Minutes of 11th Asian Harmonization Working Party Technical Committee (AHWP TC) Meeting, 7 September 2010, Taipei

(1) Welcome Address By the Chair

Dr Kang Jaw-Jou (Director-General of Department of Health, Taiwan FDA) gave opening and welcome to participants

Ms Joanna Koh (AHWP TC Chair) welcomes participants and thank you Taiwan FDA to organize this event

(2) Meeting participation and agenda

(3) Photo

(4) The team adopted last meeting minutes and meeting agenda

(5) Roll-call from participants in AHWP and GHTF

(6) Joanna gave update on Shanghai Secretariat meeting in Jul 2010 and current projects in AHWP TC

(7) TC membership update

- STG was created and lead by Miang on membership update
- Jack created a form/table for Miang to comment **by 10 Sept**. WG and STG chair & co-chair to capture the latest membership detail below. WG and STG chair & co-chair and pass back to Jack and Bryan So (HKPC) **by end Sept**. Bryan will help to upload the latest membership **by end Oct**
- One of the WG membership requirement agreed is the member should provide feedback to WG chairs as mentioned in WG01a presentation

(8) WG02 update by Miang

1. **Achievement:**
   - PMS survey report is completed and is available in AHWP website
   - 5 on-going works were reported including a number collaboration of

AHWP and GHTF projects

- On-going work on N111: FSCA definition & classification
- On-going work with SG5 on AE reporting during clinical studies
- AE coding USFDA development update
- SG2 training
- Electronic Adverse Reporting development in EU & US

2. **Work Plans:**
   - Promote SADS/NCAR and education activities
   - Seek consent from GHTF for providing on-line NCAR training through AHWP website
   - Harmonized requirements for adverse event reporting proposal
   - Simplify the SADS Form to encourage reporting and share with SG2
   - Study AHWP economy members FSCA definitions & AE reporting requirements

(9) WG01 update by Daphne

Comparison of STED and CSDT was presented and members are welcome to give their comment. Aim to present in SG1 meeting in Oct 10 and AHWP annual meeting in November 2010.

Key differences

Item	**GHTF STED**	**AHWP CSDT**
IVD requirements	1 STED for general medical devices, 1 STED for IVD (more detailed guidance for IVD).	Only 1 CSDT document covering both general medical devices and IVD.
Purpose	For pre-market (for class C and D devices) and post-market submission (if required by the Authority) to regulatory authority.	Intended for regulatory submissions for all medical devices, but did not specify what circumstances will require the submission.
Executive summary	No Executive summary	Has Executive summary
Verification and validation	Product verification and validation	Design verification and validation

Arrangement of sections	Different

AHWP CSDT finalization timeline would be discussed/agreed during Nov 10 AHWP meeting

Joanna commented that industry would need lots of guidance on what exact documentation is required during CSDT implementation.

Joanna updated on ASEAN's CSDT. ASEAN will finalize ASEAN CSDT and will be incorporated into AMDD (ASEAN Medical Device Directive).

Dr Huang Hsiau Wen and Albert Li from Chinese Taipei also did a comparison of Taiwan requirement vs CSDT. Albert mentioned that the differences are mainly editorial but not technical. Joanna mentioned the executive summary could be the key editorial difference and it really helps regulators' review job.

Mr Hiroshi Ishikawa and Michael Gropp stressed that it is important to have the Essential Principles ready so that CSDT can then be implemented.

