
Participants
21 delegates and observers from AU, BE, CA, CH[0], DE, FI[0], JA, UK, US, EUROM VI, COCIR[0], EUCOMED, MEDEC, ADVAMED, NEMA, MIAA, JFMDA

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Place / Date
Gaithersburg / 13 to 16 September 2005

Subject
Global Harmonization Task Force Study Group 2 - GHTF SG2 -Vigilance - 29h Meeting

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Chair:	Mr. Kim Dix, CA
Step-in chair:	Dr. Carl F. Wallroth, DE
Participants:	21 delegates and observers from AU, BE, CA, CH[0], DE, FI[0], JA, UK, US, EUROM VI, COCIR[0], EUCOMED, MEDEC, ADVAMED, NEMA, MIAA, JFMDA
Place/Date:	Gaithersburg, MD / 13-16 September 2005

Executive Summary
Global Harmonization Task Force Study Group 2 - GHTF SG2 - vigilance met in Gaithersburg with the following achievements:

- **SC decision at May 2005 Sevilla meeting**
  NWIP N72 electronic AE data transfer was approved, progress report expected for Nov 8 to 10, 2005 SC meeting in London.
  Dual membership issue was brought to rest by Janet Truzzo, AdvaMed.
  SG chair qualification to include project management skills, has to be capable to establish efficient secretariat, co-chair should be from the opposite party and if possible from another part of the world.
  J.G. was accepted to follow K.D. after September 2005 meeting as SG2 chair.

- **SG2 N80 R6 map of SG2 guidance**
  Scope is limited to adverse event reporting, post market surveillance aspects are left out. Document was put on the web to replace earlier version.

- **SG2 N79 R3 updating and combining N9 and N20 NCAR exchange criteria**
  Differences between JA and ROW not resolved, JA wants only to receive the confidential information.
  Regulatory pre-meeting prior to Gaithersburg SG2 gathering to resolve issue did not materialize.
  Proposal to delete '1b mfr action taken public' pending. Addition to 7.0 Term to be completed in English.
  1b to become 24b - carried. 20 field safety corrective action to replace recall. 26a this report is distributed
  5 boxes: full NCAR part
  all NCAR part
  EEA
  targeted NCA
  mfr/auth.rep.
  Comments by 23 Sept. 2005 thereafter to SC for approval as proposed document at Nov. 2005 London meeting SC to be asked to shorten public commenting by 2 weeks.

- **SG2 N38 R14 application requirements for participation in the GHTF NCAR exchange program**
  Revisited:
  SG2 N8 R4 final guidance on how to handle vigilance reporting package for NCAR – developed by Jacob Nordan.
  J.G. with help of NCA members to develop training program.
  - application
  - reply letter
  - list of trainers
  - visual aids
  - template SG 2 trainer reference
  - template SG 2 acceptance letter
  - crosscheck with ISO 13485 training requirements
  - deadline Feb. 2006, progress report for September 2005 meeting.

- **SG2 N73 R3 update of N21 adverse event reporting rules - updating**
  CA column was modified: exemptions to be implemented except for remote likelihood of occurrence and foreseeable side effects, document to become N73 R4; colour coded version for Bangkok 13 to 17 June 2004: green for dull implementation, yellow for partial implementation, red for not implemented. JA implemented N36 trending in the Pharmaceutical Affairs Law 1 April 2005, document to become N73 R6, see enclosure.

- **SG2 N32 R52 XML scheme for electronic AE data transfer**
  update discussed following SC approval for NWI, T.S. to provide updated version by October 2005 in time for November 2005 SC meeting in London.

- **Next meeting**
  SG2: 30 January to 1 February 2006 Japan (details in October 2005)

  GHTF 2006 Conference in Lübeck

SG 2	25 June 2006	Sunday afternoon
	26 June 2006	
	27 June 2006	chair to attend SC meeting in the afternoon
	28 June 2006	Wednesday morning
Conference	28 June 2006	afternoon

	29 June 2006	
	30 June 2006	
SC	1 July 2006	morning, SC debriefing

- **SG2 N57 R4 harmonization of contents of advisories**
  New definition:
  A field corrective action is an action taken by a manufacturer to reduce the risk of death or serious deterioration in the state of health associated with the use of a medical device.

