



Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

AHWP TC
Chairman's Report
(2005 - 2008)

13th AHWP Meeting

NEW DELHI, INDIA, 5-6 November 2008

Modality of TC and Work Groups



- TC Officer Bearers:
 - Chair Albert Poon,
 - Co-Chair s: Alfred Kwek, Daphne Yeh
- All WG's structure will follow suit of AHWP committee structure
 - Chair – Regulator
 - Co-Chair – Industry
- All WG's of AHWP TC will tally with SG's of GHTF
 - WG01 – Pre-market Approval
 - WG01a – IVDD's
 - WG02 – Post Market Surveillance
 - WG06 – Regulatory Training
 - STG Nomenclature
- 4. **WG03 (Quality System)**
- 5. **WG04 (Auditing)**
- 6. **WG05 (Clinical Trial)**

Achievement of Work Group Project



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

TC Meeting 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)
- Dec 2004 WG01 1st Meeting, Langkawi
- 17 Jun 2005 WG01 2nd Meeting, Bangkok
- 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 Special Task Groups



■ Nomenclature

- Recognizing the importance of one global Nomenclature system; However 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;

■ 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 will be discussed and reviewed in the Nov 2008 New Delhi Meeting.

Networking Opportunities with GHTF Study Group and Tasks



- TC and WGs started joint meetings with GHTF SG1 in Feb 2007 in Kobe. Since then established formal representation to SG01 and IVD Subgroup; 2 AHWP Representatives seat in SG1 and SG1 Subgroup meeting.
- WG02 Attended in GHTF SG02 Meetings
- WG03 Attended in SG3 Meeting
- AHWP TC members are invited to participate in the GMDN Management Group of GHTF;
- AHWP WG06 is invited to provide updates to GHTF on AHWP Regulatory Course.



Thank you for your attention!