(10) WG01a update by Jeffrey

2010-2011 Workplans:

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
• 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	The next annual AHWP meeting (Nov 2010)
• Feasibility study on the adoption of the IVD STED, definition and concepts on clinical evidence of IVD medical devices proposed by GHTF	Sep, 2011

Achievements:

The subgroup has been cooperating with GHTF 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)

(11) WG05 update by Tran Quan

Summary of status:

Current Status on Work Item	1. Established close collaboration with SG5 – Chair & Co-chair of AHWP WG5 are members of SG5 and participate in SG5 meeting/s & discussions on SG5 GD 2. VC of SG5 attended AHWP meeting in Nov' 09 and TC meeting in May' 10 respectively and provided overview training on SG5 GD namely Clinical Evidence – key definitions & concepts (SG5/N1R8:2007) & Clinical Evaluation (SG5/N2R8:2007) 3. WG5 members completed 1st review of SG5 GDs: a) AE reporting during clinical investigation (GHTF SG2-SG5); b) Post-market Clinical Follow up Studies (GHTF/SG5/N4:2010); c) Clinical Investigations (GHTF/SG5/N3:2010); d) Clinical Evidence – Key Definitions & Concepts (SG5/N1R8:2007) & e) Clinical Evaluation (SG5/N2R8:2007)
Steps Forward	1. SG5 representative to train WG5 members SG5 GD in details eg. Logic, thought processes etc behind the final doc. On 26 Nov 2010 2. Explore feasibility to form GHTF Advisory & Expert Panel by Dec 2010 – Once Advisory & Expert Panel formed: Quarterly Tcon/face to face training 2011 and support WG5 in making recommendations to AHWP member economies on feasibility of adoption

About the Advisory and Expert Panel, Quan aiming to invite SG5 members to join

GCP and ISO 14155 will be introduced but no recommendation will be given at the moment

Dr Huang Hsiau-Wen mentioned that combination products which have pharmaceuticals when you choose GCP or ISO 14155

Lindsay Tao also mentioned APEC also treats clinical research as high priority, and suggest more collaboration between AHWP and APEC

(HBD) Harmonization By Doing was introduced and could be a platform to work together

(12) WG06 update

Yiting, Jack and Dr Kelly had a teleconference on 6 Sept and agreed:

- AHWP and GHTF can jointly work out a Regulatory training;
- AHWP training syllabus and template was prepared and will be passed to AHWP & GHTF's regulators representative to comment and start prepare training material;
- AHWP and GHTF will discuss again around Nov 10 on what training platforms we can use;
- AHWP finance arrangement will be communicated to GHTF.

We aim for 2011 launch of the training.

Peter Linders and Michael Gropp mentioned finance arrangement and GHTF will focus on content provision and not on administrative.

Peter Linders also suggested students from other regulatory course should eligible for AHWP Certificate course examination.

(13) WG03 update by Ronald

A QMS survey was initiated

Objectives:

- To understand the status of current and proposed Quality Management System regulations and requirements of AHWP member economies
- To identify similarities in Quality Management System regulations and requirements of AHWP member economies and explore opportunities for sharing
- To identify major areas of differences in Quality Management System regulations and requirements of AHWP member economies for investigation and deliberation to explore opportunities for harmonization
- To identify areas or topics for recommendation to GHTF for the development of new guidance documents or revision of existing guidance documents

Next Steps:

- Compile responses from all member economies to be collected by TC representatives (
- Collate and analyze data
- Present findings

- Identify opportunities for development (new guidance documents, training)

(14) WG04 update by Albert Li

Current status:
- After TC meeting in Singapore, WG4 members proposed a survey in June.
- Draft Questionnaires were developed in July.
- Questionnaires reviewed by WG members in Aug. via telcon.

Next steps:

Action item	**Due**	**Responsibilities**
Feedback on "Questionnaires "	Sept.18	All members
Finalizing Questionnaires	Setp.24	E.H.
Gathering answers from both Industry and Regulator in each AHWP member economy	Oct.15	All members
Analyze the answers and prioritize the key action items	Oct.30	E.H.
Top priority work item will be taken for WG4 to focus on.	Nov.	All members
Auditing status at AHWP member economies and New action item progress will be presented at AHWP annual meeting.	Dec.	TBD

(15) STG – Legal entity update by Jack

Resolved to set up the AHWP Administration Services Ltd in Hong Kong in the 14th AHWP Meeting in Nov 2009
No further comments received after the discussion in the 10th AHWPTC Meeting in May 2010

