GHTF SG2 Meeting
Location: Hilton Hotel Washington DC North
Gaithersburg, Maryland, USA
Date: 13-15 September, 2005
(Special Meeting of all Study Groups on 16 September 2005)

Attendance:

Name	Organization	Email	Present
Penny Adams (PAd)	MIAA	padams@miaa.org.au	Absent
Takehiko Arima (AT)	JFMDA	tarima@jjmkk.jnj.com	X
Philippe Auclair (PAu)	EUCOMED	pauclair@guidant.com	X
Mary Brady (MWB)	FDA	mwb@cdrh.fda.gov	X
Kim Dix (KD)	Health Canada	kim_dix@hc-sc.gc.ca	X
Jorge Garcia (JG)	TGA	jorge.garcia@health.gov.au	X
Kensuke Ishii (IK)	PMDA	ishii-kensuke@pmda.go.jp	X
Hiroshi Ishikawa (HI)	JFMDA	hiroshi4.ishikawa@toshiba.co.jp	X
Ben Khosravi (BK)	AdvaMed	bkhosravi@sjm.com	X
Tetsuya Kusakabe	MHLW		X
Larry Kroger (LK)	NEMA	larry.kroger@med.ge.com	X
Tony Sant (TS)	MHRA	tony.sant@mhra.gsi.gov.uk	X
Mark Segstro (MS)	Health Canada		X
Ekkehard Stösslein (ES)	BfArM	e.stoesslein@bfarm.de	X
Stephen Sykes (SS)	FDA	Stephen.sykes@fda.hhs.gov	Absent
Carl Wallroth (CW)	EUROM VI	beate.moeller@draeger.com	X

Special Meeting to redraft N54: Tuesday 31 May 2005

Present: TA PA HI JG LK ES and CW

GHTF N54R4.2 was extensively edited based on comments arising from the SG2 meeting in Vancouver in September 2004, other comments received, and also from comments derived from GHTF SG2 N73 (status of implementation).

The purpose was to produce a new draft that would be considered on Thursday by the whole of the study group.

The Special meeting achieved its goal of producing a new draft document. The resulting document will need to be “cleaned up”. Some of the comments considered need to be inserted in the document comment template.

Day One: Wednesday 1 June 2005

The Group reviewed and edited the minutes of the meeting held in Sydney in March 2005. There were some differences in recollection of the resolutions regarding N72, N79 and N47/N61, but

these were resolved. There were some outstanding work items which were either rolled into te next current work items list, or left for discussion at the Milwaukee meeting.

It was noted that some e-mails had been missed by the recipients. JG asked the group to use the letters SG2 as the first letters of the subject line in e-mails relating to SG2 work so that they can easily be sorted in e-mail programs.

Action items:

1. JG: to distribute amended Sydney Minutes, & Summary Minutes – deadline 10/6/2005

2. All: When sending e-mails relating to SG2 matters the subject line should begin with the word "SG2" and be followed by the subject of the e-mail. Ongoing

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

KD presented a verbal report on the decisions made by the Steering committee their last meeting that was held in Sevilla, 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 ed of the document had been suggested (Full participants are to get "Public and/or Confidential" information.

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

ii. GHTF SG2 N47 was accepted as final – but Rita MacLachlan (RM) from the TGA requested the opportunity to comment further.

iii. GHTF SG2 N61 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 N68 was accepted as final – however RM requested the opportunity to comment further.

v. The new work item on the electronic format for adverse event reporting (GHTF SG2 N72) was approved. The SC requested that a progress report be provided at their meeting in November. The SC also requested that this WI be completed relatively quickly.

vi. The SC had approved the nomination of JG as the new SG2 Chairman commencing after September 2005.

KD noted that the Geithersburg meeting of SG2 and the next meeting of the SC will be very close together, and that this may cause some problems with the submission of SG2 documents

for consideration. KD had asked the SC to be aware of this fact and to be lenient with the deadline for submission of documents for consideration. The SC noted the request, but did not provide a firm commitment on this.

CW reported to the group that the SC was generally pleased with the presentation of the documents from the SG2 as being systematic and clear.

Action items:

3. KD: to inform TS that NWI N72 was approved, that SC expects progress report in November, and that SC expects this WI to be completed relatively fast – deadline 10/6/2005.

GHTF SG2 N80 – Map of SG2 guidance.

JG had changed N80 and distributed as agreed in Sydney. PA had provided comments and those had been included in the latest version. Some further changes were made during the meeting. The SG2 discussed further to clarify that the purpose of N80 is for education only. It shows the relationship of SG2 guidance on AE reporting. It may not be needed after N54 is finalised.

