



GHTF SG2 Meeting
Location: Lord Elgin Hotel, Board Room 200,100 Elgin Street,
Ottawa, ONTARIO, CANADA
Date: 15-17 October 2008

Attendance:

Name	Organization	Email	15/10	16/10	17/10
Miguel Antunes (MA)	INFARMED	miguel.antunes@infarmed.pt			
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
Barbara Harrison (BH)	Health Canada	barbara_harrison@hc-sc.gc.ca	X	X	X
Hiroshi Ishikawa (HI)	JFMDA	hiroshi4.ishikawa@toshiba.co.jp	X	X	X
Ben Khosravi (BK)	AdvaMed	bkhosravi@sjm.com	X	X	X
Larry Kroger (LK)	MITA/NEMA	larry.kroger@med.ge.com	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			
Nobuhiro Yamamoto (NY)	MHLW	yamamoto-nobuhiro@mhlw.go.jp	X	X	X
Observers					
Takuya Noro	MHLW		X	X	X
Hideto Yokoi	PMDA Advisor		X	X	X
Stela Candioro Melchoir	ANVISA (Brazil)		X	X	X
Pollyanna Costa	ANVISA (Brazil)		X	X	X
Leighton Hansel	ISO TC210 WG3		X	X	

Welcome, Introductions, Announcements:

The 35th meeting of GHTF Study Group 2 was held at the Lord Elgin Hotel, in Ottawa, Canada. There were two new members to the group. Barbara Harrison represented Health Canada and Nobuhiro Yamamoto represented MHLW. Welcome to Ms. Harrison and Yamamoto-san to SG2 and thanks to their predecessors Mark Segstro and Tetsuya Kusakabe, respectively, for their service to the group. There were several observers to the meeting including two from Japan and two from ANVISA the Brazil Regulatory Authority. Leighton Hansel also attended on behalf of ISO TC210 WG3.

Day 1 of the meeting began at approximately 8:30 AM on October 15, 2008, with a greeting from the Chair, JG, who then requested that each of the participants introduce themselves. Jorge Garcia announced that Isabelle Demade representing the European Commission would succeed him as Chair at the next meeting. LK reminded the group that this was his last meeting as he had

announced his retirement from GE Healthcare, and it would be necessary to select a new secretary to SG2. After a brief discussion Philippe Auclair representing EUCOMED agreed to accept the assignment as secretary to SG2. Congratulations to Isabelle and Philippe on their new appointments and thanks to JG and LK for their past service.

Review meeting goals and agenda; approve old minutes:

The first order of business was a review of the agenda for the meeting. PA requested that a discussion on requests for SG2 training be added to the agenda. An item assigned to CW was dropped from the agenda since CW was unable to attend the Ottawa meeting. Several items were reordered on the agenda to better accommodate participant schedules including moving the item on AE reporting during clinical trials to Friday so that several members of SG5 could participate in the discussion.

The minutes from the previous SG2 meeting in Lisbon, Portugal were reviewed. There were no corrections or additions to the previously circulated minutes. The Lisbon minutes will be posted to the GHTF website as document SG2 N109R0.

The action items from the previous SG2 meeting in Lisbon, Portugal were reviewed. A few of the actions are still in progress and will be included with the actions from the Ottawa meeting. It was noted that some action items asking for comments have resulted in no response from many SG2 members. It was requested that in the future, if a SG2 member has no comments on a particular action item, that they at least respond they have no comments so it is clear where they stand on the issue. A lack of any response creates uncertainty regarding a member's position on an issue.

Steering Committee Report

JG briefed SG2 members on GHTF Steering Committee meetings held in Kuala Lumpur, Malaysia and Ottawa, Canada. At the KL meeting the Steering Committee decided that a new work item on AE reporting during clinical trials proposed by SG5 should instead be assigned to SG2 and SG2 should collaborate with SG5 on this issue. The Steering Committee also approved the SG2 proposed work item on recalls and assigned it to SG2. JG was not able to attend the Steering Committee meeting in Ottawa in person but did participate by teleconference and shared the slides with SG2 members that were presented to the Steering Committee. The slides contained a review of the SG2 work plan and the status of each item.

