



**GHTF SG2 Meeting**  
**Location: Boston Scientific Japan Miyazaki Technology & Education Center**  
**Date: 8-10 March 2006**

**Attendance:**

Name	Organization	Email	8/3	9/3	10/3
Takehiko Arima (AT)	JFDA	tarima@jjmkk.jnj.com	X	X	X
Philippe Auclair (PAu)	EUCOMED	pauclair@guidant.com	X	X	X
Mary Brady (MWB)	FDA	mwb@cdrh.fda.gov	X	X	X
Isabelle Demade (ID)	EC	isabelle.demade@cec.eu.int	X	X	X
Jorge Garcia (JG)	TGA	jorge.garcia@health.gov.au	X	X	X
Uichiro Kimura (UK)	PMDA	kimura-uichiro@pmda.go.jp	X	X	X
Hiroshi Ishikawa (HI)	JFDA	hiroshi4.ishikawa@toshiba.co.jp	X	X	X
Ben Khosravi (BK)	AdvaMed	bkhosravi@sjm.com	X	X	X
Larry Kroger (LK)	NEMA	larry.kroger@med.ge.com	X	X	X
Tetsuya Kusakabe (TK)	MHLW	kusakabe-tetsuya@mhlw.go.jp	X	X	X
Roger Leclerc (RL)	MEDEC	rleclerc@medec.org	X	X	X
Tony Sant (TS)	MHRA	tony.sant@mhra.gsi.gov.uk	X	X	X
Mark Segstro (MS)	Health Canada	mark_segstro@hc-sc.gc.ca	X	X	X
Ekkehard Stösslein (ES)	BfArM	e.stoesslein@bfarm.de	X	X	X
Carl Wallroth (CW)	EUROM VI	beate.moeller@draeger.com	X	X	
Observers					
Kathy Chester	AdvaMed		X	X	X
Yuji Inahara	Boston Scientific		X	X	X
Kunihiko Mano	Boston Scientific		X	X	X
Yasuyuki Tabata	Boston Scientific		X	X	X
Hisanori Tokito	Boston Scientific		X	X	X
Ryuichi Vemura	Boston Scientific		X	X	X

**Welcome, Introductions, Announcements:**

Mr. Hiromi Kimura, Director of Quality Affairs for Boston Scientific Japan, welcomed SG2 members to the Boston Scientific Japan Miyazaki Technology & Education Center that provided facilities and refreshments for the meeting.

JG assumed the Chairmanship of SG2 replacing Kim Dix. LK is the new Secretary of the group. Observers from AdvaMed and Boston Scientific were in attendance.

There was one new member to the Group:

Mr Uichiro Kimura, Pharmaceuticals and Medical Devices Agency, Japan.

**Review meeting goals and agenda; approve old minutes:**

The group reviewed the previous minutes GHTF SG2 N91R1 from the Gaithersburg meeting. There were several minor corrections to the date and place of the next meeting to be held in Japan. The minutes were then approved.

The action Items from the Gaithersburg meeting were discussed – Most of the actions were completed, a few are pending. CW requested a change to the agenda to move the N21 implementation discussion to Wednesday since he was not available on Friday.

JG previewed changes to N80 for the GHTF website and discussed his report to the Steering Committee on the status of SG2 work items. JG a previewed the slides presented at the Steering Committee meeting in London in September 2005. Proposed items for the maintenance phase were outlined. It was explained to the Steering Committee that any of these activities may lead to new work item proposals for the existing documents and new proposed activities, but the meeting frequency of SG2 may be reduced.

**Action Items:**

1. Distribute PPT presentation made to SC in Nov 2005. JG by March 17 2006.

**GHTF SG2 N73: Status of N21 Implementation**

The discussion on implementation provided the following results:

- Australia – no change
- Canada – changes still pending, no further progress
- EU – only change is to the planned schedule which was revised to 3<sup>rd</sup> quarter 2006
- Japan – no change
- U.S. – no change

**Action Items:**

2. To find out the likely concerns from Canada regarding N21/N54 clauses >> N73. MS by June 2006

**GHTF SG2 N79: Updating and Combining N20 and N9**

Public comments were collected and reviewed. During discussion of these comments a number of changes were made to the document. A note was added to appendix A about how to use the flowchart. The revision number was updated to N79R7. There was an extended discussion on items 18 & 19 on the NCAR form. Japan representatives suggested the form include the name of the Market Authorization Holder (MAH) in Japan. A minor change was made to item 26b on the form. The reference to Class I recalls was deleted. It was requested that the reference section be expanded to include the full title and date of the referenced documents. This information will be obtained from the GHTF website.

**GHTF SG2 N57: Harmonizing the Content of Recalls/Advisory Notices**

Public comments were collected and reviewed. During discussion of these comments a number of changes were made to the document. Two comments from NEMA were accepted and incorporated into the document. Additional comments from the EU were also accepted. A requirement was added to recommend the use of a reference number on the field safety

notification. A suggestion was also added with regards to when a user should carry out any recommended actions (timeframes). Comments were added to encourage users to forward field safety notifications to those to whom the product was resold or to those to whom incorrect information may have been sent. A suggestion to add a definition of “advertisement” was rejected. The word “advertisement” was replaced with a description of advertising. The revised version of the document was changed to N57R7.

