GHTF SG2 Meeting
Location: The Ronald Reagan Building and International Trade Center, Washington, DC, USA
Date: 30 September – 2 October 2007

Attendance:

Name	Organization	Email	30/9	1/10	2/10
Miguel Antunes (MA)	INFARMED	miguel.antunes@infarmed.pt		X	X
Takehiko Arima (AT)	JFMDA	tarima@jjmkk.jnj.com	X	X	X
Philippe Auclair (PAu)	EUCOMED	philippe.auclair@av.abbott.com	X	X	X
Mary Brady (MWB)	FDA	mwb@fda.hhs.gov	X	X	X
Isabelle Demade (ID)	EC	isabelle.demade@ec.europa.eu	X	X	X
Jorge Garcia (JG)	TGA	jorge.garcia@tga.gov.au	X	X	X
Hiroshi Ishikawa (HI)	JFMDA	hiroshi4.ishikawa@toshiba.co.jp			
Ben Khosravi (BK)	AdvaMed	bkhosravi@sjm.com			
Larry Kroger (LK)	MITA/NEMA	larry.kroger@med.ge.com	X	X	X
Tetsuya Kusakabe (TK)	MHLW	kusakabe-tetsuya@mhlw.go.jp	X	X	X
Mark Segstro (MS)	Health Canada	mark_segstro@hc-sc.gc.ca	X	X	X
Klaus Stitz (KS)	MEDEC	kstitz@medec.org	X	X	X
Ekkehard Stösslein (ES)	BfArM	e.stoesslein@bfarm.de	X	X	X
Miang Tanakasemsub (MT)	AHWP	miang.tanakasemsub@bausch.com	X	X	X
Hiroyuki Tanishiro (HT)	PMDA	tanishiro-hiroyuki@pmda.go.jp	X	X	X
Carl Wallroth (CW)	EUROM VI	beate.moeller@draeger.com			
Observers					
Michael Cheng	WHO			X	X
Leighton Hansel	ISO		X	X	
Indira Konduri	FDA			X	
Randy Levin	FDA			X	
Howard Press	FDA			X	
Terrie Reed	FDA			X	
Lise Stevens	FDA			X	
Sandy Weininger	FDA		X		
Robert Wise	FDA			X	X
Deborah Yoder	FDA		X	X	X
Hideto Yokoi				X	

Welcome, Introductions, Announcements:

The 33rd meeting of SG2 was held at The Ronald Reagan Building and International Trade Center in Washington, DC, USA. There were four new members to the group. They are Tetsuya Kusakabe representing MHLW in Japan, Klaus Stitz representing MEDEC in Canada, Miang Tanakasemsub representing the Asia Harmonization Working Party and liaison to SG2, and Hiroyuki Tanishiro representing PMDA in Japan. Miang is the Co-chair of a WG2 Technical Committee that is assisting AHWP member countries in using GHTF SG2 documents in development of their local regulations.

Day 1 of the meeting began with an informal discussion lead by JG on the future plans of SG2 since not all SG2 members had yet arrived. It was noted that the remaining work items indicated that the meeting frequency might be further reduced. The discussion then focused on a SC WIP document regarding communications regarding Class I recalls (as defined by FDA). It was proposed that SG2 members HI and CW on the GHTF SC be briefed about the WIP document so that they might remind the SC about a possible overlap with the existing SG2 NCAR program. The discussion continued on past SC feedback to SG2 regarding enforcement issues and how that might apply to recalls.

Review meeting goals and agenda; approve old minutes:

Upon the arrival of missing SG2 members, the formal meeting began with introduction of participants and announcements about the meeting and logistics. The first item of business was to review the meeting schedule. It was decided to combine a discussion on ISO 19218 and adverse event coding originally scheduled as separate topics because of their close relationship.

The action items from the previous SG2 meeting in Melbourne, Australia were reviewed. It was decided that SG2 should respond to AdvaMed regarding the comments that were sent too late to be included in the N57 and N79 documents. JG and LK were to locate the documentation related to these comments and JG will prepare a response.

Action Items:

1. Respond to AdvaMed comments – JG by end October
2. LK to distribute final Melbourne minutes with minor corrections to SG2 members. Action completed.