A Steering Committee ad hoc group has prepared a draft document on Maintenance Mode (MM). The draft is not yet ready for circulation outside the Steering Committee. The draft represents MM as a relatively small group of perhaps 3-4 individuals. A concern was raised as to whether regional representation can be achieved with such a small group.

The issue of training came up during the Steering Committee discussion. The Steering Committee requested that SG2 nominate one or two people to work with the SC training group.

MWB volunteered to be the SG2 liaison to the SC training group. ES and PA agreed to assist MWB as required.

Action Items:

1. Forward revised N79 to SG2 – LK, Oct 08
2. Determine whether changes to N79 needs SC approval before putting on website – ID, Oct 08
3. Distribute slides shown at Ottawa SC Meeting to SG2 via SG2 secretary - JG, Oct 08

ISO TC210 WG3 report:

Leighton Hansel attended the SG2 meeting and presented an overview of the history and work on event codes development by TC210 WG3. Leighton reported that the revised list of event codes was scheduled to be finalized at the December 2008 meeting of TC210 WG3. The number of codes is proposed as follows:

Level 1 – 20 terms (as compared to 29 in the FDA scheme)

Level 2 – 86 terms (as compared to 198 in the FDA scheme)

Leighton asked for the endorsement of the list by SG2. SG2 endorsed the TC210 WG3 event code list.

FDA coding project

MWB discussed the FDA project to establish a three-element cause (evaluation) coding system. The elements of the cause codes would be 1) methods, 2) results, and 3) conclusion. SG2 continues to advocate for simplifying the coding system. MWB indicated that FDA feels that current U.S. law requires this level of detail..

TC210 WG3 requested a recommendation from SG2 for the establishment of a single table of cause (evaluation) codes. SG2 prefers this approach and recommended to TC210 WG3 to try to develop a single table for cause coding. It was suggested that TC210 WG2 might try to combine FDA elements 2 and 3 into a single cause code table and would not likely include element 1 on methods.

SG2 training requests

Multiple members of SG2 have received requests for various type of training. There is currently no established process for reviewing and assigning trainers to satisfy such requests. PA raised the issue to SG2 regarding how to best handle such requests to help avoid confusion and/or possible duplication of effort.

It was proposed that any request for training to any SG2 member should be communicated to the SG2 Chair and such requests could be compiled into a single list. It was also recommended that a list of SG2 members who would be interested in being a trainer should also be prepared. Anyone that would like to be included on a potential trainers list should contact ID.

The discussion then turned to the issue of retraining (especially as relates to the NCAR program) and under which circumstance retraining might be required. Two possibilities were discussed. The first possibility was for SG2 to develop a guidance on retaining. This would likely require the approval of a new work item by the Steering Committee. A second possibility would be to update N38 and include retaining criteria in that document.

Action Items:

4. All to send list of any training provided in 2008 on SG2 documents to ID – All, Dec 09
5. All to notify ID and PA of requests for training on SG2 documents as soon as possible after received, All, ongoing
6. Update N38 with retraining criteria...send to SG2 secretary for circulation to SG2 – JG, end Nov 08
7. SG2 to consider amendments to N38 in time for next meeting – All, Jan 09

EU AE system

ID gave a presentation on European medical device legislation and the EU Vigilance system. Areas covered were a brief history leading up to the establishment of the 'Common Market', the role of the Commission, the Council, and the European Parliament, and a list of key policies established for the EU. The development of the EU from 6 to 27 countries and the conditions required for membership was outlined. The process for creating EU Directives such as the 3 applicable to medical products and their conversion into national law was explained. The role and responsibilities of Competent Authorities, manufacturers, and Notified Bodies was explained for medical products. The communication between EU member states and the establishment of a vigilance database to ensure transparency of information related to safety-related corrective actions was also emphasized.

