



GHTF SG2- 42nd Meeting minutes – Canberra, Australia

Location: Therapeutic Goods Administration, PO Box 100, Woden ACT 2606, Australia, 136 Narrabundah Lane, Symonston ACT 2609, Australia

Attendance:

Name	Organization	Email	14/11	15/11	16/11	17/11
Takehiko Arima (TA) Vice Chair	JFMDA	tarima@its.jnj.com	X	X	X	X
Philippe Auclair (PA) secretary	EUCOMED	philippe.auclair@av.abbott.com	X	X	X	X
Mary Brady (MB)	FDA	Mary.Brady@fda.hhs.gov	X	X	X	X
Pam Carter (PC)	TGA	Pamela.Carter@tga.gov.au	X	X	X	X
Isabelle Demade (ID) Chair	Eur. Commission	isabelle.demade@ec.europa.eu	X	X	X	X
Barbara Mills (BM)	MITA	Barbara.Mills@ge.com	X	X	X	X
Iris Ratke (IR)	EUROMVI	Iris.ratke@bbraun.com	X	X	X	X
Carmen Ruiz Villar (CRV)	AEMPS Spain	cruizv@aemps.es	X	X	X	X
Klaus Stitz (KS)	MEDEC	kstitz@medec.org	X	X	X	X
Ekkehard Stösslein (ES)	BfArM	e.stoesslein@bfarm.de	X	X	X	X
Miang Tanakasemsub(MT)	AHWP	miang.tanakasemsub@zimmer.com	X	X	X	
Hiroyuki Tanishiro (HT)	PMDA	tanishiro-hiroyuki@pmda.go.jp	X	X	X	X
Michael Santalucia (MS)	AdvaMed	Michael.a.Santalucia@bausch.com				
				via Telec -see 8.1		
Observers attending						
Sayako Fukuda	PMDA	fukuda-sayoko@pmda.go.jp	X	X	X	X
Jorge Garcia – former SG2 Chair (part of the meeting)	TGA	Jorge.garcia@tga.gov.au	X	X	X	X
Sharon Hughes (NCAR section)	TGA	Sharon.hughes@tga.gov.au				X
Hideto Yokoi (HY)	University expert	yokoi@med.kagawa-u.ac.jp	X	X		
Members-excused						
Tanaka Daisuke (TD)	MHLW	Tanaka-daisuketd@mhlw.go.jp				
Yuuta Maeda (YM)	MHLW	maeda-yuuta@mhlw.go.jp				
Essam Mohammed Al Mohandis (EM)	Sector Saudi Food and Drug Authority	EMMohandis@sfdia.gov.sa				
Christopher Rose (CR)	Health Canada	rose@hc-sc.gc.ca				

1. Welcome, Introductions, Announcements

The 42nd meeting of GHTF Study Group 2 began at 12:00 AM on November 14 2011, after separate morning sessions for National Competent Authorities (NCAs) and Industry. The Chair, **Dr. Isabelle Demade**, (EU Commission) extended thanks to Therapeutic Goods Administration (TGA) for hosting the meeting. She expressed how pleased she

was to be able to have this meeting in Australia, in view of the cancellation of a previous meeting, originally scheduled in Canberra in April 2011

Ms Iris Ratke introduced herself as the new representative from EUROM VI in replacement of Mr. B.Koening and was welcomed by the group

2. Review meeting agenda. Minutes from the previous SG2 meeting

The draft agenda was adopted with changes in the sequence of items to be discussed to allow for availability of participants and organize conference calls with non attending members.

Minutes from the Madrid meeting were approved (document N125)

Action :

- Final minutes Madrid. N125. PA to ask for posting on web site**

3. Review of the actions items from the last meeting

Action items from the previous SG2 meeting were reviewed. The Chair noted the excellent progresses and placed emphasis on the major work items:

- N111 (Definition and Classification of Field Safety Corrective Actions -FSCA-, including recalls)
- Finalization of N87 (electronic transfer of Adverse Events between manufacturers and NCAs)
- SG2 input as ISO liaison for the possible revision of ISO13485 (incl. Post market surveillance section)
- Recommendations to the SC. Transfer of group work for maintenance after SG2 closure.

