



GHTF Study Group 2 Meeting Summary

LOCATION: Phoenix, USA

DATES OF MEETING: February 25-27, 2004

SUMMARY:

Fifteen representatives from industry and regulatory bodies, along with one observer from the US Competent Authority and one from the Japanese industry met in Phoenix, USA from February 25-27, 2004.

The major topics of discussion included:

- review of previous meeting action items and actions items resulting from GHTF Steering Committee (SC) meetings.
- review of the current draft of **SG2-N47R2.1**: Review of current requirements on postmarket surveillance.
- discussion on next steps for harmonisation of Postmarket Surveillance.
- review of the proposed changes in **SG2-N9R12**: Global Medical Devices Competent Authority Report.
- discussion of the **NWI** proposal on the use of National Competent Authorities Reports (NCARs) to communicate enforcement activities
- finalize **SG2-N38R11.2** Medical device postmarket vigilance and surveillance: application requirements for participation in the GHTF National Competent Authority Report (NCAR) exchange program
- finalize **SG2-N54R2**: Global guidance for adverse event reporting for medical devices.
- discussion of first draft of **SG2-N57R1**: Harmonisation of the content of Advisory Notices and Recalls.
- discussion of **SG2-N40R4.2**: To whom to report

SG2-N47R2.1: The current draft of the document was discussed at the meeting. It was confirmed that this document is a reference document according to the classification system proposed by the SC. A major discussion point was whether the scope of the document should include enforcement activities. Each NCA should decide for its own jurisdiction if enforcement activities should be included in the PMS activities or not. It was also noted that the PMS description on the comparison sheet was incomplete for some countries. NCA reps will provide missing information and the document will be redrafted accordingly and reviewed at the next meeting in June.

SG2-N9R12: a new draft of this document (currently a final document) was presented. This included mainly modifications of the instructions on how to fill-in the form. Several modifications and improvements over the current version have been introduced. It was

also decided that N9, the reporting form for the NCARs, should be merged with N20, the reporting criteria for the NCARs. A NWI proposal including the modifications of the current version of the form and the merging of SG2-N9 and SG2-N20 will be drafted and submitted to the SC for approval.

NWI on the possibility of using the NCAR exchange program to exchange enforcement action information. The NWI was turned down by the SC over concerns of confidentiality, appropriate expertise in the group and need to better define what exactly should be exchanged (enforcement vs. non-compliance). The group agreed that the current exchange programme should only be used for exchange of safety related information. It was felt that there are currently no safety related issues that are not covered by the NCAR. As a consequence this NWI will not be carried forward.

NCAR Exchange Programme - A discussion on the NCAR programme under N9 and N20 lead to a decision to share statistics on the programme to date with the SG2 members and the need for further discussion of the results of the programme.

SG2-N38R11.2: the document has been revised according to the comments received from the SC. The main remaining issues relate to the administration costs of the exchange programme. A proposal allowing dealing with the financial issue within the SG was developed. The new draft of the document, if acceptable to all SG2 members, will be submitted to the SC for advancement to PD status.

SG2-N54R2.1: The document was reformatted. Several comments from the Australian industry were discussed. The new draft of the document, if acceptable to all SG2 members, will be submitted to the SC for advancement to PD status.

SG2-N57R1: A first draft of this document was presented and reviewed by the group. The discussion showed that a comparison of the current requirements on the content of safety communications to users on recall/corrective actions for serious cases is an essential starting point and that recalls and corrective actions are defined differently by member countries/areas. A new draft of the document focusing on a comparison chart showing the existing requirement and definitions will be prepared for the next meeting.

SG2-N40R4.2: the scope and goals of the document were reviewed. Current difficulties are:

- the document includes a possible consideration to create a global database for adverse event reports; however, it is unclear how this can be achieved given both the problem associated with multiple languages and the maintenance costs.
- harmonisation on one recommendation on to whom to report is difficult as currently two different requirements exist.

As a way forward, it was decided that the document should present the two existing options of to whom to report with pros and cons. Further, the proposal for a global database will be removed

Harmonized format for electronic reporting: This topic was proposed and discussed. It was decided to discuss this further as a potential NWI proposal at the next meeting.

Next SG2 meetings:

- 2-4 June 2004 in Helsinki, Finland.
- 27-29 September 2004, Vancouver Canada.