- **SG2 N54 R5 global guidance for adverse event reporting**

  4.2 adverse event caused by patient condition
  minor change

  4.3 service life or shelf life of the medical device
  drill bit example replaced by sterile glove

  4.4 projection against a fault functioned correctly
  no change

  4.5 negligible likelihood of occurrence of death or serious injury
  example particle on contact lenses added

  4.6 expected and foreseeable side effects
  no change

  4.7 adverse events described in an advisory notice
  no change

  4.8 reporting exemption granted by NCA
  no change

  Next step
  Document to become N54 R6 to be submitted to SC next week for approval as proposed document at the 8 to 10 November 2005 London meeting.
  (N57 and N79 to follow somewhat later to allow input from T.S. and E.S.)

  Public comments to be resolved at the end Jan. 2006 SG2 meeting in hopefully Tokyo. Document to become final document at the June 2006 SC meeting in Lübeck.

- **ISO TS 19218 adverse event coding**
  ISO TC 210 WG 3 met in Toronto in mid May 2005, final vote on TS 19218 was hold up to wait for hierarchical substructure proposal by NCI, presentation of FDA efforts by Terrie Reed to SG2 at Gaithersburg meeting.

- **SG2 N12 R11 precise**
  discussed and updated to become N12 R12.

- **SG2 N40 to whom to report**
  not addressed.

- **SG2 N49 R12 SG work program**
  updated to become N49 R14

- **SG2 N92 maintenance phase**
  Implementation of N38 R15 2005 application to NCAR exchange program / maintenance of NCAR
  - development and maintenance of training material
  - handling of new applications for membership
  - review of performance

  Monitoring of the uptake / performance of SG2 guidance

- review and update documents

Improvement of reporting and exchange mechanisms

- electronic reporting
- passive data base

Any of the above activities may lead to NWIP.
SG2 meeting frequency to be reduced, work assigned, to ad-hoc groups if necessary.

signed	signed	signed	signed
Dr. Carl F. Wallroth		***Ben Khosravi***	
EUROM VI	**COCIR**	**ADVAMED**	**MIAA**
signed	present	signed	signed
Dr. Larry Kroger	***Dr.Dr.Philippe Auclair***	***Takehiko Arima***	***Roger Leclerc***
		Hiroshi Ishikawa	
NEMA	**EUCOMED**	**JFMDA**	**MEDEC**

encl.

1. GHTF SG2 meetings
2. SG2 N73 R6 status of implementation
3. SG2 N49 R14 workplan
4. program 2006 GHTF conference and meetings, 2nd accouncement

Participants

Name	Affiliation	Country	13Sep.	14Sep.	15Sep.	16 Sep.
Perry Adams	MIAA	AU				
Philippe Auclair	EUCOMED c/o Guidant, Brussels	BE	x	x	x	x
Ian Campbell - retired	Centerpulse Mgt. Zürich	CH				
Vivian Coates	ECRI, Washington, MD	US				
Kim Dix	TPP, Health Canada, Ottawa	CA	x	x	x	x
Jorge Garcia, PhD	TGA, Canberra	AU	x	x	x	x
Masakatsu Imoto	JMHLW, Tokyo	JA				
Hiroshi Ishikawa	JFMDA c/o Toshiba, Tokyo	JA	x	x	x	x
Larry G. Kessler, PhD	FDA, Rockville, MD	US			pt	
Ben Khosravi	ADVAMED c/o St. Jude Medical	US	x	x	x	-
Larry A. Kroger, PhD	NEMA c/o GE Medical Systems	US	x	x	x	x
Tony Sant	MDA, London	UK	x	x	x	x
Werner Schönbühler	COCIR c/o Siemens, Erlangen	DE				
Andrea Sparti, PhD	Swissmedic, Berne	CH				
Ekkehard Stösslein,PhD	BfArM, Bonn	DE	x	x	x	-
Carl F. Wallroth, PhD	EUROM VI c/o Dräger Medical, Lübeck	DE	x	x	x	x
Masato Yoshida	JFMDA c/o Asahi Medical, Tokyo	JA				
Deborah Yoder	FDA, Rockville, MD	US	x	x	x	x
Masaaki Naito	JFMDA c/o Nihon Kohden	JA				
Roger Leclerc	Medical Device Canada MEDEC	CA	x	x	x	x
Mark Segstro	TPP, Health Canada, Ottawa	CA	x	x	x	x
Hannu Seitsonen	CEC DG ENTR., Brussels	FI				
Niroyuki Nashiyama	JMHLW, Tokyo	JA				
Takehiko Arima	JFMDA c/o Johson & Johnson, Tokyo	JA	x	x	x	x
Centaro Azuma	JMHLW, Tokyo	JA				
Kensuke Ishii	PMDA, Tokyo	JA	x	x	x	x
Carol Herman	ISOTC210 WG 3/FDA Rockville, MD	US	pt			
Joanne Marrone	FDA, Rockville, MD	US				
Ronda Balham	FDA, Rockville, MD	US				
Stephen Sykes	FDA, Rockville, MS	US				
Masahiro Sasaki for M.I.	JMHLW, Tokyo	JA				
Mary Weick Brady	FRDA Rockville, MD	US	x	x	x	x
Isabelle Demade, PhD	CEC DG ENTR., Brussels	FR	x	x	x	x
Terrie Reed	FDA, Rockville	US	pt			
David Kelly	FDA, Rockville	US	pt			
Jean Olson	FDA, Rockville, GHTF web master	US	pt			
Tetsuya Kusakabe, PhD	JMHLW, Tokyo	JA	x	x	x	x
total			21	17	18	15

