GHTF Study Group 2 Meeting Summary

LOCATION: Lubeck, Germany

DATES OF MEETING: August 27-29, 2003

SUMMARY:

Fourteen representatives from industry and regulatory bodies, along with three observers from the US Competent Authority, one from the Japanese industry and one from the Japanese Competent Authority, met in Lubeck, Germany from September 27-29, 2003.

The major topics of discussion included:

- review of previous meeting action items and actions items resulting from GHTF Steering Committee (SC) meetings
- review and discussion of the current draft of ISO TC210 TS 19218, Coding system for adverse medical devices event reporting.
- review and discussion of SG2-N54: Global guidance for adverse event reporting for medical devices.
- discussion of the possibilities to use National Competent Authorities Reports (NCARs) to communicate enforcement activities
- discussion of SG2-N40: To whom to report
- finalize SG2-N38: Medical device postmarket vigilance and surveillance: application requirements for participation in the GHTF National Competent Authority Report (NCAR) exchange program
- discussion on the SC proposal on the categorisation of documents.
- discussion of SG2-N47: Requirements of a postmarket surveillance system
- Discussion of SG2-N57: Harmonisation of the content of Advisory Notices and Recalls.

ISO TC210 TS 19218: Carol Herman, chair of the working group in charge of this project presented the current draft document. SG2 members gave feed-back on the concept, the structure and the content of the current draft. Both manufacturers and regulators endorse this project which will provide a useful tool for adverse event coding (in particular in database applications). TC210 will move forward with the project and will keep SG2 updated on the progress of this activity.

The first draft of SG2-N54, which will consolidate all approved SG2 documents relating to adverse event reporting for manufacturers, was discussed. A lively discussion ensued regarding “trend report”, however this option was accepted within SG2-N32 which is a final document, so no changes are appropriate at this time. The document will be updated according to the discussion of the group and a new version will be presented at the next meeting for final review before forwarding it to the SC as a "proposed" document.

The possibility of using the NCAR exchange program to exchange enforcement action information was discussed. The discussion showed that several legal and confidentiality issues must be clarified before this exchange is possible. The need to modify the current form used for the NCAR program (SG2-N9) will be assessed and the challenges and potential mechanisms for this exchange will be further evaluated at the next meeting.

SG2-N40 is currently a vision document. Feed-back from the SC said that the document should reflect the current status. A lively discussion followed on whether the document should also include recommendations for evolving regulatory systems and a vision for the future. A consensus could not be reached so that the available options will be further explored at the next meeting.

SG2-N38: the document has been revised according to the comments received from the SC. The main topics discussed where the confidentiality issues (definition of what is "public" and what is "confidential") and the participation of non-NCA to the program (WHO, manufacturers, others...). The document will be revised according to the discussion and definitions will be developed.

Categorization of documents: the SC proposal was discussed and the feed-back of the group will be forwarded to the SC for its next meeting.

Consolidation of documents on the NCAR program: the suitability of consolidating SG2 documents pertaining to the NCAR program was discussed. A proposal for a new work item will be forwarded to the SC.

SG2-N47: this document reflects the current status (similarly to SG2-N6) and does not contain recommendations. The group reviewed the work plan to look at the various elements that this document should address. NCA reps were encouraged to look at various elements (annual reporting, condition of approval studies, ...) to identify areas of possible harmonization.

SG2-N57: This project was proposed by the GHTF-SC Ad Hoc group. The rationale for the document was reviewed and possible contents, issues, and definitions were discussed. Both regulators and manufacturers feel that a guidance on this topic would be a useful tool. A first draft of the document based on the discussion will be prepared for the next meeting.

The next SG2 meeting is scheduled to take place in the US in February 2004.