

9TH GLOBAL HARMONIZATION TASK FORCE CONFERENCE

REPORT OF ASIAN HARMONIZATION WORKING PARTY

On behalf of the Asian Harmonization Working Party (AHWP), let me first express our appreciation to the Global Harmonization Task Force (GHTF) for giving us the opportunity to provide an update on the progress of the AHWP at this plenary session of the 9th GHTF Conference. We would also like to thank GHTF for including the regional AHWP meeting into the GHTF Conference programme. It demonstrates clearly the support of GHTF for AHWP as a useful and important regional initiative for the global harmonization of medical device regulation.

2 This report provides an update of AHWP plans and activities since our last meeting in Ottawa, Canada (20 September 2000).

Attendance of AHWP TC at GHTF Study Group Meetings

3 Co-Chair of the AHWP Technical Committee, Jack Moore, attended the GHTF SG1 meeting at Lausanne, Switzerland from 4-6 December 2000. Chair, AHWP Technical Committee, Albert Li, attended GHTF SG 4 meeting in London, UK on February 28 - March 1 2001. AHWP would like to place on record our appreciation to SG1 and SG4 Chairs, for the invitation to attend. Participation in the discussions was found to be very useful and AHWP will continue to attend the meetings to learn and provide feedback on the working drafts.

1ST Technical Committee Meeting & Workshop, 6 & 7 Sep 2001 at Kuala Lumpur, Malaysia

4 The 1st AHWP Technical Committee (TC) Meeting and Workshop was held on 6 & 7 September 2001 at Kuala Lumpur, Malaysia. Attendees (56) included delegates from Australia, People's Republic of China, Hong Kong, Japan, Korea, Malaysia, Philippines, Singapore, Chinese Taipei, Thailand and USA, representing their respective medical device industries and regulatory authorities.

5 The invited speakers were Ms Christine Nelson and Ms Judy Strojny from FDA and Mr Michael Gropp from the industry (Guidant, Brussels). The 1st AHWP TC Meeting received the honoured presence and support from Ms Rita Maclachlan, GHTF Chair and Director of TGA's Conformity Assessment Branch.

6 Selected GHTF SG final documents (Essential Principles, Regulatory Auditing, Auditor Training and Process Validation) were introduced for training to bring participants to a better common understanding of GHTF principles. Discussions during the meeting also focused on working draft GHTF SG documents (Summary Technical Documentation and Device Classification). The meeting also discussed proposed amendments to the AHWP Terms of Reference to incorporate the roles and functions of the TC. The primary role of the TC was envisaged as facilitating the process of technical understanding and acceptance of Final GHTF SG guidance documents by AHWP for adoption and implementation as appropriate within the regulatory framework of member economies. The selection criteria for TC members was also discussed and accepted. The proposed amendments will be tabled for approval at the next AHWP meeting.

AHWP Home Page

7 AHWP Home Page at <http://www.asiahwp.org/> was launched on 4 Dec 2001 with a link to GHTF website. This website will serve to provide members and others with the latest updates and information about AHWP activities and record the progress of this young regional grouping. A contact address for e-mails (Info@asiahwp.org) was also established.

AHWP Survey Questionnaire

8 The AHWP Technical Committee conducted a survey, in March 2002, amongst medical device regulators in the Asian member economies about their efforts to harmonize the regulation of medical devices with the Global Harmonization Task Force (GHTF) recommendations and guidance and to obtain suggestions for possible collaboration and training. 9 out of 10 member economies responded enthusiastically to the survey.

9 There is wide consensus amongst Asian regulators in the adoption and implementation of various GHTF final documents which illustrates their relevance for working towards greater harmonization of medical device regulatory systems in Asia. 68% of the respondents indicated that they have considered or considering adopting and implementing various GHTF final guidance documents, while another 19% indicated they have implemented them into existing regulation.

9th Meeting of the AHWP in Singapore

10 The 9th Meeting of the AHWP was held during the 9th GHTF Conference in Singapore on 14 May 2002 and nine participating economies were represented, the highest number attending so far.

11 A major milestone and achievement of this meeting was the consensus to initiate a “harmonization” project for the Technical Committee which will involve the selection of a couple of regulatory processes for study as to how to operationalise GHTF guidance in the most practical and pragmatic manner. The two possible projects agreed upon were Quality Systems and Audit; and the Summary Technical File.

12 The meeting ratified the changes made to the Terms of Reference on procedures for the election of office bearers and the roles and functions of the Technical Committee and the status of observers to AHWP meeting.

13 The meeting re-affirmed that the consensus, recommendations and guidance documents of GHTF would serve as the basis for AHWP in working towards the development and harmonization of medical device regulation in Asia. Over the next three years, AHWP will also work towards maximising the benefit of the GHTF harmonization process to Asia.

Conclusion

14 Over the last three years, AHWP has evolved from an informal forum into an organised and structured regional group of Asian medical device regulators and industry representatives with clear objectives and a common direction to achieve harmonization of medical device regulation in support of GHTF. AHWP is strongly committed to communicating and cascading the GHTF process to Asia. We believe that AHWP will add value to GHTF in furthering the cause of global harmonization in Asia and initiate projects relating to GHTF harmonization among regulators and industry groups in Asia. We look forward to the continued strong support, collaboration and recognition of GHTF for AHWP which we believe will be critical for our success.

15 Thank you.

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Chief Executive Officer, Health Sciences Authority

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