GHTF Study Group 2 Meeting Summary

LOCATION: Vancouver, Canada

DATES OF MEETING: September 27-29, 2004

SUMMARY:

Thirteen representatives from industry and regulatory bodies met in Vancouver, Canada from September 27 to 29, 2004.

The major topics of discussion included:

- Welcome, and review of meeting goals, agenda and approval of the last meeting minutes.
- Review of SG2 documents on the GHTF Website.
- Discussion of proceedings of the GHTF Steering Committee (SC) meeting in Paris.
- Review of **SG2-N12R9** – Overview of the work of SG2
- Discussion of **SG2-N68 R1** – Comparison table of national requirements for "to whom to report".
- Discussion of **SG2-N73R1** - Implementation of current SG2 guidance.
- Discussion of **SG2-N54R4**: Global guidance for adverse event reporting for medical devices.
- Discussion of second draft of **SG2-N57R2**: Harmonisation of the content of Advisory Notices and Recalls
- Discussion of **SG2-N75** – New Work Item Proposal on the definition and classification of Recalls
- Review of **SG2-N47R4**: Review of current requirements on Post-market surveillance and **SG2-N61R3**: PMS Harmonisation Chart.
- Discussion of **SG2-N72R1** New Work Item Proposal on electronic reporting
- Discussion of **SG2-N79** New Work Item Proposal regarding combining **SG2-N9R12**: Global Medical Devices Competent Authority Report and **SG2-N20R10**: NCAR Exchange Criteria.

Welcome, and review of meeting goals, agenda and approval of the last meeting minutes.

The SG2 welcomed a new member, Mr Masahiro Sasaki. Mr Sasaki represents the Japanese Ministry of Health Labour and Welfare (MHLW) and replaces Mr Imoto Masakatsu. Mr Masakatsu, has received a promotion and his current duties do not allow him to continue to represent MHLW at the SG2.

Mr Andrea Sparti will resign as member and Secretary of SG2 from this meeting. Dr Jorge Garcia will take over the duties of secretary. The SG2 Chairman is to decide whether another member from the EU is needed.

Mr Hannu Seitsonnen has finished his term at the EU Commission. The Chairman would approach the EU Commission for an alternative nominee.

The SG2 noted the activities of ISO TS 19218. It was decided to discuss it in greater detail at the meeting in Sydney, March 2005.

Review of SG2 documents on the GHTF Website.

The Group decided that SG2-N7 (Minimum data set) had been superseded by SG2-N32 (Universal reporting format). Thus SG2-N7 should be removed from the website.

SG2-N80 is a set of PowerPoint slides that provide a useful "map" of SG2 guidance documents. The group is updating the content and will publish it in the updated version on the website.

Discussion of proceedings of the GHTF Steering Committee (SC) meeting in Paris.

The main outcomes affecting the work of SG2 of the meeting in Paris are as follow:

- N38R14 was approved as a Proposed Document, comment period ends on October 7 2004.
- NWI proposal N71 (consolidation of N20 and N9) was agreed but the deadline for Proposed Document was moved to May 2005.
- ~~N54: the SC requested that the SG2 revise the N21 part of N54.~~ The SC supported the consolidation of the documents N21, N31, N33 and N36 into one document N54 and in this context the revision of N21.
- Chairmanship: Mr Kim Dix was to serve as Chairman for one more year.

Review of SG2-N12R9 – Overview of the work of SG2

It was decided that the document should be revised to reflect the fact that documents are non binding. It was further decided to delete Annex 2 from the document and to maintain SG2-N12 as an informative, annotated document. This means that the document will not be published on the website, but rather it will remain an internal SG2 document.

Discussion of SG2-N68 R1 – Comparison table of national requirements for "to whom to report".

This document is in the form of a table summarising the national requirements regarding the expectations about receiving reports of events, which occurred outside their national borders. The document is almost complete but it is too complicated, particularly regarding its direct references to national laws and regulations.

The next revision will address these issues.

Discussion of SG2-N73R1 - Implementation of current SG2 guidance.

There are concerns that this document sends the wrong signal to NCA with respect of "obligation" to implement documents. On the other hand it was noted that this compilation is a good foundation for the revision work on N21 as it identifies areas that are difficult to implement. It was also noted that it would be helpful to know the reasons why some parts of documents encounter resistance.

It was agreed that the document is an internal SG2 document and that there are no plans to publish this or distribute it outside of the group. It will continue to be updated and be a standing item of discussion.

Discussion of SG2-N54R4: Global guidance for adverse event reporting for medical devices.

The SG2 discussed the document in some detail and is actively redrafting the document with particular attention to the parts of the document derived from SG2-N21R8. This is in accordance with the direction from the Steering Committee. SG2-N54 will be the subject of further discussion in the meeting scheduled on March 2005

Discussion of second draft of SG2-N57R2: Harmonisation of the content of Advisory Notices and Recalls.

This work is progressing. There have been some problems relating to the fact that "Safety Alert" "Safety Notification" etc have specific meanings in some jurisdictions, and different meanings in different contexts. This was resolved at the meeting and further work will be done to the document before March 2005.

Discussion of SG2-N75 – New Work Item Proposal on the definition and classification of Recalls

This work item proposal was rejected and will not proceed. While everyone on the group felt that a common definition of recall and a common classification system for recalls would be desirable, in some jurisdictions these definitions are entrenched in the law and would be virtually impossible to change. The work item proposal was turned down for lack of consensus.

Review of SG2-N47R4: Review of current requirements on Postmarket surveillance and SG2-N61R3: PMS Harmonisation Chart.

In summary, ~~the work~~ SG2 has decided that there is very little in the area of harmonisation of post market surveillance that has not been already done, either by the SG2 or by some other group such as an ISO technical committee or another SG. The documents will be used to report back to the Steering Committee regarding this finding.

Discussion of SG2-N72R1 New Work Item Proposal on electronic reporting

This new work item proposal is receiving careful consideration. The group is certain that the work would be useful, but not that ~~it is the premise of SG2 to work on it, or that~~ the group has the right mix of expertise to deal with the technical issues. Some further research was commissioned before the proposal is accepted.

Discussion of SG2-N79 New Work Item Proposal regarding combining SG2-N9R12: Global Medical Devices Competent Authority Report and SG2-N20R10: NCAR Exchange Criteria.

The original intention was to simply combine the two documents, but one member has suggested changes that would fundamentally change the number and types of reports being sent through NCAR. This will receive more discussion in March 2005.

Next SG2 meetings:

- 1-3 March 2005, Sydney, Australia
- 1-3 June 2005 in Milwaukee
- Week of September 12, 2005 in Washington DC