

**GHTF SG2. 38th Meeting**

Location: Bausch & Lomb (HK) Ltd. 15/F, One Kowloon, 1 Wang Yuen Street, Kowloon Bay, Hong Kong.

Date: 3-5 November, 2009

Attendance:

Name	Organization	Email	03/11	04/11	05/11
Philippe Auclair (PA)	EUCOMED	philippe.auclair@av.abbott.com	X	X	X
Mary Brady (MWB)	FDA	Mary.Brady@fda.hhs.gov	X	X	X
Isabelle Demade (ID)	EC	isabelle.demade@ec.europa.eu	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
Barbara Mills	MITA	Barbara.Mills@ge.com	X	X	X
Carmen Ruiz Villar (CRV)	AEMPS Spain	cruizv@aemps.es	X	X	X
Yoshihiko Sano	MHLW	sano-yoshihiko@mhlw.go.jp	X	X	X
Klaus Stitz (KS)	MEDEC	kstitz@medec.org	X	X	X
Hiroyuki Tanishiro (HT)	PMDA	tanishiro-hiroyuki@pmda.go.jp	X	X	X
Miang Tanakasemsub(MT)	AHWP	miang.tanakasemsub@bausch.com	X	X	X
Members-Not attended					
Takehiko Arima	JFMDA	tarima@its.jnj.com			
Ekkehard Stösslein (ES)	BfArM	e.stoesslein@bfarm.de			
Carl Wallroth (CW)	EUROM VI	beate.moeller@draeger.com			
Observers					
G. LeBlanc	SG5 liaison	gregleblanc@cookcanada.com		X	
Hideto Yokoi	PMDA	yokoi@med.kagawa-u.ac.jp	X	X	X

Welcome, Introductions, Announcements

Day 1 of the **38th meeting of GHTF Study Group 2** began at 9:00 AM on November 3rd, with a greeting from the Chair, **Dr. Isabelle Demade**, (DG Enterprise and Industry) extending thanks to Miang Tanakasemsub (Bausch and Lomb) for hosting the meeting. Apologies received from E. Stosslein and Arima-san for not attending the meeting.

Hideto Yokoi (PMDA) attended the meeting as an observer.

Review meeting agenda

The agenda was adopted, with appropriate modification allowing Dr. E. Stosslein to join by phone on Day 2 to present agenda item 12. (Pilot on electronic reporting)

Minutes from the previous SG2 meeting

Minutes from the last meeting held in Toronto, Canada were approved (document N119), with modification on the spelling of the Spanish Agency (AGEMED) and a correction on the email address of Mary Brady.

✚ Action 1: PA to modify the minutes and request posting of N119 on the GHTF SG2 web site

Review of the actions items from the last meeting

Action items from the previous SG2 meeting were reviewed. The Chair noted the excellent progress.

✚ Action 2: ID to finalize Memorandum of Understanding with TC215 (Pr Kwak) by Feb. 2010

Report on GHTF Steering committee. I. D

ID reported on the latest SC teleconference.

- ☐ It was mentioned that SG2 Chair has given recommendation to accept Thailand (Thai FDA) in the NCAR program and that an application was received by China SFDA
- ☐ Revised documents N79 and N38 were approved by the Steering Committee after minor changes and are now posted on GHTF website.
- ☐ next dates for SC in 2010 are : Feb 5th 2010 / March 26th, 2010 (teleconferences) Meeting Singapore May 9-11, 2010 / July 9th, 2010 / August 27th, 2010 (teleconferences), Meeting in Sydney . October 10-12th, 2010

N1R4 paper on regulatory model ID

The comments received on the text – Sano-san and B. Harrison were reviewed. Agreement on final wording was reached. The Japanese delegation helped to finalize the “Spaghetti” chart.

Fig 5 - 6 - 8 are modified; Text of 11.2 revised.

✚ Action 3:
- PA to consolidated documents (group comments on wording / fig 5/6/8) and send to ID
- ID to communicate the SG2 comment to the SC by Nov 7th with rationale for changes.

N111 - Harmonization FSCA classification –PC and team

The output definitions and examples of the sub group (JG - lead/MWB/BH/BM/Miang /Arima-san) were discussed and agreed upon, including renaming of FSCA actions (Type 1 to 5).

 Action 4:

- PC to review examples. Revise in format N111R3 (SG2 guidance format)- PA to circulate new version.
- PA to revise the Chart “Universe of FSCAs”
- Team -PC lead with MB/BH/BM/Miang/Arima-san/ CLV to start classification FSCAs. First draft to be circulated no later than Feb10, 2010
- PA to add to the next meeting agenda revision of N57 incl. N 57 formatting in N 111R3.

SG2-SG5 -clinical AE reporting

G. Leblanc (MEDEC, SG5 Vice-Chair) attended as SG5 liaison.

Document prepared by the joint SG2-SG5 working group (SG2 Participants: BK/ES/ID/BH/MWB/PC/PA) was reviewed with the larger SG2 group.

 Action 5:


- PA to circulate the working document annotated by SG2
- PA and ES to participate as SG2 liaison at the SG5 in Brussels Nov. 10 and report to SG2 on progresses.