Action items:

4. JG: to distribute SG2 N80 R6 (as amended in Milwaukee to SG2 – Forward to SC with request to replace existing document on GHTF website.

GHTF SG2 N79: updating and combining N20 and N9

During the discussions at this meeting it became clear that due to differences in understanding of what was agreed to in the Sydney meeting of SG2, the group has not reached consensus regarding the threshold for exchange of NCAR reports:

MHLW had believed that only issues relating to serious public health threat or confidential matters should be reported – moreover they believed this to have always been the case, and wish to be strongly stated in N79. MHLW believe that there has been too much reporting and that many of the reports are too trivial and this causes some problems to Japan especially because of the difficulties associated with translation of the reports. Finally they believe that much of the information exchanged is publicly available through regulatory agency websites and this in particular should be eliminated from the NCAR program.

The other NCAs currently participating in the NCAR Program have interpreted the reporting criteria described in N20 differently and believe that the criteria suggested by MHLW are too high and restrictive. The other NCA's believe that their interpretation of the reporting rules has led to a more or less appropriate level of reporting, the differences in numbers from each NCA being more or less associated with the level of resource and commitment allocated to this task by the individual NCA. They point out that the fact that a piece of information is considered "public" does not necessarily make that information insignificant – Also passive

exchange may not be a suitable means of transmission of public OR confidential information that is urgent.

The group agreed to wait for the next revision of N79R1 (which was not available at the time of the discussion) and comment on that item as appropriate. If the comments on N79 still reveal deep differences then the NCA's in the SG2 should schedule a special meeting to try to reconcile the differences.

Action items:

5. TS: To prepare N79 based on discussions in Sydney and distribute to the SG2 by end of June.
6. All: to provide comments to amended N79 document – End of July.
7. NCA representatives: to be prepared to have a special meeting on the threshold for the submission of NCAR reports (N79) before Geithersburg SG2 meeting IF COMMENTS RECEIVED ON N79 MAKES THIS NECESSARY.

GHTF SG2 N73 - update on N21 implementation

KD had updated N73 in accordance with his interpretation of upcoming changes to Canadian Laws and regulations. However, this revision had not been distributed to the rest of the group. During the Milwaukee meeting, MS provided an update on Japan's implementation of GHTF SG2 N36. There had been no other changes.

The group reviewed the ammendments and requested that KD explain a little further – eg when are the proposed changes to the law expected to take place? Also in a couple of items the entry suggests that the clause is unlikely to be implemented using the wording in N21… more details would be useful here.

The group also noted that changes to the MDDEV are flagged in N73 for 2004. ES explained that these had not taken place as scheduled but progress was expected soon. ES agreed to provide details of the proposed changes.

Action items:

8. JG: to send N73R5 with KDs and MHLW amendments to SG2
9. KD: to provide more information about the planned changes in the Canadian law including the proposed time schedule – for next meeting (September).
10. ES: to provide the group with a short note about the planned changes in the European MEDDEV - End of June.

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. The group disagreed about the level of complexity and formality required from this process.

Finally it was agreed that a training and application package would 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.

CW suggested that the training provided comply with the requirements set down in ISO13485. This was accepted.

Action items:

11. JG (with help from other NCA members): to develop a training and application package for NCAR participation containing:

    - Application forms or templates (do we need this?)
    - Letter of reply from the SC chair informing the applicant about the process
    - List of available trainers (JG to ask TS and KD whether they are willing to be trainers).
    - Visual aids and other training materials for both associate & full membership applicants.
    - Template - SG2 trainer reference
    - Template - SC acceptance letter

    (Check this list and procedure with ISO 13485 part about training)

    Deadline : February 2006 – Sooner if applications arrive earlier. Progress report in September Meeting of SG2.

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

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

Action items:

12. ALL SG2: to make comments about GHTF SG2 N87 R1: An XML Schema for Electronic Transfer of Adverse Event Data … to TS by mid July

Day 2: Thursday 2 June 2005

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 which is to be held in Bangkok. BK LK and JG said that they would be willing to participate and so they received nominations from their respective organisations and the SG2 Chair (KD).

JG BK and LK ran through the presentation noting the liberal use of N80. JG requested permission to use N73 for the concluding part of the talk and received it. It was suggested that for this purpose N73 may be "colourised" to reflect the degree of convergence. Eg geen= fully implemented yellow = partly implemented and red = nor implemented.

JG LK and BK would make further refinements to the slides in the next few days before the conference.