Actions :

- ID to update the log (N115) with Taiwan NCAR training & presentations made in South Africa**
- ID to inform the SC about the group recommendation to archive N8R4: 2000 (Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices)**

4. Report on GHTF Steering Committee (SC) Activities

4.1 Current GHTF organization and transition to the International Medical Device Regulator Forum (IMDRF)

ID gave an update on the establishment of the new forum in line with the statement published on GHTF website after the meeting of the representatives from the MD regulatory authorities of Australia, Brazil, Canada, China, European Union, Japan and United States in Ottawa on Oct 6-7.

IMDRF will be an enlarged regulator forum. Participation has been offered to Brazil, Russia, India and China in addition to the GHTF participating regulators. The main concern of the new forum will be Public Health. The new group composed of regulatory officials will provide guidance on strategies and policies direction, will not create permanent working groups and intends to focus on emerging issues for which ad hoc working groups will be established.

Discussion took place on the new proposed governance and implications for SG2 phase out. SG2 members raised some questions associated with the transfer of SG2 documents such as: maintenance of the GHTF web site, future promotion of the existing guidance, update of existing guidance, endorsement of GHTF documents not finalized at GHTF closure and IMDRF liaison with AHWP and other existing harmonization forums.

4.2 Statement from SG2 to Steering Committee to contribute positively to IMDRF

BM reviewed the document prepared after the Madrid meeting.

The document was reviewed (now N126R4- working document- STATEMENT FROM GHTF-SG2 to GHTF SC). Some changes were made, focusing on the use of SG2 documents, accomplishments in term of regulatory uptake of the guidance by various geographies, the NCAR Exchange Program, collaboration with AHWP and future actions recommended to IMDRF.

✚ Actions:

- ✚ BM/MB to review and finalize the document that will be circulated for review and approval by the group.
- ✚ The group to update the 3 following documents:
 - ✚ N73 (implementation of SG2 documents in GHTF founding members). CRV to coordinate review
 - ✚ AHWP adoption Chart. MT
 - ✚ N115 (NCAR and other training log).ID

ID to send the updated versions to the SC in view of the closure of SG2.


4.3 Review and adoption by SC of GHTF documents

I. Demade reported on SC highlights:

SG2 documents:

✧ SG2 N111 R8 (Field Safety Corrective Actions Recalls and Non Safety related Field Corrective Actions.): SC members asked SG2 to clarify the relationship between the FCA classes and the FSCA types in a preamble. The revised document (N111 R9) was sent to the SC for review. None of the comments received objected to the posting of the revised version on GHTF website for public consultation.

 **Action:**

 ID to ask GHTF Secretariat to post N111R9 as PD for a 4 months public comment period.

✧ SG2N80R10 (SG2 presentation) was approved for posting on the GHTF web site

Other documents approved as final – for information

- AHWG N2R3:2011 Unique Device Identification (UDI) System for Medical Devices
- AHWG N1R13:2011; Global Harmonization Task Force Medical Device Regulatory Model

5. Proposed SG2 guidance & finalization of existing SG2 guidance

5.1- SG2&5(PD1)/N05R10 - Reportable Events During Pre-Market Clinical Investigations

Public consultation is ongoing until Mid December 2011.

SG2 reviewed the comments received so far. (ASQ Biomedical; EU Clinical Investigation & Evaluation Working Group) and prepared recommendations.

 **Action:**

 ID to contact SG5 and bring the SG2 position for consideration by the SG2-SG5 Task Force

5.2 SG2 N111 R9 (Field Safety Corrective Actions, Recalls and Non Safety related Field Corrective Actions)

Comments received were discussed. An alternative structure of the document was discussed in view of facilitating the review of comments at the end of the PD. The end of the PD is planned for mid March 2012 and all comments will be considered at the next meeting.

