

Meeting summary for SG2

Dates: 25-28 Feb 2003

Location/Host: Canberra, Australia/ TGA

Seventeen SG2 members and three observers convened at the government offices of the Therapeutic Goods Administration (TGA) in Canberra, Australia for four full days of meetings. Participants represented industry groups and regulatory agencies from Australia, Canada, Europe (the European Commission, and Germany), Japan, New Zealand and the United States.

Overall, the SG2 meeting resulted in sixteen action items to be completed before the next meeting, which will be held in Tokyo, Japan, in May 2003, as part of the 10th Conference of the Global Harmonization Task Force (GHTF).

Chairman Kim Dix was pleased to announce that three more SG2 documents have reached “final draft” status. SG2 notes that all “final” documents are expected to be reviewed at least every three years to re-evaluate appropriateness of the guidance provided. The newly finalized documents are:

- **SG2 N9 R11: Global Medical Devices Competent Authority Report**-This is a revision to the approved version of this form for exchanging information. Confidentiality commitments and SOPs regarding the international exchange of this type of information are currently under development. All participant NCAs are requested to use this form.
- **SG2 N33 R11: Timing of Adverse Event Reports** (by Manufacturer to the Regulatory Authority). NCAs will work towards implementation of this guidance.
- **SG2 N36 R7: Manufacturers Trend Reporting of Adverse Events**. This is an informative document, providing criteria for the identification of an increase in the rate of adverse events; it does not define statistical techniques for trending. This document must be reviewed and implemented in conjunction with the guidance of SG2 N21 R8: Adverse Event Reporting Guidance for the Medical Device Manufacturer or Authorized Representative.

During this meeting SG2 reviewed and reached consensus on the disposition of public comments received on two additional documents. The documents were revised accordingly, and will be presented to the GHTF Steering Committee with a request that they also be accepted a “final”.

These two documents are:

- **SG2 N31 R8: Proposal for the Reporting of Use Errors with Medical Devices by a Manufacturer or its Authorized Representative**.
- **SG2 N32 R5: Universal Data Set for Manufacturer Adverse Event Reports**. SG2 recorded this document as final during the GHTF plenary session of 1999. For a variety of reasons, the document was never posted as final, and then SG2 lost consensus on agreement of the defined data set. Consensus being revived, SG2 will be submitting this document to the GHTF Steering Committee for consideration as “final”.

Otherwise SG2 continues work on the following items:

- Harmonization of requirements associated with Postmarket Surveillance

- To whom manufacturer adverse events must be reported
- Finalize N38:Application Requirements for Participation in the NCAR exchange program

New work item proposals that will be forwarded to the Steering Committee which are based on the “Common Data” working group documents:

- Harmonization of the Content of Recall notifications and Advisory Notices
- Review the applicability of using the National Competent Authority Report (NCAR) exchange program for the communication of enforcement activities

New work item based on direction from Steering Committee:

- Consolidation of SG2 documents N21, N31, N32, N33, and N36 into a comprehensive global reporting guidance for manufacturers and authorized representatives

More information about GHTF, the Study Groups, and the coming plenary meeting is available at www.ghf.org

PREPARED BY: Deb Yoder **DATE:** March 10, 2003