GHTF Study Group 2 Meeting Summary

LOCATION: Helsinki, Finland

DATES OF MEETING: June 2-4, 2004

SUMMARY:

Fourteen representatives from industry and regulatory bodies met in Helsinki, Finland from June 2-4, 2004.

The major topics of discussion included:

- review of previous meeting action items.
- review of implementation of **N21, N31, N32, N33 and N36** by member NCAs
- finalize **SG2-N54R3.2**: Global guidance for adverse event reporting for medical devices.
- discussion of **SG2-N40R4.3**: To whom to report
- review of **SG2-N47R3**: Review of current requirements on postmarket surveillance and **SG2-N61R1**: PMS Harmonisation Chart.
- Discussion of the current experience with the NCAR exchange
- finalize **SG2-N38R13**: Medical device postmarket vigilance and surveillance: application requirements for participation in the GHTF National Competent Authority Report (NCAR) exchange program
- Discussion of the **NWI proposal** on electronic reporting
- discussion of second draft of **SG2-N57R2**: Harmonisation of the content of Advisory Notices and Recalls.
- review of the **NWI proposal** regarding **SG2-N9R12**: Global Medical Devices Competent Authority Report and **SG2-N20R10**: NCAR Exchange Criteria.

Implementation of N21, N31, N32, N33 and N36 by member NCAs: the current status of implementation of the SG2 documents on AE reporting was reviewed and tabulated in a new document.

SG2-N54R3.2: Although the group has agreed on the content of the new version, it could not find consensus on the status that it should have (guidance vs. reference document). Different options were discussed, including revision of N21, but none was agreeable to all members. The issue remained unresolved at the end of the meeting.

SG2-N40R4.3: After discussion of the issues, the group decided that the document will be replaced by a comparison table summarizing the current requirements by participating countries. A proposal to carry N40 forward as a guidance document, in addition to the status document mentioned above, did not find consensus within the group.

SG2-N47R3 and SG2-N61R1: The group reviewed all identified PMS activities with respect to harmonisation potential and expertise within the group. Several areas of potential harmonisation were identified, however all but one were considered to be outside of the scope of the group. A NWI proposal in this sense will be developed.

NCAR Exchange: the experience with the NCAR exchange programme was discussed. The discussion showed that they may be a need to review the threshold for information exchange. This will be addressed during the revision on SG2-N20 in the NWI proposal on SG2-N9 and SG2-N20 below.

SG2-N38R13: the document has been revised and consensus was found on the remaining issues concerning the administration costs of the programme. The new draft of the document will be submitted to the SC for advancement to PD status.

NWI proposal on electronic reporting. A first draft of the proposal was reviewed and several comments were made. The proposal will be refined at the next meeting.

SG2-N57R2: A comparison table of current requirements/guidelines was reviewed. The main issues with the further development of this document relate with the definition of Recall and Advisory Notices, which are not harmonised. Terminology to be used in the document will be defined.

NWI proposal on SG2-N9R12 and SG2-N20R10: A NWI proposal including the modifications of the current version of the form and the merging of SG2-N9 and SG2-N20 was discussed and approved by the group. The proposal will be submitted to the SC for approval.

Next SG2 meetings:

- 27-29 September 2004, Vancouver Canada.
- 21-23 February 2005, Sydney, Australia