



# **AHWP Seoul Meeting TC Report**

Seoul, Korea  
Thursday, 15 September 2006



Technical Committee

## TC Core Team (since June 05)

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### *The Core Team*

- Mr. Albert POON - Chair
- Mr. Alfred KWEK - Vice-chair
- Ms. Daphne YEH - Vice-chair
- Ms. Jacqueline Monteiro, Mr. Jack WONG – Acting Secretary
- Members – Being proposed (NR+WG01+RP)



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*TC Meeting 2006  
Participants*

## Participating Delegates

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A total of 63 delegates attended TC Meeting on 14 Sept 2006

- 26 Representatives
- 37 In Attendance



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## TC Past Activities

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*Progress Report*

- 6-7 Sept 2001 TC1 in KL, Malaysia
- 2002 TC assisted AHWP Survey on Pre-market Requirements & STED
- 12-13 Dec 2002 TC2 in Bangkok
- 29-30 Apr 2004 TC3 in Chinese Taipei (Formation of WG01)
- 8 Dec 2004 WG01 1<sup>st</sup> Meeting, Langkawi
- 17 Jun 2005 WG01 2<sup>nd</sup> Meeting, Bangkok (TC4 with election of office bearers)
- 14 Sept 2006 – TC5 Meeting in Seoul



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## *Achievements Update*

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*Progress Report*

1. Training Workshops
2. 2002 AHWP Survey on Pre-market requirements and STED
3. WG01 Comparative Study on MD requirements in Asia (STED Matrix)
4. Common Submission Dossier Template (CSDT)
5. Draft Proposal for Regulatory Training (New)

