Global Harmonization Task Force
Working Towards Harmonization in Medical Device Regulation

SG4 N88

SUMMARY REPORT
GHTF – SG4 PARIS, FRANCE MEETING

Location: SNITEM Maison de la Mécanique
39/41 rue Louis Blanc
92400 Courbevoie (Paris), France

Tuesday	April 1, 2008	09.00 to 17.00
Wednesday	April 2, 2008	08.30 to 17.30
Thursday	April 3, 2008	08.30 to 16.00

Chair: Markus Zobrist Secretary: Jan Welch

Participants:

Name	**Country**	**Govt**	**Industry**	**CAB**	**Member/ Observer**
Members					
Edelhäuser, Rainer	EU	X			M
George, Elisabeth	USA		X		M
Hamelin, Frédéric	CAN	X			M
Koenig, Bertram (only 4-1)	EU		X		M
Krumme, Reiner	EU			X	M
Lartigue, Philippe	EU		X		M
Li, Albert	TWN	X			M
Missios, Tim	CAN		X		M
Miura, Shigetaka	JPN		x		M
Ruff, Robert	USA	X			M
Simondet, Francois	EU		X		M
Welch, Jan	USA	X			M
Worroll, John	EU			X	M
Zobrist, Markus	EU	X			M
Total: 14 Members		6	6	2	14
Observers					
Asai, Hideki	JAP		X		O
Frankenberger, Horst	EU		X		O
Koga, Yukiko	JAP				O
Makino, Tsutomu	JAP	X			O
Miyamoto, Yuichi	JAP	X			O
Preiss, Stefan	EU			X	O
Studer, Peter	EU	X			O

Goals of the meeting:

- Finish edition of WD N83 - Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – **Part 2: Regulatory Auditing Strategy, Supplement No. 1 Multi-site Audits**
- Define title, content of and get started with WD N 84 Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy, **Supplement No. 2 Audits of supplier controls**
- Refine definitions of GHTF terms (Glossary)
- Develop comments on SG3 work item N19, Quality Management System – Medical devices - Criteria for characterizing the significance of quality management system deficiencies
- Preliminary discussion on comments received on SG4 (PD)/N28R3 Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – **Part 1: General Requirements**

1. Welcome by the chairman Markus Zobrist

Markus Zobrist welcomed all participants.

Apologies were received from Dragana Milic from the TGA, Mr. Kato from PMDA and Mr. Takae from MHLW. Mr. Miyamoto and Mr. Makino from PMDA attended as their alternates. A roll call was made, participants introduced themselves, and the member list was updated. The agenda was adopted with minor changes. Former SG4 Chairman Horst Frankenberger provided thoughts to the study group about the death of former SG4 Secretary Dierk Bellwinkel in January of this year. Dr. Frankenberger reflected on Dierk's distinguished career.

2. Reports from the March 2008 Steering Committee Meeting in Kuala Lumpur

Tim Missios provided a summary of pertinent items from the Steering Committee's March meeting. The following items were summarized:

a. Working with CASCO – GHTF needs to develop a formal proposal for working with CASCO and sharing information
b. Timing of SG meetings – Study groups should not hold their meetings too close to the SC meetings in order to allow time for the SC to review work products from the SGs
c. AHWP – There was a discussion of the need for more GHTF partnering with AHWP
d. Consolidation of SG3 and SG4 – This topic was again an agenda item for the SC; no final decision was made on this topic at the SC meeting

It was also noted that IAF wants a relationship with GHTF and that that AHWP wants GHTF SG members on their technical committees. Albert Li offered to be the contact person for SG4 for AHWP.

3. Action points of the GHTF-SG4 Washington meeting

The homework assignments on the working draft N83 and N84 documents) were reviewed and found to be completed.

4. Discussion of ISO Standards

Shigetaka Miura presented a written proposal for the revision of ISO 13485 to incorporate into the QMS standard the regulatory requirements on risk management and on software. His proposal is based on the argument that specific standards such as ISO 14971 (risk management) or IEC 62304, IEC 60601-1-4 (software) had been designed for technical purposes and not specifically for regulatory purposes as it was the case for ISO 13485. Their usability for regulatory purposes might therefore not be optimal in all cases. Part of the issue with a revision to ISO 13485 relates to the timing of the revision to ISO 9001. Is it possible for a revision to ISO 13485 to be made before the next revision is made to ISO 9001? Miura-san indicated that TC 210 WG1 accepted his proposal in principle. At their March 2008 meeting the GHTF SC did not accept the proposal to revise ISO 13485:2003. Miura-san provided a proposal with several options to consider:

a. To establish a new Ad Hoc working group to develop the temporal supplement for ISO 13485 which includes software, risk management, combination product etc.
b. To change mind set of related SGs and accelerate revise of ISO 13485:2003
c. Not to regulate emerging issues for these several years and not to audit them
d. To use existing voluntary standards such as ISO 14971, IEC 62304, IEC 60601-1-4 etc. for regulatory purposes
e. To do nothing

SG4 has not taken developed a consensus view yet on the need to revise ISO 13485.

The next standards to be discussed were ISO 19011 and ISO 17021-2. CASCO is responsible for ISO 17021-2 and they are taking over part of what has been in ISO 19011, which is being revised by TC 176. ISO 17021-2 CD from February 2008 was reviewed by the group. John Worroll noted that ISO 17021-2 is good for general audit statement, but that the GHTF guidance focusing on medical devices is still needed. Our guidance sections on audit competence are very valuable to the medical device sector. From a discussion on exactly SG4 guidance on how auditing should be designed resulted that this guidance must be a stand alone for the medical device sector, containing the principles listed in standards and the specific details required by this sector.

