Global Harmonization Task Force
Working Towards Harmonization in Medical Device Regulation

SG 4 N 76

SUMMARY
GHTF – SG4 LUEBECK - MEETING

Location: Drägerwerk AG
Moislinger Allee 53 – 55
23542 LUEBECK – Germany

Monday	June 26, 2006	09.00 to 16.30
Tuesday	June 27, 2006	08.30 to 17.00
Wednesday	June 28, 2006	08.30 to 10.30

Chair: Prof. Horst Frankenberger, Europe

Participants: 17 members and 3 observers, 8 from government, 8 from industry and 4 from CABs

Goals of the meeting are:

- **Consistency of definitions – used in GHTF-SG4 documents**
- **New work items?**
- **Discussion on comments concerning: "Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 3: Regulatory Audit Reports" and advancement to Stage 4 of GHTF Operating Procedures (Proposed Document)**
- **Update work of the final document: "Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 1: General Requirements" (Stage 2 of GHTF Operating Procedures)**

1. Welcome by the chairman Horst Frankenberger

Horst Frankenberger welcomed all members, observers and guests.

Apologies

Anne-Marie Coutu could not join; Egan Cobbold represented Health Canada at the first half day.

Roll call of the participants and actualisation of the list of participants of SG 4

All participants introduced themselves, the member list was updated.
The chairman introduced Mr. Bertram Koenig and Francois Simondet as new members of SG 4. Bertram Koenig (EUROM VI) replaces Horst Frankenberger (EUROM VI); Francois Simondet (EUROM VI) replaces Dierk Bellwinkel (EUROM VI and FIDE).

Adoption of the agenda
The agenda was adopted.

Action points of the GHTF-SG4 Taipei meeting
The action list from the Taipei meeting was checked, the items were taken care of.

Proposal of Health Canada to N30R18
The proposal from Health Canada includes some modifications for the scope of N30 which were circulated with the circular letter no. 9 dated 23 June 2006. The proposed modifications were explained by Egan Cobbold and accepted by GHTF-SG4. Markus Zobrist asked for feed back from auditors after having conducted audits according to this document.

Horst Frankenberger presented the document as N30R20 to the Steering Committee at the next day. N30R20 was accepted by GHTF-SC as final document. It will be published on the GHTF web-site.

2. Consistency of definitions – used in GHTF-SG4 documents

The document SG 4 N 74-2 was revised, but should contain definitions from final SG 4 documents only.

3. Discussion on general comments concerning: "Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 3: Regulatory Audit Reports" and advancement of the document to Stage 4 of GHTF Operating Procedures (Proposed Document)

The document N33R12 was discussed. GHTF-SG4 agreed that this document will be sent to GHTF-SC as N33R13 as proposed document latest 2 weeks after the SG4 meeting in Luebeck by Horst Frankenberger and Markus Zobrist.

The version N 33 R 13 contains the discussed modifications and will be presented to the Steering Committee as Proposed Document. The open action point 2 will be treated together with the comments.

4. Update work of the final document: "Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 1: General Requirements" (Stage 2 of GHTF Operating Procedures)

In general:
This document was the first final document of GHTF-SG4 and is transposed by many countries especially in Asia via the AHWP. Before sending it to the GHTF-SC for approval it was the basis for observed audits done by GHTF-SG4. A revision has to be done very carefully. A round table inquiry confirmed these statements by all participants.

The general tasks:
The annexes should be implemented into the Part 1 document. The standard references and further details have to be updated. It should also be respected that new standards dealing with the contents of "Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 1: General Requirements"

The tasks in detail:
The new version of N28 starts with the revision number R 1. The general chapters

1 to 4 were fully redrafted in line with the new structure of documents.
Chapter 5 “Definitions” has to be redrafted following the standards ISO 17000:2004 and ISO 9000:2005 based on action point no. 1.

The new chapter 7 “General principles for auditing organizations” should not be changed more than necessary, but must be aligned to relevant standards! Since the finalization of this document N 28 in 1999 new standards in the field of auditing and conformity assessment were developed and adopted and are relevant for a large portion of this document. So it had to be decided:
- Either to develop a completely new document with a different scope, (would need a decision to be taken by the Steering Committee),
- Or taking over parts of the in the new standards. That means alignment to standards in large parts,
- And add the additional requirements needed specifically for medical devices. That would lead to a guideline clearly showing the gaps to existing standards.

