Global Harmonization Task Force
Working Towards Harmonization in Medical Device Regulation

SG4 / N 69 - 2

Global Harmonization Task Force, GHTF
Study Group 4 "Regulatory Auditing"

Meeting Summary

Location: Drägerwerk AG Lübeck.
Moislinger Allee 53 - 55
23542 Lübeck
Germany

Monday	November 14, 2005	09:30 – 17:00
Tuesday	November 15, 2005	08:30 – 17:00
Wednesday	November 16, 2005	08:30 – 12:30

Chair: Prof. Dr. Horst Frankenberger, EUROM VI, European Industry
Participants: 9 members and 3 observers

Goals of the meeting were:

- Finish the GHTF guidance document: "Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 3: Audit Reports" as a working draft (Stage 3 of GHTF Operating Procedures)
- Start the update work of the final document: "Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 1: General Requirements"
- Update the SG4 work plan

1. Opening and Welcome

Horst Frankenberger welcomed the participants especially Mr. Rainer Edelhäuser from ZLG (German designating authority) as an observer. Inga Kuhls welcomed the participants on behalf of the hosting company Dräger medical.

Apologies were received from Dierk Bellwinkel, John Worroll, Albert Li, Philippe Lartigue, Andrew Muir, and Tim Missios.

After the roll call of the participants, the list of SG4 members was actualized. The agenda was adopted.

2. Report on GHTF Steering Committee Meeting

The GHTF-SC met on November 9 – 10, 2005 in London. The first day was a closed meeting, the second day an open meeting with the participation of members of the World Health Organisation, the International Organisation for

Standardization and the Asian Harmonization Working Party.

Relevant for the work of SG4 was the decision to forward the document **Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy (**SG4 N30 R16) as a proposed document for publication on the GHTF website. Accepted was also the proposal of a reduced comment period until February 1, 2006 allowing SG4 to work on the received comments (on GHTF template) during the next SG4 meeting scheduled for February 2006 in Taiwan. Horst Frankenberger presented the GHTF-SG4 report given to the GHTF-SC (Attachment 1).

The GHTF-SC decided to set up an ad-hoc group for creating a GHTF Wordbook and Glossary – as proposed by Japan. Each SG has to deliver the definitions of vocabulary used in their documents.

Information was given by M. Gropp that members for a new ad-hoc workgroup on "Software" are looked for.

Concerning the Luebeck GHTF-Conference in June 2006 participants and GHTF SG and SC members are urgently advised to make an early registration and hotel reservation – at the latest before end of March 2006. Details are provided on **www.ghtf.org** .

No	Action Point / Task	Responsible	Address to	Until latest
1	Information on GHTF conference and registration see: www.ghtf.org	All GHTF-SG4 members	Address see GHTF-website	Registration: February 15, 2006 Hotel: March 2006

GHTF-SC encourages SGs to continue to have joint meetings for guidelines and topics of joint interest.

A report on the update of main developments in founding members regulatory members system was given,

A special attention was given to the new revisions of "GHTF Operating Procedures", "GHTF Roles and Responsibilities" and "GHTF Guiding Principles". It was reminded that work of GHTF is based on consensus.

Following the "GHTF Roles and Responsibilities" especially the chapters concerning "GHTF Study Groups" and "GHTF Study Group Chairs" were discussed. Unanimously **Markus Zobrist** was nominated Vice-Chair of GHTF-SG4 and **Dierk Bellwinkel** confirmed as secretary.

Special attention was given to the "GHTF Document Management" and the seven stages development process.

GHTF SC endorses GHTF training seminars especially also to be held in regions

of non-founding members.

3. Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 3: Regulatory Audit Reports

SG4 accomplished the working draft SG4 N33 R10 for stage 3 “consultation on working drafts” during this meeting. The working draft shall be electronically distributed to the SG4 members in November 2005. SG4 members are invited to hand in comments on behalf of their organizations (on the GHTF Template) to the secretary until February 1, 2006. These comments will be treated at the February SG4 meeting in Taipei.

4. Revision of “Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 1: General Requirements”

Before starting the revision of the final document SG4 (99) 28 the following decisions were taken:

- Existing Supplements (Final Documents)
Supplement 1 “Audit language requirements SG4 (99) 14”,
Supplement 3 “Training requirements for auditors” SG4 (00) 3
Supplement 4 “Compilation of Audit Documentation SG4/N(99)24R3:2002
shall be integrated into the revised document.

- Supplement No. 6 “Observed Audits of Conformity Assessment Bodies”
SG4/N26R1:2001 shall not be integrated and it is proposed to the Steering Committee to archive this document and to remove it from the list of final documents.

The scope, purpose and the rationale for the document SG4 (99) 28 were redrafted. The work on this working draft continues at the next meeting.

5. Work Plan and Document Stages
The work plan was updated.

6. Closure
Horst Frankenberger thanked Jan Welch for her assistance to the chair, the Dräger Medical Company for the excellent hospitality and Beate Möller for the excellent help.

Horst Frankenberger
Chair GHTF-SG4

Markus Zobrist
Vice-Chair GHTF-SG4

Lübeck, November 16, 2005