GHTF guidance doc.
- Chinese Taipei will consider to accept when it's finalized
- South Africa: NA

4. Are there any interested in adoption of GHTF guidance documents on Clinical Safety/Performance by SG5?
Yes/No/Not yet

- Most members showed interests in adoption of GHTF documents

Comparative study of Clinical Evaluation of Medical Devices in AHWP member economies

5) Is your authority interested in a harmonized Asian countries guideline on Clinical Safety/Performance, eg. AHWP guidelines ?

- All members showed interests in AHWP guideline.

6) Which topic your authority would be interested in regarding to clinical training organized by AHWP?

a) GCP & ISO guidelines b) GHTF SG5 document

c) Clinical regulation sharing of AHWP member economies

- All members showed interests in the training program

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Comparative Study

- **Review & analyzed survey results**
  - By Q4, 2009
- **Collect updated clinical study related regulations among member economies**
  - By Q2 2010
- **Study on regulations from member economies**
  - Q1-Q3, 2010
- **Provide an update on comparative study and analysis to AHWP at annual conference**
  - By Q4, 2010
- **Final comparative study analysis report out to AHWP at annual conference**
  - 2011

SG5 Document Review & Adoption

- **Additional Documents to be reviewed by Dec '2009**

  a) Clinical Evaluation Key Definition (GHTF SG5N1:2007) - officially released

  b) Clinical Evaluation (GHTF SG5N2:2007) - officially released

- **Review & understanding of SG5 guidance documents on possible adaptation/adoption for AHWP-- by '2010**
- **Present recommendation to AHWP on possible adaptation/ adoption-- AHWP Annual conference 2011**

Training Plan

- **Training Workshop for WG5 members (1)**
  - Topic: Introduction of GHTF SG5 Document
  - Time: 1st half, 2010, 1~2 days
  - Place: TBD
  - Speaker: GHTF SG5, and WG5 SubG2
- **Training Workshop for WG5 members (2)**
  - Topic: Introduction of AHWP Economies regulations established clinical trial regulations
  - Time: Q3, 2010
  - Place: TBD
  - Speaker: WG5 SubG1

Training Plan

- **Training Workshop at AHWP annual meeting for AHWP member economies**
  - Topic: Introduction of GHTF SG5 Document/ ISO14155
  - Time: 2nd half, 2010
  - Place: AHWP annual meeting
  - Speaker: Experts from SG5

- Training Workshop at AHWP annual meeting for AHWP member economies
  - Topic: Clinical Trials Regulations/GCP
  - Time: 2nd half, 2011
  - Place: AHWP annual meeting place
  - Speaker: TBD

AHWP

THANK YOU !

Working Towards
Medical Device
Harmonization
in Asia

Asian Harmonization Working Party
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