Action Items:

8. ID to seek approval to distribute slides on EU system & send to LK for distribution to SG2 – ID, Nov 08

AHWP report

MT made a presentation on the recent activities the Asian Harmonization Working Party (AHWP) and the work of the AHWP Technical Committee (TC). The Technical Committee carries out much of the work of AHWP. The AHWP Technical Committee has established six Working Groups and a Special Task Group on Nomenclature. MT currently serves as the industry Co-chair on TC WG02 which is charged with Post Market Surveillance and the development of the Safety Alert Dissemination Systems (SADS) that is similar in purpose to the GHTF NCAR system for sharing medical product issues among the regulators that join SADS. Nine AHWP countries have now applied to become participants in SADS. MT included in her presentation many details on the operation of SADS. She also summarized the recent NCAR

training sessions held in Asia. The current ongoing projects for TC WG02 include the development of proposed harmonized post-market surveillance and vigilance requirements for AHWP members and the development of a Safety Alert Assessment Guideline for AHWP Regulatory Authorities. One of the current issues facing AHWP members is the cost of GMDN membership.

The 13th AHWP meeting is scheduled for November 3-6 in New Delhi, India. At this meeting there will be elections for chair & co-chairs for AHWP, AHWP TC, and the AHWP TC WG's.

The following new developments were reported in Asia: Thailand will soon issue new post-market surveillance requirements; Singapore is now implementing new post-market surveillance requirements; ASEAN is working on a safety alert system; China has a new recall regulation; and Taiwan has expressed interest in joining the GHTF NCAR program.

Action Items:

9. MT (Miang) to distribute slides on AHWP developments to SG2 via SG2 secretary – MT, Oct 08

Discussion on plan for pilot of N87PD

ES gave a status report on the pilot project for electronic adverse event reporting using the XML format. The project is expected to begin January 1, 2009. Efforts are also underway to reconcile the differences between the XML format and the HL7 format being developed for other electronic reporting systems. There are currently seven items contained in the XML scheme that are not included in the current HL7 format. Changes to HL7 require approval of a standards committee since HL7 an ANSI document that is a subset of a standard. There is a plan to add the seven fields to HL7 but this cannot be implemented until approved by vote. It is felt that since the changes for the added fields are relatively minor, that the chance of the vote passing is quite good.

Action Items:

10. Once HL7 work on 7 remaining items finished, complete mapping table between N87 and HL7 – MWB/ES/HL7, Jan 09

Access to public information

PA presented a draft document in the form of a new work item proposal for discussion by SG2 members. The purpose of the document is to establish what information regarding product issues should be made publicly available by regulators via websites or in other media. It was suggested that the scope of the document be limited to field safety corrective actions. It was pointed out that a number of current regulator websites present information about the same issue in different ways so that the reader may be confused regarding whether the information on one website refers to the same issue on another website. The proposed first phase of the work item would be to review existing official sources of information and their usefulness to the public.

Feedback from SG2 members indicated that the rationale should probably be further strengthened before presenting the document to the Steering Committee for their review and approval.

Action Items:

11. All SG2 to provide comments on communication of public information Work Item proposal – All, mid Jan 09

NWI – Definition and Classification of Recalls

JG collected inputs on current regulatory requirements related to the definition and classification of field safety corrective actions or recalls from each of the GHTF founding member regulators and created a draft document on the new work item for discussion at the Ottawa meeting. The draft document is entitled “Definition and Classification of Product Safety Corrective Actions, Including Recalls” and designed N111R1. It includes a table comparing the current regulatory requirements from each GHTF member country or region in the case of Europe. Japan inputs were submitted in narrative form and were to be inserted into the table later.

SG2 members reviewed each section of the draft document during the meeting and provided verbal feedback to JG. A number of comments were captured in the action items listed below.

Action Items:

12. Def of FSCA & recalls: replace “product with field” – JG, Oct 08
13. Def of FSCA & recalls: add Japan entries, add definitions of adjustment, modification, inspection, repair, and relabeling – JG, end Nov 08
14. Def of FSCA & recalls: reshuffle row entries to reflect alignment of definitions - JG, end Nov 08
15. Def of FSCA & recalls: distribute to SG2 – JG, end Nov 08

Review of GHTF SG2 website documents (N6, N8, N16, N38, N68)

SG2 members spent time discussing the status of the following SG2 documents on the GHTF website: N6R3 - Comparison of the Device Adverse Reporting Systems in USA, Europe, Canada, Australia & Japan, N8R4 - Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices, N16R5 - Charge & Mission Statement, N38R15 - Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program, and N68R3 - Summary of Current Requirements for Where to Send Adverse Event Reports. The first three documents have not been updated in the past six years. It was agreed that they should be either updated or archived, as the information is no longer current. The following actions resulted from the discussion on these documents by SG2 members.

