SG 4 N 57 - 1

SG4 GHTF Study Group 4

SG4 BERNE MEETING
Summary

Location: Berne, Switzerland
Swissmedic Main Office
Date: **September 22 until September 24, 2003**

Interim Chair: Prof. Horst Frankenberger, EUROM VI, Europe

Participants: 16 incl. 2 observers

Goals of the meeting:

- To finalize the draft of the GHTF guidance document: "Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy"
- To structure the first draft of the GHTF guidance document: "Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 3: Audit Reports"
- To answer the questions of the GHTF Steering Committee

To Do List			
Agenda No.	Task	Responsible	Date
2.2	Status of GHTF documents	All members	20 Oct. 2003
3	Check references to ISO 13485 and 21 CFR 820	C. Nelson, A. Muir, J Rader, J. Worroll	As soon as possible
3	References with JGMP	M. Isozaki	Not before mid 2004
4	Contact to SG 3 for NWIP	H.Frankenberger	Nov. 2003
5	Completion of N 351	AHWP via M. Tanemura and A. Li	Febr. 2004

1. Opening

The agenda (N 56 R3) was adopted, containing correction in the numbering and a proposed time table.

2. Development of GHTF

The interim chairman reported about the agenda of the Steering Committee meeting on 5 – 7 November in San Francisco. The following points were treated in some more detail:

2.1 Common Data (N42 – 2)

The comments of GHTF SG 4 were intetrated in N42-2, the document was sent to the GHTF secretariat with the no. N42 – 2 R1at the end of the meeting.

2.2 Scorecard Template (N 44)

Aim: Clarification of the status of the documents, the focus of GHTF and its SG's. The status of each region will be sent by the participants to the secretary (latest 20 October 2003)

2.3 Categorisation of GHTF Documents (N 45)

Comments of GHTF SG 4 were given and sent to the GHTF secretariat:

2.4 Further activities

The interim chairman gave an overview on ongoing work of GHTF SG 4 to the Medical Devices Expert Group in Brussels and has asked the chairman of the Notified Bodies Observer Group (NBOG), for input to the document: "Guidelines for regulatory auditing of quality systems of medical device manufacturers – Part 2: Regulatory auditing strategy" (N 30 R5).

3. Finalising of Document N 30 R 5 (Part 2)

The document: "Guidelines for regulatory auditing of quality systems of medical device manufacturers – Part 2: Regulatory auditing strategy" was revised and completed – including the 3 appendices. The new revision with the number R 6 will be sent as a final working draft to the GHTF Steering Committee in November 2003 for advancement from a working draft to a proposed document.

The title of the item has been changed from "Auditing Strategy" to "Regulatory Auditing Strategy" for better indicating the purpose of this guidance document.

A definition of "Regulatory Auditing" has been added.

Numbering used in the proposed document has been aligned with ISO 13485:2003 and 21 CFR Part 820 section numbers have been added.

Tasks to be done before sending the document to GHTF SC:
Chapter 6:
Christine Nelson will check the references to 21 CFR chapter 820, Andrew Muir the references to ISO 13485:2003.
Makiko Isozaki will check the references with the incoming Japanese regulation JGMP; these will be implemented when available.

4. Proposed new work items

It is planned to ask the GHTF SC for an information project which gives guidance to regulatory auditors auditing the quality systems of manufacturers – based on ISO 13485:2003 and 21 CFR Part 820. Before applying for this project it will be discussed with GHTF SG 3 whether to initiate a common SG3 and SG 4 project. It

is planned to present this item to the GHTF SC in March 2004 after the next meeting of SG 4.

A further work item will be the review of “Guidelines for regulatory auditing of quality systems of medical device manufacturers – Part 1: General requirements” (GHTF / SG 4 / N 28 R2) and the existing supplements. This is necessary because the documents on which these guidance documents are based on principles in all three parts of ISO 10011:1990, the auditing principles in ISO 14000 series and the quality systems of ISO 9000:1994 series. The documents have also to be streamlined according to the structure given in 1. This project will be started after the proposed document “Guidelines for regulatory auditing of quality systems of medical device manufacturers – Part 2: Regulatory auditing strategy” (GHTF / SG 4 / N 30 R6) will be published as a proposed document and after the project “Guidelines for regulatory auditing of quality systems of medical device manufacturers – Part 3: Regulatory auditing report” will be finished as a proposed document – this means not before end of 2004.

