



AHWP TC Chairman's Report

The Work Team

The current Technical Committee (TC) is the second TC session committee commencing June 2005. During the Bangkok meeting in June 2005, the office bearers Mr. Albert POON of Hong Kong (Chair), Mr. Alfred KWEK of Singapore (Co-chair) and Ms. Daphne YEH of Chinese Taipei (Co-chair) were elected as the core team leaders of the TC. The Committee first met on 17 June 2005 and carried on the mission of technical development for member economies of AHWP. To enable a fast-track build up of development potential, the Committee decided to acquire the working team of the previous WG01, put our shoulders to the wheel and, with your dedicated participation, was able to share our contribution and experience with all of you in the past several years.

Organizational Development

In the 3 years term, apart from the nominated representatives of the member economies, the Committee has secured a basic working team that has established a continual working relationship and experience sharing. Through numerous teleconferences and occasion face-to-face meetings, the team shared joy and work together and I must thank the team members for their unrestrained efforts in these years.

In the work process and continued evolution, the committee developed in 2007 a level of working groups, namely, WG01, WG01a, WG02, WG03, WG04 and WG05 corresponding to the 5 Study Groups of the GHTF. There have been great progresses in the works of WG01, WG01a and WG02; whilst the WG03, 04 and 05 are being consolidated. On top of the 5 WGs, TC has developed a WG06, dedicated to provide Capacity Building and Regulatory Training, unique of AHWP. Furthermore, to enable a proactive approach, TC formed the Special Task Groups (STG) for the task of MD Nomenclature and the task of Legal Entity.

Coupled with all these developments, TC took up a review on the Terms of Reference (TOR) and Constitution for AHWP and TC. The Working Party's New Delhi Meeting in November 2008 will consider the adoption of the revised TOR and updated Constitution.

TC Meetings At A Glance

- 6-7 Sept 2001 TC1 in KL, Malaysia
- 12-13 Dec 2002 TC2 in Bangkok

- 29-30 Apr 2004 TC3 in Chinese Taipei (Formation of WG01)
- 8 Dec 2004 WG01 1st Meeting, Langkawi
- 17 Jun 2005 WG01 2nd Meeting, Bangkok (TC4 + election of office bearers)
- 14 Sept 2006 – TC5 Meeting in Seoul, Korea
- 25-27 April 2007 – TC6 Meeting in Hong Kong, China
- 24 Oct 2007 – TC7 Meeting in Chengdu, China
- 3-4 Nov 2008 – TC8 Meeting in New Delhi, India

Achievement of Work Group Projects

The formation of work groups proved to be successful in consolidating regulators, practitioners and industrial partners in the MD field. An aggregate of over 100 participants, experts and resource persons join the initial foundation of the WGs. Together, we are seeing the following achievements through these enthusiastic members:

- (a) Old WG01 – Comparative Survey and Matrix Table of STED Compliance, Common elements and Country specific requirements for AHWP member economies;
- (b) WG01 – Proposal on Common Submission Dossier Template (CSDT);
WG01a – Review on STED applicability for IVDD;
- (c) WG02 – Development of SADS and Qualification Training for NCAR;
- (d) WG03, 04 and 05 – project works to be developed;
- (e) WG06 – Development of University Certificate Course on Regulatory Training, course to be launched in Dec 2008.

Achievement of Special Task Groups

- (a) Nomenclature – Raised major concerns on applicability, continued application and technical and financial sustainability for Nomenclature, in particular, of the viability for GMDN, in comparison to UMDN of ECRI;
- (b) Legal Entity – For long term development of AHWP and TC, the STG has taken up a review to establish legal entity and setting up of a permanent secretariat in Asia. A proposal of the Memorandum of Association will be considered for adoption by the Working Party in the Nov 2008 New Delhi Meeting.

Networking Opportunities on Technical Aspects and Project Tasks

- (a) TC and WGs started joint meetings with SG01 in Feb 2007 and since then established formal representation to SG01 and IVD Subgroup; further attendance to other SGs are also in place as a experience sharing and networking mechanism among WGs and SGs;

- (b) TC members are invited to participate in the GMDN Management Group of GHTF;
- (c) WG06 is invited to provide updates to GHTF on AHWP Regulatory Course.

Report by

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Chair, AHWP TC (2005-2008 Session)

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