



**Global Harmonization Task Force, GHTF
Study Group 4 “Regulatory Auditing”**

SG4 / N 72-2

Summary
SG 4 Meeting

Location: Far Eastern Plaza Hotel
201 Tun Hwa S. Road Sec. 2
Taipei 106
Taiwan

Tuesday	February 14, 2006	09.30 to 17.30
Wednesday	February 15, 2006	08.30 to 17.00
Thursday	February 16, 2006	08.30 to 18.00

GHTF-SG4-Training Seminar – Program see Attachment 1
Harmonization on Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers

Location: Room 401 National Taiwan University International Convention Center,
No. 2 Xu Zhou Rd. Taipei, Taiwan

Friday February 17, 2006 09.00 to 13.30

Vice Chair: Dr. Markus Zobrist, Swissmedic, Switzerland, Europe

Participants: 14 members and 4 observers

Goals of the meeting are:

- **Advancement from Proposed Document to Final Document (Stage 6 of GHTF Operating Procedures) of GHTF guidance document: “Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy“**
- **Discussion on the comments received from Consultation on the Working Draft: “Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 3: Regulatory Audit Reports“ and advancement from Working Draft to Proposed Document (Stage 4 of GHTF Operating Procedures)**
- **Continue the 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. Opening

Markus Zobrist welcomed the participants and observers. He pointed out that the doctors recommended strongly that Horst should not fly this long distance because of his newly heart attack. He was not able to come to this meeting, but is already in connection with Markus Zobrist and Dierk Bellwinkel and greets the group cordially.

All participants introduced themselves, the list with members and observers were updated.

The agenda was adopted.

The action list from the Luebeck meeting was checked, all items were taken care of.

2. Document N 30 “Regulatory Auditing Strategy”

Advancement from Proposed Document to Final Document (stage 6 of GHTF Operating Procedures)

There came in 10 sets of comments, some very extensive. The Steering Committee asked for the finalisation of this document, therefore it had the highest priority.

All the comments were reviewed in a two days work. Proposal for fundamental changes could not be approved because the Steering Committee has put this document into the end of stage 5.

For the nomenclature of the stakeholders of SG 4 documents the following proposals were taken into consideration:

Regulator	The authority having the responsibility to regulate the products and/or to designate the CABs or auditing organisations
Competent Authority	The authority regulating the products
Designating Authority	The authority, responsible for identifying, designating, monitoring, suspending and withdrawing designation of the CAB conducting the observed audit. (GHTF SG 4 N 26 R1)
Auditing Organisation	A body designated, on the basis of specific regulations, to carry out audits according to assigned tasks (GHTF SG 4 N 28: Part 1)

The definitions for these 4 terms are proposed to be included into the revision of the SG 4 N 28 Part 1, to make them consistent with the terms used in the other documents of SG 4.

The scope of the existing SG 4 documents has addressed the auditing of single sites. For multisite auditing SG 4 waits for a guidance developed by SG 3 for the control of outsourced processes. The principles developed in such a guidance are expected to have an impact also to requirements for multisite quality systems. In order to produce another SG 4 document how such requirements have to be audited, SG4 awaits the result of the guidance developed by SG3.

In the present document N 30 R 16, it is possible to use the “Purchasing Subsystem” in order to link the information of quality management systems between multisite partners. However no extensive guidance is given for multisite audits. The chairman is asked to propose a new work item on this issue to the

Steering Committee.

Consensus was reached to limit the table in Appendix 3 “Country specific requirements” to ISO 13485:2003 and the Quality System Regulations of USA: 21 CFR Parts 820.

After finishing the document a roll call among all participants showed a very high acceptance of this status and the study group 4 proposed it for stage 6.

It was proposed:

- that an editorial check will be done by Jan Welch
- the document will then be circulated within SG 4 for approval within 3 weeks
- the chairman will send the document to the Steering Committee at least two month before the next meeting in Luebeck for approval as a final document.

3. Document N 33 “Audit Report”

Advancement from Working Draft to Proposed Document (stage 4 of GHTF Operating Procedures)

4 sets of comments were received for this document. They all could be treated at the meeting. The result led to the document as “proposed document stage 4”.

To work on the definition on nonconformity, a working group will define major and minor nonconformities, taking into account the existing information in document SG 4 N 28 and other relevant standards and documents.

After finishing the discussions on this document, participants showed a very high acceptance of this status and the SG 4 proposed to have it prepared for stage 4 with a an additional set of corrections included. The document should then be sent to the Steering Committee for approval as “proposed document”.

4. Document N 28 “General Requirements”

The document N 28 “Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 1: General Requirements” has to be revised (stage 2 of GHTF Operating Procedures)

Due to the excessive time used for the discussion of the comments for the N 30 document, no advancement were achieved for the document N 28. The proposal was to asked the SG 4 members to give in any conceptual proposals concerning the revision of this document prior to the next meeting.

5. Miscellaneous

5.1 Next meetings

Planning of SG 4 meetings after June 2006 will have to be done by the new chair to be appointed by the SC.

26 – 27 June 2006

Luebeck, Germany before the
GHTF Conference 28 until 30 June 2006

April 2007

Joint SG meeting in Los Angeles

September 2007

GHTF Conference in Washington DC

5.2 Workshop on Auditing Quality System including Risk Management

Chair and members of SG 4 are engaged on a work shop on risk management during the GHTF Conference. Further information is available under www.gh tf.org.

5.3 Document GHTF SG 4 N 26 “Supplement 6: Observed Audits of CABs”

This document had been proposed to be archived at the previous meeting in Luebeck. However during this meeting it was noted that some Notified Bodies still make extensive use of this document in the context of shadow auditing of auditors. SG 4 therefore proposes that this document remains on the web-site.

5.4 Task of next meeting

- Revision of N 28 “General Requirements”
- Discussion on possible new work item proposals:
 - Multisite audit
 - Virtual manufacturer
 - Software
 - Human factors / ergonomics

5.5 Definitions

The secretary refers to the compilation of definitions used in SG 4 documents which is asked by the SC. See circular letter 9th Information dated 28 January 2006.

5.6 Secretary of SG 4

Dierk Bellwinkel announced that he is going to leave SG 4 after the next meeting in Luebeck.

6. Closure

Markus Zobrist thanked all participants for the excellent work done in the three days which was very effective. SG 4 expressed their thanks to Albert Li, to DOH and to ITRI for the excellent arrangements and hospitality for this meeting.

The following day SG 4 held another training seminar for industry, regulators and students to promote the GHTF ideas. About 150 participants joint and it was a great success. The agenda is enclosed as annex and the presentations will be circulated among the members.

Taipei, 16 February 2006

Markus Zobrist
Vice Chair

Dierk Bellwinkel
Secretary