It was suggested that the slides may also be used as part of the training program for N38, and that the files be distributed to the SG2..

Action Items:

13. JG: Slides from APEC meeting to be circulated to all SG2 – 10/06/2005

Discussion of Future Meetings:

CW provided an update on the Luebeck meeting which has been scheduled to coincide with the conference "Design for Patient Safety". Arrangements are proceeding well.

KD discussed the arrangements for the meeting in Geithersburg, which will feature concurrent eetings of the study groups followed by a day for intergroup interaction. However SG's may decide to schedule special interaction sections at any time.

There is some confusion about the structure for the last day but it is expected that this would involve presentations from each of the study groups.

JG suggested and 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.

Action Items:

14. KD: to contact Larry Kessler to find out what is expected from the session scheduled for Friday 16 September. Who is organising/coordinating/structuring this meeting? – End of June
15. PA KD: To prepare a presentation (DON'T FORGET N80)for the purpose of presenting to other SG's at the Geithersburg meeting – PA for N61 items – circulate the presentation materials- End of June

GHTF SG2 N57 – Contnt of Field Safety Corrective Action Notices

ES reminded the group that a stalemate had been reached at the Sydney Meeting of the SG2 because of a disagreement over the wording used to describe the level of risk that applies before a field safety corrective action must take place.

JG presented a chart similar to that which appears in ISO 14971 to explain what level of risk he thought the current wording describes and also what he thought the wording should describe. PA suggested alternative wording. Finally the group agreed to chage the definition section to 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 also agreed that the redrafted document should be circulated so that the group can consider the other aspects covered at the next meeting.

Action Items:

16. JG: To distribute N57R4 by 10 June 2005
17. All: To provide comments to ES on N57 by 1 August 2005.

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 decisions of the group are too numerous to describe in these minutes but they were recorded either on the draft document itself or in a standardised comment template developed for this purpose.

The group decided that the document should be "cleaned up" and distributed, as GHTF SG2 N54R5 to the whole of the study group once again for consideration, this time at a high level.

The group also agreed that all of the comments considered and the decisions made in regards to those comments will be transcribed onto the comment template for N54.

The group agreed to discuss N54 once again at the next meeting.

Action Items:

18. ALL: to find an appropriate example for N54 4.5 (instead of the blood bag example) – by end of July.
19. JG: to complete the N54 comment template and provide reasons for accepting or rejecting any proposed changes. By mid July.
20. JG: to "tidy up" N54 as amended in Milwaukee, assign revision 5 and distribute to the SG2. By end June.
21. All: to consider N54R5 and provide feedback by end August 2005.

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

MWB provided a brief verbal update: The NCI has bee working on a system based on "three tier" Type and Cause code tables. The FDA NCI group had made good progress and discussed the developments with the ISO TC 210 WG3. WG3 had agreed to hold ISO 19218 at the draft technical specification stage until the work of the NCI was available for examination.

MWB thought that a fairly complete working example would be available by September and offered to ask the NCI representatives to demonstrate it at the next meeting of the SG2. The offer was gratefully accepted.

Action Items:

22. MWB: MWB & NCI group to provide update and demonstration of new nomenclature system developed by NCI – September 2005
23. JG: to include NCI report and demonstration in Geithersburg agenda – September 2005

Day 3: Friday 3 June 205

GHTF SG2 N12R11 Precis.

The group considered the revision of N12 sent by MWB just prior t the meeting. There were some editorial comments that were recorded directly onto the new draft document, but there were also some higher level comments:

The layout of the first section and perhaps of the document as a whole needs revision. In particular the group felt that a "miscellaneous" section should be created where higher level ideas regarding communication, the meaning of a report, confidentiality and the vision of a global database may be placed.

The introductory section needs to mention that 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.

MWB agreed to redraft the document in accordance to discussions in Milwaukee.

Action Items:

24. MWB: to amend N12R11 as discussed in Milwaukee and distribute to SG2 – 9 July 2005.

25. All: to comment on the amended N12 provided by MWB – end August

Other Business:

The group proceeded to review the action items and to update the work plan (N49). It was noted that the only outstanding action item from the Sydney meeting was the preparation of the combined (1 spreadsheet, two charts) NCAR statistics.

Action Items:

26. KD: to distribute NCAR statistics, N76R2 – by end June 2005

Meeting Closed 12:00 PM 3 June 2005

Future meetings:

12-16 September 2005:	Gaithersburg, Maryland, USA
27-29 February 2006:	London or Tokyo?
25-30 June 2006:	Luebeck, Germany