Nomenclature and ISO TC 210 WG3 progress report

(Leighton Hansel-LH joined as ISO liaison)

○ Part 1- Event type codes-

ISO DTS 19218-1 released for public comments. Comments open until end October 09. ISO WG meets on Dec 9-10 and technical draft specification should be ready end of 2009. A committee draft to be subject to vote on May 2010 with a projected finalization of the document by end 2010.

 Action 6:

- PA to circulate L. Hansel’s presentation

○ Part 2- Evaluation codes-

ISO will review the first FDA draft , to be available mid 2010. ISO will include 2 of the 3 current FDA groupings (Methods and Results. Evaluation is currently out of the scope).. SG2 support may be required to work on an early draft early 2010. TGA mentioned that they monitor results and conclusions in the IRIS database.

 Action 7:

- PC to provide the TGA codes by next SG2 meeting. PA to circulate to the group

SG2 electronic reporting program (N87)

Dr. E. Stosslein presented by telecom the report on the EU pilot. UK / France / Ireland and Germany participated .

A discussion took place on possible link between the various existing systems: (FDA / Japan / EU) via compatible HL7 tagging.

 Action 8:

- ID to- approach TC215 to identify WG and liaison and attendance- with support ES/MB/ by Jan 15, 2010
- ES to provide MB with the additional forms to be added to HL7 by Dec15, 2009
- ES to re circulate his final form and database structure . PA to distribute. Dec 15, 2010
- ID with ES support to report to the steering committee on progresses on N87. Feb 5, 2010

National Competent Authorities Reports (NCARs) Open items

- PC presented review of NCAR reports and “common areas” when the form is incomplete or incorrect.

- PC presented the update NCAR statistics

The group noted a downwards trend in circulating confidential information and the drift to use the system to primarily communicate recalls / FSCA information. It was proposed to have a “regulators- only” session from next SG2 meeting onwards, to enable review of NCAR system and to define best practices.

Discussion about possible simplification in the NCAR form: to be discussed between NCAs during a ad hoc conf call

 Action 9:

- Common areas document to be circulated / . PA
- PC/ NCAR secretariat to contact recurrent non compliant NCAR authors
- PC / ID to consider organizing regional retraining for participants – next meeting
- PA to circulate PC updated stats document
- ID to organize teleconference among regulators. Proposal: simplification form. Tentative: January 20th, 2010

SG2 Trainings

- PA / MWB presented an update on the SC ad hoc group led by J Welch (FDA). Note: an ad hoc meeting was organized on Nov 3rd with J Welch and the ad hoc group members present in HKG.

- PA presented an updated version of N115. (Compilation of SG2 trainings)

- MWB presented the China SFDA training planned for November 11-12

A discussion took place on the NCAR application of China SFDA and the allocation of trainers on N54 and N38 to ensure good use of the reporting system. The group proposed to consider a team of trainers (e.g. MHLW / TGA/ FDA, and a local advisor) to evaluate China SFDA training needs and to conduct the training.

- MWB presented the document N120 R1 on application of N38 for NCAR trainings

Discussion and proposed modifications:

- > proposal to enlarge the document to include the SG2 trainings on N38 and on N54 in two different sections.
- > Precise criteria for trainer to be revised. Consider dropping of the formal maintenance of a list of trainers
- > inclusion of an evaluation form on NCAR trainings recommended.
- > feedback from trainer to be required.

Action 10:

- PA to circulate N115 R5, after the training in China. Nov 2009
- MWB to circulate a revised version of N 120 by Dec 15, 2009

GHTF SG2 - AHWP WG02 joint meeting (ad hoc meeting on November 5th)

A meeting was organized with AHWP WG02 at the Hong Kong Intl Conference Center during the Asian Harmonization Working Party meeting on Nov 5th.

SG2 members attended, as well as members of AHWP WG02. (Chair M. Lau HKG mdc)

- Presentation of WG02 and of the SADS system (M Lau and Miang)
- Presentation of SG2 and the NCAR program (ID and PC)
- Exchange of view/ Operational conclusions
- Request for support in developing electronic reporting system

It is proposed for SG2 and WG2 to establish cross representation between SG2-WG02 by having observers present at each other's meetings.

There is a desire to encourage convergence of the 2 adverse event reporting systems (SADS and NCAR).

This can be achieved as a first step by using a common reporting form. Link to be made with the possible revision of the form by SG2. It is also suggested to review implications of the confidentiality clause of SG2 to enable more AHWP countries to be included in the NCAR exchange program.

Review of actions and work plan

- **N49- Work plan:** to be reviewed

- + Action 11:
 - PA / ID to review and circulate N49
 - PA / ID to finalize and circulate **N 118- - Actions items**

Future SG2 meetings

It is proposed to the next meeting in Los Angeles on February 23-25th, 2010.

- + Action 12: B. Koshravi to consider possible organization.

ID closed the meeting, recognizing all participants' engagement and positive input. Many thanks for Miang Tanakasemsub (Bausch and Lomb) for hosting the meeting.

End of minutes (PA/ID)