**Action Items:**

3. Distribute N79R7, N57R6. LK by March 17, 2006.
4. Last editorial comments on N79R7, N57R6. All by April 7 2006.
5. If no comments or minor comments, send N79R7 N57R and N54R to SC for consideration as final. LK/JG by April 15 2006.
6. As soon as N79 is final request that N9 and N20 documents are deleted from the website. JG by July 2006.

**Luebeck Meeting Update**

CW reviewed the plans for the GHTF meeting in Luebeck. JG was requested to provide CW a list of SG2 attendees for a possible meeting on Saturday, July 1. CW urged everyone to complete the registration form for the meeting. All registration materials can be obtained from the GHTF website. Everyone was encouraged to book flights early as other activities in the area could create conflicts during this time. The early registration deadline was extended to March 15 for those who want to take advantage of the 25% discount on the registration fee.

**Action Items:**

7. To provide Draeger a list of SG2 potential attendees. Clarify about possibility of meeting on 1<sup>st</sup> of July. JG by 1 April 2006.
8. Complete conference registration and send in (if going to the Conference, early registration deadline March 15). All ASAP.

**GHTF SG2 N54: Global Vigilance on Adverse Event Reporting**

Public comments were collected and reviewed. During discussion of these comments a number of changes were made to the document. All comments were copied into a single GHTF comments template. A comment to add a definition of “adverse event” was rejected. Actions on this and the other comments discussed were recorded in the comments template. Due to the numerous comments received, there was not time to discuss them all. Therefore, the review and decisions on the remaining comments will be added to the agenda for the next meeting in Luebeck.

**Action Items:**

9. Consider comments to N54 and what the response should be (prepare for yourself before meeting). All by 25 June 2006.

**GHTF SG2 N87: An XML Schema for the electronic transfer of adverse event etc.**

TS presented further work completed on electronic reporting. A supporting Excel matrix was created with 76 reporting fields, 14 of which are in addition to those given in N32, Universal Data Set. After discussion, it was decided the XML-coded fields should be based only on the N32 defined fields. Comparison with the additional fields that are included in the HL7 formulation will however remain on the SG2 supporting spreadsheet for informational purposes only. Items added for trend reports were deleted but will remain on the spreadsheet for future discussion. Members were reminded that it is not the goal of SG2 to incorporate all fields developed by HL7, but to limit the XML report form to N32 only items. TS will recompile the matrix and append it to N87. The revised version will be N87R6. TS will also continue to work on the XML code. Any further comments should be provided to TS by 5 May 2006. JG, MB, LK & PA volunteered to try out the XML code when available.

**Action Items:**

10. To prepare N87R6 – including table agreed in Miyazaki as Appendix. Add XML code as attached. Preferably before May otherwise postpone submission of N87 as PD until XML code is complete. TS/MB/LK/JG by 21 April 2006.
11. Circulate N87R6 within SG2. LK by 22 April 2006.
12. Provide Comments on N87R6 to TS. All by May 5 2006.
13. Submit as N87R? as PD to SC. JG by May 17 2006.
14. TS to circulate the HL7 stuff to the group. TS by 1 May 2006.

**ISO 19218: Discussion developments**

MWB led a discussion on the ISO document on event coding. The ISO document is the result of a SG2 request. If FDA decides on an alternate approach, then the ISO document will not likely be used. Therefore SG2 was requested to examine the FDA work and perhaps provide further comments to the working group for ISO 19218.

MWB provided a copy of the alternate FDA approach in a document entitled “Device Issues”. SG2 was requested to review the new document and provide comments to MWB.

SG2 will plan to use ISO 19218 and perhaps use the FDA document to prepare further inputs to TC210 for recommended changes to ISO 19218.

**Action Items:**

15. Provide comments on the FDA NCI type/cause table to MWB. All by 1 May 2006.
16. Provide the national comments on ISO19218 send to SG2. All by 1 June 2006.
17. To “map” draft FDA code table with ISO 19218 and send to SG2. MWB by 1 June 2006.

### **NCAR performance and statistics**

MS provided printed charts on the cumulative results from the NCAR program. Charts were shown for each participating country with the number of reports submitted by year. Additional charts were included showing the cumulative number of reports submitted by country to March 1, 2006 and the number of participating countries by year from 1999 through 2005.

### **Action Items:**

18. Send MS request for wishes how to see NCAR statistics. All by 1 June 2006.

### **Other Business:**

The Group discussed briefly the APEC Meeting scheduled for Santiago, Chile. BK, LK and Kim Dix were all nominated and accepted as trainers. The materials to be used are essentially the same with a few minor updates as used in the Bangkok, Thailand APEC meeting.

The meeting closed at approximately 4 pm on Friday, 10 March 2006 after a review of the action items (GHTF SG2 N49, Revision 15 after Miyazaki).

### **Future SG2 meetings:**

26-28 June 2006: Luebeck, Germany