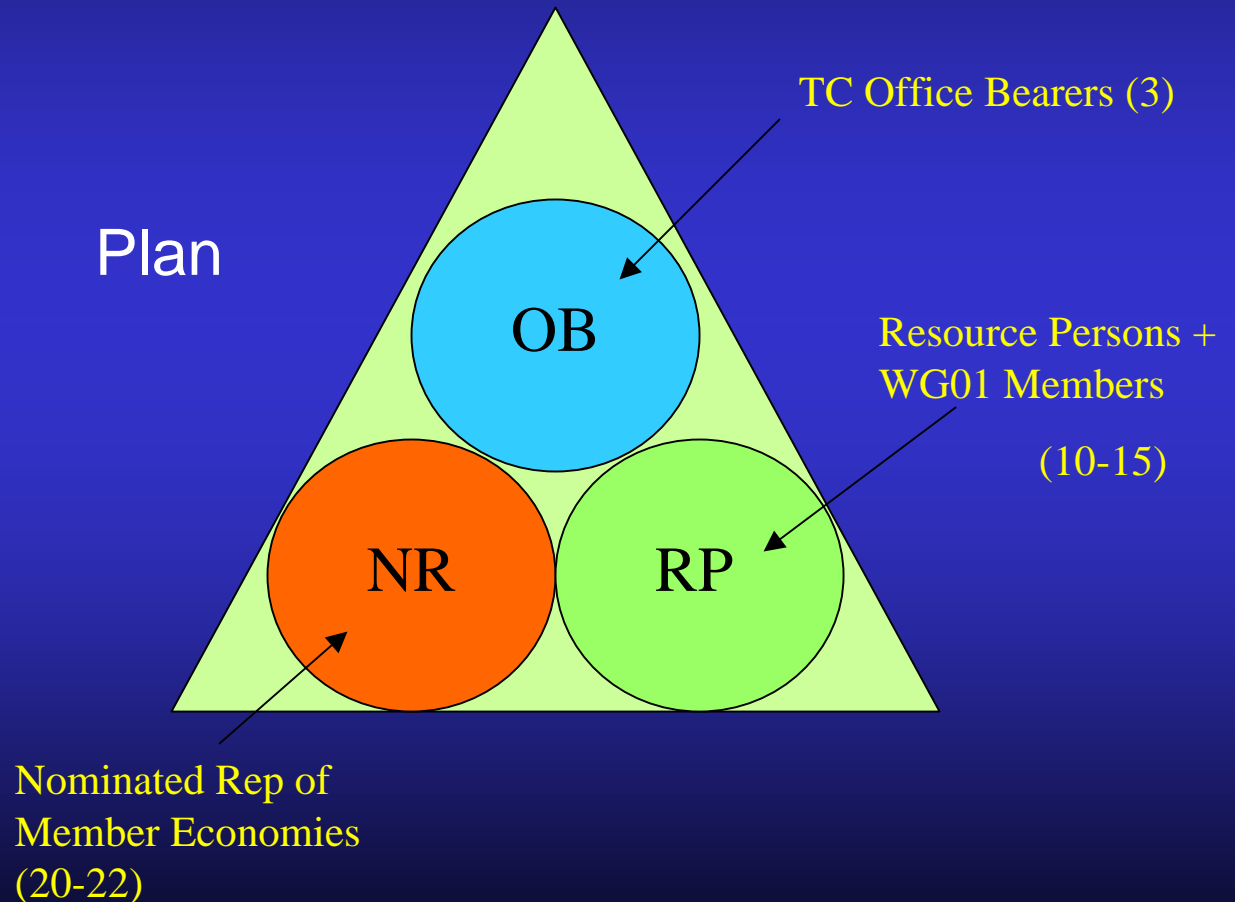


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## Review on TC Structure

*Proposed TC Structure*

Plan





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## Asian Harmonization Working Party

### Milestone – Enhancement on TC membership

*Proposed TC Structure*

*Implementation &  
Milestones*

1. Discussion and collection of views for refinement of proposed structure (14 Sept 2006)
2. Report to AHWP on 15 Sept 2006 (Friday)
3. Nomination form to be sent to members economies (regulator) for nomination of 1 regulator & 1 industry rep to TC (Email by end Sept 2006)
4. For the office bearers, the respective member economies (HK, SG and Chinese Taipei) can provide a further backup representative.
5. Nominations to return within end Oct 2006
6. By end of year, updated TC membership will be sent to all member economies.



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## Asian Harmonization Working Party

### TC Execution Plan – WG01 Project on Comparative Study on MD Regulations in Asia

#### Comparative Study on MD Regulations in Asia

WG01 team nomination - *May-Sept 04*

Team telecon to appoint Chair, co-chairs and secretary - *13 Sept 04*

Chair and co-chairs meeting to draft execution plan and organize first team meeting - *Oct-Dec 04*

1st WG01 meeting in Langkawi to discuss and adopt the WG01 execution plan - *8 Dec 04*

Identify STED compliance status and explore ideas to meet STED in member economies (2<sup>nd</sup> WG01 meeting in Bangkok - *17 Jun 05*)

- Define Relevant Dossier Elements and Requirements
- Seek review on path to market and pre-marketing requirements
- Address if there are any country-specific requirements that should be prepared. - *by 3Q 06*

Draft Common Pre-Market Dossier format with guidance notes (in line with STED) - *by 4Q 06*

Start pilot study to using STED for sub and review in pilot countries and pilot companies – *1-2Q 07*

Draft and consensus of STED implementation plan – *3Q 07*

Propose to TC and AHWP – *4Q 07*

*Project Activities – STED  
Survey*

*Implementation &  
Milestones*





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## Review on CS DT

### Draft Guidance – Common Submission Dossier Template

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1. Comments on CS DT; Comments on inclusion of IVDs in CS DT
2. Comments on determination of Submission Matrix in CS DT
3. Reaching consensus on adoption of the GHTF Definition of a MD
4. Reaching consensus on a 4-class risk based classification system
5. Reaching consensus on the adoption of GHTF classification rules

Next Steps – Papers will be posted to AHWP web for further discussion

*Project Activities - CS DT*

*Implementation & Milestones*



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## Milestone for Regulatory Training

- Initiative for Training Proposal - Jun 05 at TC4 Bangkok Meeting
- Draft and preliminary proposal prepared Sept 06
- End 06 Finalize proposal
- 1Q-3Q 07 Prepare training material and website logistics
- 3Q 07 Kick-off date for training course
- End 08 Anticipating first batch of graduates

*Project Activities –  
Training Course Proposal*

*Implementation &  
Milestones*



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## Future Projects And Plans

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1. **IVDD – extension from CSDT**
2. **QS Requirements such as QSR and ISO 13485**
3. **Post-market surveillance**
4. **Other topics**
  - **Cert of Origin / manufacturing**
  - **Asian Mark etc.**

*Future Projects & Plans*



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## End of TC Report

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TC's Appeal for Volunteering  
Resource Persons to join

Thank You

*Thank You*