Changes to the following documents may be required to align the FSCA definition of N57 and N79 with N111 definitions:

- SG2-N57R8:2006- Medical Devices Post Market Surveillance: Content of Field Safety Notices. Changes may be required to align with the definition of FSCA.
- SG2-N79R11:2009- Medical Devices: Post Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form. .

Action:

- ID to inform the SC. Suggestion is that the changes are processed as technical changes. Changes to be introduced after the result of the Public Consultation.

- 5.3 N87R8 - An XML Schema for the electronic transfer of adverse event data between manufacturers, authorized representatives and National Competent Authorities

The document was reviewed to identify changes before finalization

Actions:

- ES to review, update and finalize N87 and related documents, including N32v5.2v2.xls
- ID/ES/ MB to prepare cover page informing the Steering Committee on need to align XML and HL7 tag names- Send to SC with final version of N87.

6. Training

6.1 SG2 N120 R8: 2011

The document was approved as an internal SG2 document by the SC. SG2 did not recommend its publication on the GHTF web site. The document will be part of the hand over file for the maintenance of the NCAR program.

Documents revised and modified during the meeting:

- N120 R8 Training for Post Market Surveillance, including the National Competent Authority Report Exchange Programme
- N128 list of trainers.

Actions

- MB to finalize the draft documents N120 R8 and N128
- PA to circulate for the group (information only)
- Transfer of the final documents for maintenance to the NCAR secretariat

6.2 Public training documents

N121 – basic training slides on SG2 documents

Actions:

- PA to coordinate review of the slides.
- Final slides to be transferred for maintenance to the NCAR secretariat

7. NCAR Exchange Program.

7.1 Documents for web site

The GHTF SC endorsed SG2 proposal to post information on the NCAR Exchange Program on GHTF website.

A set of 3 documents was finalized for posting on the web site

- N122-1 Introduction to the NCAR program
- N122-2 NCAR list of participants
- N122-3 NCAR statistics

Actions:

- PA/ BM to harmonize format and distribute to the group for final review.**
- ID to seek SC approval for posting the set of 3 documents on the GHTF website**

7.2 Final 2010 statistics

Presentation from PC

Actions:

- PA to distribute to the group as confidential document**

8.0 Standardization and related documents

8.1 Revision of ISO 13485

Background documents:

- N 60 TF PMS (Summary of PMS documents & recommendations to ISO TC 210)
- N 62 TF PMS (Final Report overview)
- N 63 TF PMS (Brief Minutes of ISO/TC 210/ TF Post Market Surveillance (PMS) meeting on 18-19 October 2011)

MS joined the group by teleconference and gave a summary of the recent ISO TC210 TF1 meeting held in Alexandria (USA). MS reviewed the initiative of the ISO TC 210 TF on PMS and the various TF proposals. He commented on the perceived gap of regulatory requirements on Post market Surveillance (PMS) in the EU.

The TF PMS identified 7 PMS activities "of interest" (see N60):

- Complaint / user report handling
- Continuous clinical evaluation and Post Market Clinical Follow Up (PMCF)
- Corrective actions including recalls
- Relevant information and user surveys
- Strategies for maintaining the required level of safety and effectiveness during the whole device lifecycle (production and post market)
- Risk Management strategies for PMS activities

- Vigilance handling of incidents and near incidents

They were distributed in 4 “buckets” (see N 63) to be addressed to specific ISO and GHTF groups for review of their relevance:

1. A new general document on the concept on Post Market Surveillance to GHTF SC.
2. A call for revision of ISO 13485 to address and clarify PMS topics to ISO TC210
3. A recommendation to develop new guidelines/standards on specific topics related to PMS to ISO TC210 in cooperation with GHTF
4. A recommendations to review the anticipated guideline of GHTF/SG 2 on field safety corrective actions to GHTF SG2.