Event Coding and ISO 19218: Discussion developments:

MWB reviewed the FDA work on event coding. FDA has identified approximately 600 codes with five levels. Level 2 has 29 elements and level 3 has 169 elements.

Leighton Hansel (LH), the convener of ISO TC210 WG3, reviewed the work on ISO 19218. The current version of ISO 19218 has 20-22 basic event codes. An issue was raised about whether the work on event codes should be completed before cause codes are developed. A document was circulated to the Study Group showing a comparison of ISO and FDA codes with a caveat that it should be viewed only with the full list of event codes, which were not included. Additional coding is desired by regulators for patient outcomes. Some patient outcome codes are included in ISO 19218 but are rephrased as event codes.

LH proposed that he and MWB could develop some improved terms for level 2. It is also important to do a final lockdown of level 1 terms.

Action Items:

3. Work on taking FDA Level 3 terms to TC210 Level 2- MB, PA, JG, ES, HI – by December 2007

    a. Leighton Hansel to work with TC group- send to SG2- by end November 2007
    b. SG2 to comment back to Leighton Hansel – ASAP
    c. Cause codes will be worked on later- 3rd quarter 2008

Discussion of N61: PMS Harmonization Chart

JG next led a discussion on potential SG2 activities. Previous decisions on potential topics for harmonization by SG2 are documented in N61: therefore, it was decided to review N61 in light of recent GHTF Steering Committee discussions to determine whether any of the potential harmonization topic decisions should be reevaluated. A topic entitled "NCA Assessment of postmarket information" was added.

Action Items:

4. Circulate changes to N61- discussion items- review to see if it needs any changes for future work items – JG to send by Oct 12, 2007; comment back by February 2008

Discussion on plan for pilot of N87PD

Day 2 of the SG2 meeting began with a discussion by Indira Konduri from FDA who made a presentation to the study group members on FDA developments for an adverse event electronic reporting system based on the use of HL7 standards. The HL7 standard being used by FDA was identified as ISO 21731: 2006, version 3.

JG then conducted a discussion using N80 to illustrate how adverse events are reported by manufacturers and processed by regulators. Electronic reporting will need to fit into the current reporting and processing model.

It was noted that N87 field code tag names for electronic reporting that were developed by SG2 are not consistent with HL7. ID expressed concern that changing from XML which is the current coding scheme used in N87 to HL7 would possibly undermine the investment by European NCAs who have already contracted for the XML coding development.

It was reported that several EU NCAs would proceed with the N87 pilot using a PDF form for the manufacturers to complete and submit. The current plan in the EU is for the pilot to begin no later than January 2008.

Action Items:

5. Provide table of N87 tags and map to HL7 tags with a view to add to HL7 - (with Lise Stevens), and send to ES- MB by end October 2007

Confidentiality of NCAR reports

The next item on the agenda was to continue the discussion, which began at the last SG2 meeting in Melbourne about public access to information regarding medical products that is held by regulators. One question that was raised for discussion concerned the types of information that should be made public on NCA websites.

Action Items:

6. Prepare document about what should be made public after investigations- ID
    a. All SG2 to identify and list where regulators post public information- the url addresses-, send to ID, and cc LK, before next meeting- end Jan 2008

The SG2 meeting adjourned at noon on day 2 so that the meeting of the study group chairs with the steering committee did not conflict with the SG2 meeting.

JG Report from Steering Committee

Day 3 of the SG2 meeting began with a report by JG on the Steering Committee discussions from the previous afternoon. The first item was on the topic of recalls. It was suggested that SG2 prepare a proposal for further work on harmonizing recalls. For the NCAR program it was suggested that administrative tasks be shifted to a subgroup of the Steering Committee. With regards the N87 pilot, the Steering Committee requested a work item (including program plan) be submitted for the electronic adverse event reporting pilot. It was requested the plan include a description of how success would be measured.

Action Items:

7. Prepare/update pilot project plan, establish goals and measures of success- ES (with TS) by Dec 2007 (must to go SC)

New work item proposal SG2 N96R1

MS reported on a new work item proposal to revise N79 (National Competent Authority Report Exchange Criteria and Report Form) and N38 (Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program) to address the language related to confidentiality. It was reported that the definition of confidential differs in the two documents. MS will clarify the definition of confidential and also check the wording in N38 and N79 related to the 'release of reports'.