Action Items:

16. Notify GHTF SC Sec that N6 is to be archived – ID, Nov 08

17. Review N8 – All, Jan 09
18. Review need for N16 – ID, Feb 09
19. Check that N80 on the website is the latest version – JG, Oct 08

AE reporting during clinical trials

For this portion of the meeting SG2 members were joined by Greg LaBlanc, vice-chair of SG5, and Maria Carballo also from SG5. The group discussed the request from the Steering Committee to prepare a definition for the term ‘adverse event’ as it applied to clinical trials.

Greg LaBlanc led much of the discussion on behalf of SG5. He outlined some of the concerns that are different for AE reporting during clinical trials and post-market AE reporting. During clinical trials, events may be reportable even if the event is not directly attributable to the device. Reporting timelines during clinical trials are different than for post-market reporting. There are differences in the level of severity for required reporting.

During the discussion it became clear that there currently is no established global model for AE reporting during clinical trials. It was determined that in order to move forward on this task, it would be necessary to first create a comparison table of existing regional regulatory requirements for clinical trial reporting. It was felt that SG5 had the necessary expertise to create such a comparison table. Following completion of the comparison table, it was proposed that SG2 and SG5 form a joint task subgroup to complete the work on this project.

Action Items:

20. Track progress of SG5 activities – ID, ongoing

Discussion of N73: status of implementation

SG2 members reviewed N73 R9 and provided several updates. JG recorded the changes and the document was revised to N73 R10. Most of the changes were relatively minor. There is still some disagreement as to what constitutes harmonization or convergence to GHTF SG2 AER requirements when the regional regulatory requirements are similar but not identical to GHTF guidance.

It was agreed that a sheet be added to N73 to track the progress of AHWP members as they establish their own AER reporting systems. MT will take the lead in working with AHWP members.

Action Items:

21. Distribute N73 R10 to SG2 via the SG2 secretary – JG, Oct 08
22. Update N73 with AHWP harmonization status details – MT, Feb 09

NCAR performance and statistics

Mark Segstro, the NCAR secretariat, announced that he would be ending his participation as a member of SG2 at the last meeting in Lisbon, Portugal. However, despite not being in attendance at the Ottawa meeting, Mark agreed to prepare his last NCAR performance and statistics report for Ottawa. JG presented the NCAR data provided by Mark for the period from January 1, 1999 through August 31, 2008 for review and comment by SG2 members.

The data analysis included trends by product sector. The number of NCAR's year to date in 2008 is 110 and is projected to be about 165 for all of 2008 compared to 174 for all of 2007..

The secretariat for the NCAR program will now move from Canada to Australia.

Action Items:

23. Distribute N76 R10 to SG2 via the secretary – JG, Oct 08

Other Business:

JG reminded SG2 members to review a paper on combination products prepared by Michael Gropp from the Steering Committee and be prepared to offer any comments as to whether combination products might require any changes to SG2 documents.

The meeting adjourned at approximately 1:15 pm on Friday, 17 October 2008 after an update of the SG2 Work Plan N49 R18 and a review of the action items for the next meeting. The document number for the Work Plan was updated to N49 R19.

Action Items:

24. Distribute N49 R19 to everyone via the SG2 secretary – JG, Oct 08
25. Distribute Action Items to all via the SG2 secretary – JG, Oct 08

SG2 Announcements:

Barbara Harrison has been appointed as the replacement for Mark Segstro representing Health Canada on SG2.

Isabelle Demade from the European Commission has been appointed chair of SG2 replacing Jorge Garcia representing the TGA in Australia.

Philippe Auclair representing EUCOMED in Europe has been appointed secretary to SG2 replacing Larry Kroger who represented MITA/NEMA in the United States.

Future SG2 meetings:

- 11-13 February 2009: 36th SG2 meeting – Brussels, Belgium
- 10-15 May 2009: GHTF Conference and SG2 meeting - Toronto, Canada.