Attachment 1

GHTF SG 2 meetings

#	Date	Place	Region	Sponsor	Reg.	Ind.	Conf.
1	26-27 Feb 1996	Rockville, MD,USA	NA	FDA	X		
2	30-31 May 1996	Lübeck, Germany	EU	Dräger		X	
3	6-7 Oct 1996	Lisbon, Portugal	EU	GHTF Conf.			X
4	26-28 Jan 1997	Dallas, Texas, USA	NA	J&J		X	
5	4-6 June 1997	Prague, Czech Republic	EU	CZ Min.	X		
6	15-17 Oct 1997	Tokyo, Japan	AP	JMHLW	X		
7	18-18 Feb 1998	Canberra, Australia	AP	TGA	X		
8	3-5 Jun 1998	Toronto, Ontario	NA	MEDEC		X	
9	23-25 Sept 98	Bern, Switzerland	EU	Swissmedic	X		
10	25-27 Jan 99	Irvine, California	NA	Baxter		X	
11	19-21 April 99	Stuttgart, Germany	EU	Agilant/HP	X		
12	30 Jun-2 July 99	Bethesda, USA	NA	GHTF/NIH	X		(x)
13	18-20 Oct 1999	Minneapolis, Minnesota, USA	NA	Medtronix		X	
14	16-17 Mar. 2000	London, UK	EU	MDA	X		
15	21-23 June 2000	Tokyo, Japan	AP	JMHLW	X		
16	18-22 Sept 2000	Ottawa, Canada	NA	GHTF/Health Canada	X		(x)
17	21-23 Feb 2001	Sunnyvale, California, USA	NA	St. Jude		X	
18	18-20 June 2001	Paris, France	EU	AFSSAPS	X		
	Oct 2001 (cancelled)	Barcelona, Spain	(EU)	(GHTFConf.)			
19	25 Feb 2002	Rockville, USA	NA	FDA	X		
20	12-16 May 2002	Singapore	AP	GHTF Conf.			X
21	25-27 Sept 2002	Bonn, Germany	EU	BfArM	X		
22	25-28 Feb 2003	Canberra, Australia	AP	TGA	X		
	May 2003 (cancelled)	Tokyo, Japan	(AP)	(GHTF Conf.)			
23	26-29 Sept 2003	Lübeck, Germany	EU	Dräger		X	
24	25-27 Feb 2004	Phoenix, Arizona	NA	St. Jude		X	
25	2-4 June 2004	Helsinki, Finland	EU	FI auth.	X		
26	27-29 Sept 2004	Vancouver, Canada	NA	Health Canada	X		
27	1-3 March 2005	Sydney	AP	TGA	X		
28	1-3 June 2005	Milwaukee, MI,US	NA	GE		X	
29	13-16 Sept 2005	Rockville, MD, US	NA	GE	X		
30	30 Jan -1 Feb 2006	Japan	AP	JFMDA		X	
31	25-30 June 2006	Lübeck, DE	EU	GHTF Conf/EUROM VI		X	(X)

Totals: EU = 11 European Union
NA = 13 North America
AP = 7 Asia Pacific

Sponsors:
Regulator = 18
Industry = 11
GHTF conf. = 2