



ASIAN HARMONIZATION WORKING PARTY

Working towards medical device harmonization in Asia

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Working Towards Medical Devices Harmonization in Asia



Introduction of AHWP Delegation

- Wang Hwee Beng – Head of delegation, Director, Medical Devices Bureau, MOH Malaysia
- Alfred Kwek-Regulatory Scientist, HAS, Singapore
- Mark Lau- DOH, HK
- Henry Chiu – DOH, HK
- Albert Poon – EMSD, HK
- Dr. Saleh- SFDA, Saudi Arabia
- Abdulrahman Al-Gifari, SFDA, Saudi Arabia
- Hye Won Roh, KFDA, Korea
- Jacqueline Monteiro- Industry rep, SIN
- Tran Quan – Industry, SIN
- Nellie Ong – Secretariat AHWP, Industry Rep, MY
- Chern Jiin Feng –Chinese Taipei, ITRI, Designated Evaluation Body
- Jack Wong - CAB



Introduction

- ❑ AHWP was established as a non-profit organization in 1998, Ottawa, Canada
- ❑ AHWP is an informal regional forum comprising of both government regulators and industry representatives from member economies in Asia
- ❑ AHWP is the GHTF Liaison Member



Objectives

- To forge a common direction for harmonization of medical devices regulation in Asia
- To encourage increased understanding on the benefits of harmonization
- To facilitate a linkage with GHTF



Aims

- ❑ To provide a forum for discussion and training, facilitate information exchange and initiate projects relating to GHTF harmonization among regulators and industry groups in Asia
- ❑ To establish AHWP as a formal regional grouping under GHTF



AHWP Member Economies





AHWP – TC Activities

- ❑ 6-7Sept 01 TC1 met in KL, Malaysia
- ❑ Assisted AHWP survey on Pre-market requirements & STED
- ❑ 12–13 Dec02 TC2 met in Bangkok
- ❑ 29-30 Apr04 TC3 met in Chinese Taipei (formation of WG01)
- ❑ 8 Dec04 WG01- 1st meeting in Langkawi, Malaysia
- ❑ 17 Jun05 WG01-2nd meeting in Bangkok (TC04 meeting with elections of office bearers)
- ❑ 14 Sept06 – TC5 meeting in Seoul



Accomplishments on CSDT

- ❑ Initiation of CSDT project in Dec 04 – WG01
- ❑ Seek review on path to market and pre-market requirements from AHWP member economy
- ❑ Address any country specific requirements
- ❑ GHTF SG1 guidance documents on STED – reference
- ❑ Voluntary pilot study on using CSDT for submission & review
- ❑ Draft CSDT posted on AHWP website for 4 months for comments– closed end Jan07



Next Steps for CSDT

- Review on comments received from member economies from web consultation
- Solicit comments from SG1 (5&6 Feb 07)
- Results on pilot study on CSDT – to complete by mid 07
- Summarize and update revised CSDT to member economies
- Conduct voluntary trial scheme on revised CSDT template – Chinese Taipei, HK & Korea (to be invited)
- Publish results in Q4/07
- For presentation in next AHWP meeting

Thank You

The next AHWP meeting will
be in PRC