



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

**Summary
SG 4 Meeting**

Location: Hilton Washington DC North Gaithersburg
620 Perry Parkway
Gaithersburg, Maryland 20877
United States

Monday	September 12, 2005	09.00 to 12.30	SG4 Meeting
Monday	September 12, 2005	13.30 to 17.30	SG3/SG4 Joint Meeting
Tuesday	September 13, 2005	09.00 to 17.30	SG3/SG4 Joint Meeting
Wednesday	September 14, 2005	09.00 to 12.30	SG3/SG4 Joint Meeting
Wednesday	September 14, 2005	13.30 to 17.00	SG4 Meeting
Thursday	September 15, 2005	09.00 to 17.30	SG4 Meeting
Friday	September 16, 2005	09.00 to 14.00	Joint Meeting of all Study Groups

Step in Chair: Dr. Markus Zobrist, Swissmedic, Zwitterland, Europe

Participants: 14 members and 7 guests

The GHTF-SG4 meeting is separated into two parts: The first part took place before the joint meeting together with GHTF SG3 (see the summary SG 3+4: SG4 N65 – 3), the second part after this joint meeting.

Goals of the SG4 meeting 2nd part:

- To finalize the document SG4 N 30 “*Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 2: Regulatory Audit Strategy*” as final document after reworking together with SG 3
- To continue with the first working draft of the GHTF guidance document SG4 N33: “*Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 3: Audit Reports*”
- Update of the SG4 work plan – including proposals for updating: “*Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 1: General Requirements*”

1. Opening the first part

Markus Zobrist welcomed the participants and observers. He pointed out that Horst Frankenberger recovered in the best way from a serious heart attack. He was not able to come to this meeting.

The new list of participants was accepted.

The agenda was adopted.

2. Preparation of the joint meeting with SG 3

Marcus Zobrist pointed out the task given from the Steering Committee at its meeting in May 2005 in Sevilla. The document GHTF SG 4 N30 R14A2 was accepted but requirements for auditing Risk Management have to be implemented with about 8 to 10 questions. The Drafting Team 1 has prepared the document N 30 R 15 for this meeting which will be the basis for the ongoing discussions, thanks were given to Jan Welch.

The second task is to discuss the modifications proposed by SG 3 which were circulated with the document N 30 R 15A. This proposal will change the structure of the document N 30 in a strong way. It is the unanimous consensus not to change the structure and the content of the document N 30 generally, but to take over the constructive proposals. This is the speediest process to follow the task given by the SC.

Second part

As a résumé from the joint GHTF SG3 / SG4 meeting Markus Zobrist pointed out:
The joint meeting

- was a very good impact from and for both sides and
- the document SG4N30R15 could be finalized and got the number SG4N30R16.

Because of several editorial changes in the document R 15, the document had to be updated in detail and got the number R 16.

Main changes were:

- The document correspondences to ISO 13485:2003 only. All references to other jurisdictions were moved to appendix 3.
- The implementing of risk management was mainly done in the chapter 7, but also other chapters incorporate references, where applicable.
- The definitions were brought in congruence with other GHTF documents.

This document was sent to the GHTF Secretariat as the end of the meeting for adopting at the next meeting of the Steering Committee in November in London.

3. Preparing of a Working Draft Document of N 33 “Audit Report”

Basis for the discussion is the result from The Drafting Team 2 “Preparing a draft of GHTF N 33”. The first part of this document could be reviewed. The result got the number R 9.

It was decided to look through the chapter 7 (until chapter 7.5) with the highest

priority; the elements have to be congruent with the document N 30. But also scope and rationale were redrafted.

Basis for this document is the document N 30 R 16 "Regulatory Auditing Strategy", which was just finalised, as well as the ISO 13485:2003. Also the earlier matrix (N 33 R 339) has to be taken into account.

It was stated that there could be different kinds of reports, depending on findings and some parts of the report can be distributed at the end of the closing meeting. The first part of this document could be reviewed. The result got the number R 9.

4. Miscellaneous

6.1 Next meetings

14 – 16 November 2005	Luebeck, Germany
14 – 16 February 2006	Taipei, Taiwan
23 – 27 June 2006	Luebeck, Germany in the frame of the GHTF Conference until 30 June 2006

6.2 Task of next meeting

N 33 should become a proposed document. For that, this document should be circulated soon in its recent stage.

The document N 28 "Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 1: General Requirements" has to be revised.

6.3 Closure

Markus Zobrist thanked all participants for the excellent work done in the four days. The following day (Friday 16 September 2005) all Study Groups are going to meet jointly and will report of their work.

Gaithersburg, September 15, 2005

Markus Zobrist
Step in Chair

Dierk Bellwinkel
Secretary