It was suggested that changes to N38 and N79 should be accompanied by training for NCAR members. JG agreed to prepare a strategic document dealing with the retraining issue.

Action Items:

8. Clarify definition of "Confidential"- MS sends out and gets feedback by end Oct 2007
    a. Check N79 and N38 about release of reports i.e., recipient handling of NCARs
9. Prepare document on re-training for NCAR – JG by end Jan 2008

10. Revise N79 form- re: confidentiality – JG, MT, MS by end Jan 2008

Report on Asia Harmonization Working Party

MT gave a report on the activities of AHWP Work Group 2 that is developing requirements for vigilance and postmarket surveillance for AHWP members based on SG2 guidances. The presentation included details on existing requirements and regulatory authority for each AHWP member country. WG2 consists of AHWP regulator and industry representatives that have developed an NCAR-like system called Safety Alert Dissemination System (SADS) that will exist until AHWP members are able to join and participate in the NCAR program. Any AHWP member country may apply to join the SADS program. Training is required for participants. SADS includes manufacturer involvement similar to that of the NCAR program.

NCAR performance and statistics

MS presented all NCAR data up to September 25, 2007 for review and comment by SG2 members. The reported included data on 1181 NCAR reports. There are currently NCA participants in the program from Asia, Europe, and North America. The data analysis included trends by product sector. The number of NCARs received continues to grow each year. The largest contribution by product type involves cardiovascular products (22%). Overall, software related issues accounted for about 13% of NCARs. About half of all NCARs involved product recalls.

WHO Update

The World Health Organization has in the past expressed an interest in becoming a full NCAR participant so they might alert emerging counties about product issues. However, such use of confidential NCAR information is not in accord with the requirements of the NCAR program. In subsequent discussions JG extended an invitation to WHO to participate as an Associate Member which limits access to only nonconfidential reports. WHO has declined the invitation and will instead encourage its member countries to apply for NCAR membership. JG reported that WHO expressed interest in facilitating training for NCAR participation.

Discussion of N73: status of implementation

There was only a brief discussion of N73 at this meeting. There were no changes reported by any of the SG2 regulators on the status of implementation of SG2 guidances. It was recommended that the EU regulators update the implementation chart in N73 to reflect the latest revision of the EU MEDDEV document on medical device vigilance.

Action Items:

11. Update the N73 to reflect MEDDEV changes – PA by end Jan 2008

Sharing non-public information

JG invited David Kelly, Associate Director, Europe, Harmonization and Trade, from FDA to discuss a paper that he prepared entitled "Proposal to GHTF Steering Committee on the Founding Member Regulators Sharing Non-Public Information on Serious Public Health Events". This paper had been circulated to SG2 members prior to the meeting and it was unclear why this information sharing could not be part of the NCAR program. It was explained that the main concern was due to the fact that FDA has legal restrictions on the sharing of non-public information with other regulators that requires confidentiality agreements between parties that are more restrictive than NCAR requirements. While the NCAR program has restrictions on the sharing of confidential information, it does not specify that NCAR participants have confidentiality agreements with all other NCAR participants.

Other Business:

JG reported that the outcome of SG1 discussions on the definition of 'manufacturer' would be a proposal that will be distributed for comment.

The meeting closed at approximately 4 pm on Tuesday, 2 October 2007 after an update of the SG2 Work Plan N49R17 and a review of the action items.

Action Items:

12. Bring GHTF website up to date – LK, and JG by next meeting
    a. Minutes
    b. N80
    c. Training materials
13. Draft a compelling new work item for "Definition and Classification of Recalls" – JG by beginning Dec 2007, submit to SC shortly after
14. Consider the meaning of "Public" and "Confidential" information within national jurisdiction- all SG2, before next meeting
15. Review next draft definition of "Manufacturer" from SG1- JG will disseminate when received; SG2 to comment according to SG1 timeframes, before March 2008

Future SG2 meetings:

27-29 February 2008: Possible location Lisbon, Portugal (alt. location Brussels). Miguel Antunes subsequently confirmed the dates and Lisbon as the location for the next meeting.

October 2008: Tentative location Toronto, Canada.