- AHWP Representatives (Regulator) could join as Regulator Members (limited to 1 for each member economy)
- AHWP Representatives (Industry) could join as Industry Members (limited to 1 for each member economy)
- Others could join as Associate Members (limited to 100 for each member economy)

Representatives and interested persons could join as:

- Founding Regulator Members;
- Founding Industry Members; or
- Founding Associate Members
- Send a CV to the AHWP Secretariat (email: secretariat@ahwp.info) **before 30 Sep 2010**

The Memorandum and Articles of Association will be finalized
The Company will seek tax exemption status before full operation
It was stressed the members are not paid for the above roles

(16) STG – Nomenclature by Joanna

2 AHWP members to be nominated to the Board of Trustees of GMDN
Proposed participants from AHPW is China and Singapore
Fees for regulators not finalized yet
GMDN Agency considering National License

ECRI will give presentation in AHWP Saudi meeting. AHWP has no decision on which nomenclature system yet. This is still in negotiation phase.
Japan is not using GMDN but JMDN.

(17) Terms of Reference discussion by Joanna

WG Chair should have written working procedure for

- Organizing regular meetings and activities
- Responsibilities of WG Chair and co-chairs
- Responsibilities of WG members
- Template can be reference to GHTF Steering committee procedures
- Feedback to Jack **by mid Oct**

(18) TC agreed

- AHWP TC should have written procedures and criteria to ensure that participants from non-AHWP members economies can only be observers or advisers to the WG. Nomination should come from AHWP member economies
- Consultants are allowed to be members of WG
- To allow a maximum of 2 WG memberships
- Minimum attendance at WG meetings are required e.g. Minimum 1 TC meeting and 1 Teleconference attendance within 12 months effective now. WG chair and co-chair can make the decision on the membership cancellation
- For WG membership, they should apply to WG chair who approve and send to TC chair for endorsement

(19) Terms of reference

- Joanna request members to review the Terms of reference and give comments
- Joanna gone through the terms of reference during the meeting

(20) Pakistan Country and Regulation sharing by Mr Nadeem Alamgir

The following topics were shared

- Background of Pakistan's healthcare system
- Regulatory environment and regulation which cover some medical devices e.g. contraceptive devices and control as drug
- Drug control Organization structure
- Price control
- Draft Medical Device Act was proposed in the year of 2010. Proposed regulation is similar to EU system. A list of medical devices will be controlled as drug at the moment
- Application procedure and flow was described

(21) CAB Working Party update by Jack

Further to last TC teleconference, CAB and 3rd party assessment bodies should form a group for good practice sharing and facilitate communication. A CAB Working Party was formed in HK. BSI, SGS and TUV SUD are the members. More members are welcome.

Albert Li will be our contact in Chinese Taipei and Albert to help to inform other 3rd party assessment bodies to join the CAB Working Party by end Sept

(22) AHWP Annual meeting update by Jack

Jack reported the 1 Sept meeting teleconference progress

1. Programme of the 15th AHWP Meeting

The team has no concern on the meeting program

2. Invitations to Guests and Speakers

Mark and Jack will help to invite Dr Larry Kelly to be AHWP keynote speaker

Quan will continue to follow up with Dr Susanne Ludgate (SG5)

For SG1, Mark will write to SG1 chair for nomination

3. Sponsorship to Guests and speakers

3 Sponsorships (GE, Boston Scientific, Mindray) with total USD66k obtained
19 speaker sponsorships requests obtained with total USD48k and the team agree to support

Bryan will write to India to participate AHWP meeting and see any sponsorship require

4. Progress of Registration

Ali will request Yemen to join AHWP membership

5. Date of Next Organizing Committee Teleconf.

Ali will report registration progress in next teleconference

28 Sept 3pm (HK time)

Accommodation information need to be provided in AHWP website. Bryan will handle

Meeting started at 0845
Meeting finished at 1705

(Prepared By Jack WONG)