Outcome of the ISO TC 210 meeting (Oct. 2010):

- ISO TC 210 to ask WG1 to consider the TF recommendations on PMS during the revision of ISO 13485.
- ISO TC 210 to liaise with GHTF to review the recommendations deemed more appropriate to be handled by GHTF and to consider whether further work is necessary within GHTF or ISO.

A TC210 ad hoc group will be established to consider the relevance of the recommendations for TF1.

During the meeting, SG2 reviewed and updated document N61 on mapping of PMS possible activities (Working document).

 **Actions:**

-  PA to place N61 (PMS activities) with Canberra comments on “parking lot “ for future reference
-  ID / MS to prepare a presentation of the work of mapping SG2 activities and remit with the TC 210 recommendations
-  ID to present to the SC as a possible work item and propose SG2 representation in TC210



8.2 ISO TC210 DTS 19128-2 evaluation codes

PA presented an update on behalf of Leighton Hansel, Chair of the ISO TC210 TF. .
Only TGA commented. .

The final document is expected for publication in Q2 2012.

SG2 commends the work of TC210, identified 2 minor editorial issues which will be brought to the attention of the TF Chair

 **Actions:**

-  PA to communicate comments (typo header and reference to SG2 documents) to L. Hansel
-  PA to circulate the final DTS , when available

8.3 Harmonization of adverse event reporting codes. The Japanese example.

Yokoi-san presented an example of a pilot project for the harmonization of Adverse Event reporting terminology.

The system maps FDA codes with ISO 19218 codes and MEDRA.

It also classifies patients' problem codes, device problem codes and components codes. Japan recommends sharing the information of this pilot with the other geographies.

✚ Actions:

- ✚ PA to distribute Yokoi-san presentation

9 AHWP TC WG2 update**9.1 Update on Bali AHWP meeting -Miang**

The new AHWP Chair is Dr Saleh Al Tayyar (Saudi FDA) replacing Dr Wang Boating (China SFDA). The two Vice Chairs are Ms Li-Ling Liu (Taipei FDA) and Ms Lindsay Tao (J&J, China).

Joanna Koh (Health Sciences Authority, Singapore) was reelected as the Technical Committee Chair. Co Chairs are Ali Al-Dalaan (Saudi FDA) and Miang Chadaporn Tanakasemsub (Zimmer, Hong Kong).

9.2 Update on AHWP WG2

Miang tabled an update.

WG2 Chair is Yorkie Choe (HKG DoH). Co chair is Dr Saini Kulwat (J&J India).

Essam Al Mohandis and Miang will remain the representatives from AHWP WG2 in GHTF SG2.

WG2 next steps are:

- Transfer the AHWP WG2 documents to ASEAN to be considered during the elaboration of the ASEAN legislation on medical devices.
- Develop an electronic reporting form possibly based on GHTFSG2 N87
- Establish a SADS secretariat
- Strengthen collaboration with SG2

✚ Actions:

- ✚ PA to distribute Miang's presentation

10. Document log update

PA presented the legacy document log compiled from the various SG2 secretariats

✚ Actions:

- ✚ PA to distribute to SG2 for identification of docs to be kept beyond SG2 closure
- ✚ SG2 to review and identify essential documents during its next meeting

✚ ID to ask the SC to have these document posted on the confidential section of the GHTF web site

11. Meeting follow up

The group finalized the work plan N49R6
PA reviewed the action items from the meeting N118R9

✚ Actions:
✚ PA to distribute N49R6 and N118R9

12 Next SG2 meeting

The next meeting of SG2 will take place on May 7-10, 2012, tentatively set in Chicago IL,USA. Miang will consider Zimmer to accommodate the meeting, PA as a back up at Abbott.

The Chair of SG2, I Demade, closed the meeting, recognizing all participants' engagement, positive input and thanking TGA for the excellent organization of the meeting.

End of minutes (P Auclair / I Demade)