5. Work Item – N83 - Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy, Supplement No. 1 Auditing of Multiple Site Facilities

The use of terms was clarified and the language content could be completed except for some restructuring work and the rewording of a section. These tasks assigned for homework in order to have the document ready for stage 4 in Fall 2008.

6. Report on Joint Meeting with Study Groups 1 and 3 in Bonn in February 2008

The documents SG1 N55 R6 (Definition of a Manufacturer) SG1 N65 R5 (Registration of Manufacturers and Device Listing) were discussed. The definition of the manufacturer will reflect that the manufacturer is the entity whose name is listed on the label of the finished device. SG4 members have been invited to comment on both documents.

7. Discussion on SC (PD4)/N4 Definition and Glossary of Terms Used in GHTF Documents

The next agenda item was a review of the SG4 definitions which are included in the SC glossary document. The first definition discussed was the term “audit.” The study group discussed which source document should be used for the definition of this term, i.e., ISO 19011 or ISO 17000. The group decided to use definitions from standards if definitions are available and appropriate. If there are two definitions (TC 176 and CASCO), the definition from CASCO, the ISO 17000 series, should be used. If there is no definition available, then SG4 will write their own definition.

As a result of this discussion, The definition of “audit” will need to be revised in the N30 document to align to the ISO 17000 definition as in the N28 document.

There was a discussion of the terms “critical supplier” and “supplier.” The definition of critical supplier in N33 does not include the finished device. The definition of supplier includes the term product, which does include the finished device. A definition of product is needed to complete the use of these terms.

It was decided for the terms “compliance” and “conformity” which are in N33, that these two definitions would be added and the note would remain.

The Chairman will send SG4’s revisions to the glossary to the SC.

8. Overview of Software Ad Hoc Group/ISO 13485 Issues

Miura-san presented an overview of the GHTF Software Ad Hoc group and how this topic is interconnected with ISO 13485. Miura-san reviewed his five page memorandum on this topic.

Two points to consider relating to this topic include whether a revision is needed to ISO 13485 to add requirements relating to software within a QMS and correspondingly whether additional guidance is needed for the regulatory auditing of software within a QMS.

Based on the mandates of the SC, the Software Ad Hoc working group proposed 12 work recommendations. Recommendations 7, 8, 9 and 12 were assigned to SG 3 and SG 4. In response, SG 3 and SG 4 sent a joint memorandum to the Ad Hoc Software group requesting clarification on these recommendations. SG4 will not be able to plan activities before the Ad Hoc Software Group has given clarification.

9. Preliminary Review of Comments on Proposed Document N28

The formal comment period ends on May 14, 2008 for the submission of comments on PD N28. To date SG4 has received 3 sets of comments. Former SG4 Chair Horst Frankenberger was in attendance on day three of the meeting and presented his 20 comments to SG4. There were no questions about these comments. The additional sets of comments were also briefly reviewed.

Dr. Frankenberger also made a brief presentation on suggested revisions to the scope of N28, which would include guidance for auditing third parties. A discussion of regulatory models and the scope of SG4 followed. The study group was informed that there is an Ad Hoc Group on Global Models. The Chair will contact this group to identify any action items for SG4.

10. Report on AHWP Meeting in Kuala Lumpur

Albert Li presented a summary of the AHWP meeting in March 2008. He presented information on the structure of the various technical committees in the AHWP and how they align with the study groups in GHTF.

11. Report on status of N84 document

John Worroll presented key points to the draft of N84, the supplement addressing the auditing of a manufacturer's control over its suppliers. John provided information on four key points:

a. The manufacturer is responsible for control of its suppliers
b. Inclusion of a definition of critical supplier (with examples)
c. The auditing of purchase controls

d. Definition of the term virtual manufacturer

A small work group was developed to continue drafting this document. Members include: John (the lead), Rainer, Fred, and Elisabeth. See the action item list for the time frames established for this document.

12. Next Meeting Plans

The next meeting will be October 14-17, 2008 in Ottawa, Canada. This will also include a one day joint meeting with SG1 and SG3.

The next meeting after Ottawa could potentially be the GHTF conference and Global Device Conference May 10-15, 2009 in Toronto, Canada.

13. Additional Action Item

SG3 N17 R3 working draft – Control of products and services obtained from suppliers

SG3 would like SG4 comments on their draft document. If anyone has comments, they should be sent to the SG4 Secretary who will forward all comments to SG3.

14. Updated Work Plan

There was some final discussion on meeting dates and the work plan. The following chart summarizes the study group plans.

Year	**2008**			**2009**		
Quarter	2	3	4	1	2	3
N28 Part 1	Stage 5		Stage 6			
N83 Auditing of Multiple Site Facilities	Stage 2		Stage 4			Stage 6
N84 Auditing of Supplier Controls	Stage 2				Stage 4	Stage 6
SG 4 Meetings	April 1-3 Paris		Oct 14-17 Ottawa		May 10-15 Toronto	

15. Recognition of Retiring Study Group Members

The SG Vice Chair and Secretary recognized Reiner Krumme and Markus Zobrist, both of whom are concluding their service to Study Group 4 and the GHTF. The Vice Chair and Secretary thanked both members for their contributions over the years. Both members were presented with signed certificates from all the study group members.

Paris, France April 3, 2008

Markus Zobrist
Chair, GHTF SG4

Jan Welch
Secretary, GHTF SG 4