GHTF SG2 Meeting
Location: Dräger Medical, Lübeck, Germany
Date: 26-28 June 2006

Attendance:

Name	Organization	Email	26/6	27/6	28/6
Penny Adams	MIAA	padams@miaa.org.au			
Miguel Antunes	INFARMED	miguel.antunes@infarmed.pt	X	X	
Takehiko Arima (AT)	JFMDA	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
Kensuke Ishii	PMDA	ishii-kensuke@pmda.go.jp	X	X	X
Hiroshi Ishikawa (HI)	JFMDA	hiroshi4.ishikawa@toshiba.co.jp			
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	X
Observers					
Kathy Chester	AdvaMed			X	X
Irene Schmidt	EDMA		X		X
Leighton Hansel	ISO TC210 WG3		X		
Kazuo Yano	JFMDA		X	X	X
Nellie Ong	AHWP			X	

Welcome, Introductions, Announcements:

The 31st meeting of SG2 was held at Dräger Medical AG & Co. KG in the Tokyo room, 5th Floor, Dräger Studio, House 72a, Moislinger Allee 53-55, D-23558 Lübeck, Germany. The meeting immediately preceded the 10th GHTF Conference hosted by EUROM, the European Industry Federation for Precision Mechanical and Optical Industries including Medical Technology, in cooperation with Dräger Medical.

Day 1 of the meeting began with introductions of the participants. The meeting was chaired by JG with LK assisting when JG had to leave to meet with the Steering Committee. Observers from AdvaMed, EDMA, ISO TC210 WG3, JFMDA and the Asia Harmonization Working Party (AHWP) were in attendance during the three days of the meeting.

There were two new members to the Group:

Mr. Miguel Antunes, Healthcare Products Vigilance Department, INFARMED, Portugal and Mr. Kensuke Ishii, Pharmaceuticals and Medical Devices Agency, Japan.

Review meeting goals and agenda; approve old minutes:

The group reviewed the agenda for the meeting. One item was added for the review of N38 documentation requirements.

The Action Items from the Miyazaki meeting were discussed – Most of the actions were completed, two are pending and one was questionable.

Action Items:

1. Send training doc (from Santiago) to GHTF Secretariat. LK by 30 August 2006.
2. Update membership list on website – SG2 to send to LK. All by 30 August 2006.

GHTF SG2 N54: Global Vigilance on Adverse Event Reporting

The review of public comments on N54 that began at the previous SG2 meeting in Miyazaki, Japan was resumed. During discussion of these comments a number of changes were made to the document. All comments were documented into a single GHTF comments template. Actions on the comments discussed were recorded in the comments template. A number of changes were made to N54 describing types of events. Due to the numerous comments received, this review occupied the remainder of the first day of the meeting.

JG was called into a Steering Committee meeting during the review and LK acted as temporary chair for a portion of this review.

Action Items:

3. Submit N54R9 to SC for consideration as final. JG, LK by 30 August 2006.

JG Report from Steering Committee on N57, N79, and N87

The Steering Committee suggested minor wording changes on N57 and N79. The revision number of both documents was updated from revision 7 to 8. With these changes the documents will be approved as final.

The Steering Committee expressed concern about SG2 developing code for electronic reporting. It was felt that justification for the use of the XML coding system was needed. The Steering Committee requested a progress report be provided in September 2007 regarding the progress on the electronic reporting project using XML. N87 on electronic reporting was approved as a proposed document and will be posted on the GHTF website for comments. An explanatory note about the pilot and protocol will be published on the GHTF website along with N87

JG also reported that WHO has applied for participation in the NCAR program. A concern with WHO participation is the expected dissemination of reports to non-NCAR members.

Action Items:

4. Ensure that changes to N79 and N57 (use > “consider”) and send for posting on web as Final. LK by 30 August 2006.

5. As soon as N79 is final, request that N9 and N20 documents are deleted from the website. JG by July 2006.
6. Justification for use of XML. TS by 30 September 2006.
7. Report on the progress of the Pilot. JG by November 2006.

New Work Item, Meeting Conflicts

At the beginning of Day 2, JG presented a draft new work item N96 for the NCAR program in response to a Steering Committee request. The draft was discussed and modified by SG2.

Subsequently, the new work item was not approved by the Steering Committee.

MB raised a discussion point regarding simultaneous meetings of the Steering Committee and the Study Groups. It was generally agreed that this causes significant disruptions to the Study Group meetings.

Action Items:

8. Write letter to Larry Kessler and SG Chairs indicating concern over co-scheduling SC and SG meetings. JG by 31 July 2006.

Comments on GHTF SG2 N57 and N79

Additional public comments were received from AdvaMed on N57 and N79 and reviewed during the meeting. One comment suggested a clear distinction be made between safety and non-safety modifications. SG2 members agreed that is no ambiguity in the documents and rejected the proposed change. A second comment objected to deletion of the word 'advertisement'. The word "advertisement" was replaced with a description of advertising at the previous meeting in Miyazaki. This comment was also rejected because SG2 members decided to omit the term 'advertisement' to deliberately prevent the inclusion of promotional information in Safety Notices. It was agreed that JG would provide feedback to AdvaMed on the status of all their comments.

Action Items:

9. Reply to AdvaMed regarding the status of their comments. JG by 31 July 2006.

ISO 19218: Discussion developments

MWB led a discussion on FDA event coding versus the ISO 19218 approach. The FDA system uses a multi-tier approach. Nine (9) of the FDA 2nd tier codes match the ISO 19218 codes and seven (7) of the FDA codes are not matched to any ISO 19218 codes.

Leighton Hansel, who is the convener of ISO TC210 WG3, gave a PowerPoint presentation on the Status of ISO TC 210 TS19218, 'Coding Structure for adverse event type and cause/effect'. He discussed possible ways to harmonize ISO TS19218 to the FDA event-coding scheme. He

expressed a desire to see more detail in the lowest level of event and cause codes. A small working group was proposed to be made up of SG2 members and TC210 members. TS, MWB, JG, ES, HI, and PA will work with Leighton and a subgroup from TC210 to create the next iteration of ISO 19218.

It was discussed and agreed to use ISO 19218 coding for the N87 pilot on electronic reporting.

Action Items:

10. Subgroup of SG2 to work with Leighton Hansel to revise ISO 19218. By July 2007.

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

TS presented further work on a pilot for electronic reporting. It was suggested that participants would need clear work instructions to proceed.

Action Items:

11. Develop protocol for pilot phase of N87. TS, ES, PA, TK by 30 September 2006.

NCAR performance and statistics

On day 3 of the meeting MS provided updated data on the 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 June 17, 2006 and the number of participating countries by year from 1999 through 2006.

Other Business:

RL raised a question regarding a SG2 definition of the term 'recall'. There currently is no harmonized definition of the term. There currently is no plan to create such a definition. It was recommended that SG2 create a glossary of the definitions used in SG2 documents. HI and LK agreed to develop a glossary.

It was also decided to reserve time in the next meeting to discuss whether SG2 needs to consider further new work items to complete a global model for post-market surveillance.

The meeting closed at approximately 3 pm on Friday, 28 June 2006 after a review of the action items.

Action Items:

12. Compile definitions from SG2 documents in one place. HI, LK by 30 August 2006.
13. Include in next agenda:
    discussion of gaps in SG2 guidance
    discussion on N73
    AdvaMed comments

Future SG2 meetings:

Late January 2007: Australia, JG to decide on venue.