GHTF Study Group 2 Meeting Summary

LOCATION: GE Healthcare Educational Facility, Milwaukee, Wisconsin, USA.

DATES OF MEETING: 1-3 June 2005.

SUMMARY:

Twelve representatives from industry and regulatory bodies met in Milwaukee, Wisconsin, at the GE Healthcare Institute (educational facility) from June 1 to 3, 2005. A special meeting was held at the GE Healthcare Headquarters to revise GHTF SG2 N54 on 31 May 2005.

Special Meeting to redraft N54: Tuesday 31 May 2005

A subgroup of SG2 comprising members from industry and regulatory agencies met to revise GHTF SG2 N54. This document is a consolidation of SG2 guidance on Adverse Event Reporting.

GHTF N54R4.2 was extensively edited based on comments arising from the SG2 meeting in Vancouver in September 2004 and other comments collected, and also from GHTF SG2 N73 (status of implementation). The group achieved its purpose, which was to produce a new draft to be discussed at this meeting.

Report on Decisions Made by the Steering Committee at their Last Meeting

The Chairman reported on the decisions made by the Steering committee their last meeting that was held in Seville, Spain in May 2005.

The key decisions affecting SG2 were:

i. The SC had accepted GHTF SG2 N38R14. A minor change to the table at the end of the document had been suggested (Full participants are to get "Public and/or Confidential" information. Also, a reference to GHTF SG2 N54, should be deleted because that document is not yet complete.

   The issue of funding of the NCAR program was not discussed.

ii. GHTF SG2 N47R4 was accepted as a status document and approved for publishing on the GHTF website.

iii. GHTF SG2 N61R5 was accepted as a report to the SC. It will be passed on to the other SC chairs but it will NOT be published on the GHTF website.

iv. GHTF SG2 N68R3 was accepted as a status document and approved for publishing on the GHTF website.

v. The new work item on the electronic format for adverse event reporting (GHTF SG2 N72R4) was approved. The SC requested that a progress report be provided at their meeting in November. The SC also requested that this be completed relatively quickly.

vi. The SC had approved the nomination of Jorge Garcia (TGA) as the new SG2 Chairman commencing after September 2005.

GHTF SG2 N80 – Map of SG2 guidance.

Discussion at the meeting clarified that GHTF SG2 N80 is for education only. It shows the relationship of SG2 guidance on AE reporting. It may not be needed after the work on consolidation of SG2 guidance on Adverse Event Reporting (GHTF SG2 N54) and NCAR reporting (GHTF SG2 N79) is completed.

GHTF SG2 N79: updating and combining N20 and N9

The group agreed to produce a new revision of N79R1 (which was not available at the time of the discussion because the leader for the project was absent) and comment on that item as appropriate. If the comments on N79 still reveal differences in opinion, then a special meeting will be convened to try to reconcile those differences.

GHTF SG2 N73 - update on N21 implementation

GHTF SG2 N73 is a table, which outlines the status of implementation of SG2 guidance in each of the member regions. A new revision of N73 had been produced which incorporated references of Canadian and Japanese regulations. The group also noted that Europe would be making changes to their MDEV guidance document.

Discussion: Strategy for implementation of N38

GHTF SG2 N38R14 describes the application requirements for NCAs wishing to participate in SG2's NCAR program. The group agreed that a process needed to be established to receive and deal with applications from NCAs.

SG2 agreed that a training and application package will be developed including template letters for application, reply and confirmation of acceptance as well as the training materials by way of power-point slides and printed material. A long deadline (February 2006) was given to this task because of other work commitments, but it was understood that if applications were received between now and the deadline, that the package would be put together in the course of dealing with the first application.

GHTF SG2 N87 (NWI N72): Standard for electronic reporting

A first draft of N87 was submitted to the group for consideration, but this was received on 2 June 2005 (during the meeting) and none of the group had had a chance to consider it. Also members requested the chance to take it home to show their IT

professionals for comment. Members agreed that feedback would be provided on N87 by mid July in time for further work to be done as a result of the comments in time for the next meeting of SG2.

Update on APEC meeting for medical device manufactures and NCAs – Bangkok June 2005.

The Asia Pacific Economic Community Organisation (APEC) had requested for representatives from the GHTF study groups to become trainers at an upcoming conference.

The presentation material that was compiled for the conference was shown to the SG2. Further refinements will be made to the material in the next few days before the conference.

Discussion of Future Meetings:

The SG2 noted the progress of arrangements for the Conference entitled “Design for Patient Safety” which will be run in Luebeck, Germany at a time that coincides with the Meeting of SG2 in June 2006.

The SG2 also discussed the arrangements for the meeting in Gaithersburg, which will feature concurrent meetings of the study groups followed by a day for inter-group interaction. SG’s may also decide to schedule special interaction sections at any time.

The group agreed that it would be a good idea for the SG2 to highlight that the work of the other study groups impinges on the work of the SG2 especially that associated with the content of the manufacturer’s QMS and Technical File. Similarly the SG2’s recent discussions on PMS (N61) concluded that much of the PMS harmonisation work had either been done or will be done by one or more of the other groups. It would be important to take the opportunity to communicate this finding to the other groups to ensure that the work has indeed been done.

GHTF SG2 N57 – Content of Field Safety Corrective Action Notices

The group agreed to change the wording used to describe the level of risk that applies before a field safety corrective action must take place. The definition will now read:

“A field safety corrective action is an action taken by a manufacturer when an unacceptable health hazard is identified based on risk analysis. Such actions should be notified via field safety notice.

Unacceptable health hazard is defined by the intolerable region in the chart described in Figure E.1 of ISO 14971:2000.”

The group will consider other aspects of the issue raised in the document in the next meeting.

GHTF SG2 N54 – Revision based on comments received

The group considered N54 as redrafted at the special meeting on Tuesday. Some further refinements were made. The group agreed that the new revision of N54R5 would be reviewed at the next meeting.

Developments regarding ISO19218 and the nomenclature being developed by the NCI on behalf of the FDA.

The US National Cancer Institute has been commissioned by the FDA to develop a coding system for medical device adverse events. The NCI system is based on "three tier" Type and Cause code tables. The NCI group had made good progress and discussed the developments with ISO TC 210 WG3, which developed ISO 19218. WG3 had agreed to hold ISO 19218 at the draft technical specification stage until the work of the NCI was available for examination.

A fairly complete working example is expected to be available, which will be demonstrated at the next meeting of SG2 in September 2005.

GHTF SG2 N12R11 Precis.

There were some higher-level comments:

The construction of the first section of the document was discussed. The Group agreed to revise the first section and create "miscellaneous" section.

The group has abandoned the use of the term vigilance because it is used loosely to mean different things in different regions. The preferred term is now Adverse Event Reporting, but Vigilance will be retained in the title of the document because it is part of the official SG2 name. This needs to be mentioned in the in introductory section of N12.

A new draft of N12 will be produced fro discussion at the next meeting of SG2 in September.

Other Business:

The group proceeded to review the action items and to update the work plan (N49R13). There was one outstanding action item from the Sydney meeting and this was rolled into the next action items list.

Future meetings:

12-16 September 2005:	Gaithersburg, Maryland, USA
27-29 February 2006:	TO BE CONFIRMED (London or Tokyo)
25-30 June 2006:	Luebeck, Germany

Meeting Closed 12:00 PM 3 June 2005