Because of the high acceptance of this document also outside of the GHTF and its necessity for the harmonization of the SG 4 documents, SG4 decided to continue with the existing document and take up the work to align itto the standards.

As starting point for the definitions and for the following discussions Jan Welch proposed the matrix as compilation of existing definitions and content:

Sections of Document N28	To trace content/ definitions to relevant sections in the following standards:	ISO 17000	ISO 9000: 2005	ISO 17021 FDIS	ISO 19011	ISO 13485	ISO 14969

The following standards are relevant for this task:

ISO 9000:2005	Quality management systems – Fundamentals and vocabulary
ISO 17000:2004	Conformity assessment -- Vocabulary and general principles
ISO 19011:2002	Guidelines for quality and/or environmental management systems auditing
ISO/IEC DIS 17021	Conformity assessment – requirements for bodies providing audit and certification of management systems

Treatment of the existing supplements:
N 14 R 2 Supplement 1: Audit Language Requirements: Should be integrated into the main document N 28.
N 3 R 2 Supplement 3: Training Requirements for Auditors: Should become an annex to N 28, definitions have to be transferred to N 28.
N 24 R 3 Supplement 4: Compilation of Audit Documentation: Should be either implemented into N 28 or should become an annex to N 28. This document is helpful for understanding the documentation.

N 26 R 1 Supplement 6: Observed Audits of CABs: Should not be integrated but remain. The role and responsibilities of observers should be treated in a new chapter in N 28.

5. Report of the meeting with Steering Committee

Horst Frankenberger attended the meeting of the Steering Committee partially for reporting about the GHTF-SG 4:

- The SC nominated Markus Zobrist as new chair of GHTF-SG4. His activities as chair start after the sending out of the minutes of the Luebeck meeting by Dierk Bellwinkel and Horst Frankenberger.
- The discussion of the merging of SG 3 and SG 4 is postponed. Both of the groups have new chairs, but the SC decided that the previously assigned tasks have to be solved first.
- N 30 R 20 is accepted as final document
- N 33 will be sent to GHTF-SC as proposed document after the Luebeck meeting.

Miura-san reported as member of the Steering Committee:

- software: An own document is not envisaged, an ad-hoc group will survey this item.
- An ad-hoc group on “Definitions” will be set up. Mr. Ichikawa from the Steering Committee is the contact person. Tim Missios will represent SG 4 in this ad-hoc group.

6. New members of Study Group 4

Horst Frankenberger as chair and Dierk Bellwinkel as secretary will remain in their positions until end of this meeting, and then they will retire and leave this group.
They will be succeeded by:
Markus Zobrist as new chair and
Jan Welch as new secretary.
Tim Missios and Robert Turocy are becoming vize-chairs.

New members representing European industry:
Francois Simondet (France) and Bertram Koenig (Germany), both joined this group.

7. New work items? – proposed at the Taipei meeting and by ISO TC 210

SG4 treats only auditing guidances for given quality system requirements.

A roll call to the importance of the tasks results in:

- For multisite audit and virtual manufacturer:
  40 votes: First priority on basis of SG 3 work
- For handling software an own ad-hoc group is founded
  29 votes, wait for input from ad-hoc group depending on auditing requirements
- Human factors
  21 votes

8. Miscellaneous

- Based on small changes in ISO 9001, ISO 13485 will be revised. The risk management concept will be explicitly incorporated into ISO 13485.

9. Next meetings

October 11 – 13, 2006 Bern (has to be confirmed by the chair)
May 2007 all SGs in Los Angeles

10. Survey by the chair on "GHTF-SG4 – 1994 – 2006"

Horst Frankenberger gave an survey on activities in GHTF-SG4 "Regulatory Auditing" since 1994 and thanked all members of the study group of their active cooperation. Especially he thanked Dierk Bellwinkel for his contributions and work as secretary. He wishes all the best for the ongoing work of GHTF-SG4, the new chair and the new secretary.

11. Thanks to the leaving team chair and secretary of SG4

SG4 expressed their gratitude to Horst Frankenberger for his outstanding leadership and to Dierk Bellwinkel for his excellent secretarial work and wishes all the best for the retirement!

Luebeck 28 June 2006

Horst Frankenberger	Dierk Bellwinkel
Chair GHTF-SG4 "Regulatory Auditing"	Secretary