5. Additional Regulatory Auditing Requirements N351 R3 and N 353 R1

N 351”Additional regulatory requirements for QMS, Asia”: Initiated by Morishika Tanemura and Albert T.W. Li nearly all AHWP member states have given input. The next meeting of AHWP is in February 2004, then the implementation of GHTF documents will be compiled.

N 353” Additional regulatory requirements for QMS, Canada”: Since July 2003 the ISO 13485:2003 is final. Then a 3 years transition period started. Beginning October 2003 both standards (13485:1996 and 13485:2003) will be accepted.

6. Regulatory Audit Reports N 33 ”Guidelines for regulatory auditing of quality systems of medical device manufacturers – Part 3: Regulatory auditing report”

This item was started during the Berne meeting. The goal of this guidance document was updated as follows:

The purpose of this guidance document is to assist auditing organisations to prepare a regulatory audit report to a standard content and format. The audit report should provide all essential details of the audit, the auditor’s observations and recommendations on the manufacturer’s compliance status.

The report should be prepared in a format that can be used by:
- the manufacturer to get feed back for further improvement of the quality system, and
- the regulatory body for evaluating the compliance of the manufacturer and making regulatory decisions, and
- the conformity assessment body and supervising authorities to assess the competence of the auditing organisation / auditor.

Users of audit reports have been identified and their needs have been discussed.

The brainstorming showed:
- a standardised format and a harmonised content is necessary for mutual understanding and acceptance for all involved.
- the report must show the conclusions for both sides, the auditee and the auditing organisation
- there is a double target: The manufacturer learns about the situation and improvement, the CAB gets a justification for its supervising organisation

6.1 Review of the document N 6 R2 (old SG4(00)6R2) from Robert Allen: "AUDIT REPORTS: USER NEEDS"

The first part (inclusive § 1) was revised. The document became N 6 R3.
Task for each member of GHTF SG 4 until the next meeting in February 2004:
- harmonising administrative information with N 30 no. 5.6 A
- definition of "audit report"
- examples of audit reports
- differentiation between the document remaining with CAB and sent out to the manufacturer

7. Work Plan of SG 4 for 2003 - 2005

The work plan 2003 – 2005 (N 43) was revised and became the no. N 43 R1. The work plan 2003 – 2005 was sent to the GHTF SC at the end of the meeting.
(see annex N 43 R1)

8. Miscellaneous

Structure of the SG 4 guidance documents
SG 4 proposes a presentation of a process oriented structure of the SG 4 guidance documents

- **Guidance documents for regulatory auditing organizations and manufacturers to be used before a regulatory audit starts**
  SG 4 has finalized at the Berne meeting a proposed document:
  "Guidelines for regulatory auditing of quality systems of medical device manufacturers – Part 2: Regulatory auditing strategy" (GHTF / SG 4 / N 30 R6)
  This is a basic guidance document which will be followed by supplements giving more detailed guidance information both to the regulatory auditing organization and to the manufacturer.

- **Guidance documents for regulatory auditing organizations and manufacturers to be used for a regulatory audit**
  SG 4 has worked out the following final guidance document:
  "Guidelines for regulatory auditing of quality systems of medical device manufacturers – Part 1: General requirements" (GHTF / SG 4 / N 28 R2).
  This is a basic guidance document which is followed by final documents as supplements giving more detailed guidance information both to the regulatory auditing organization and to the manufacturer:

Supplement 1	Audit Language Requirements	N 14
Supplement 2	Estimation of Audit Duration	cancelled
Supplement 3	Training Requirement for Auditors	N 3
Supplement 4	Compilation of Audit Documentation	N 24
Supplement 5	Report on Observation of audits by SG 4	cancelled
Supplement 6	Observed Audits of CABs	N 26

- **Guidance documents for regulatory auditing organizations and manufacturers to be used after a regulatory audit**
  SG 4 has started at the Berne meeting the working document:
  "Guidelines for regulatory auditing of quality systems of medical device manufacturers – Part 3: Regulatory auditing report." (GHTF / SG 4 / N 33 R1).

9. Next meetings

The next meetings were planned:

2 – 4 February 2004	USA West coast
19 – 21 May 2004	Tokyo, Japan
27 – 29 September 2004	Canberra, Australia

10. Closing of the meeting

In the name of all participants Horst Frankenberger thanked Swissmedic, especially Marcus Zobrist and Reiner Völksen, for the excellent organisation of the meeting and the hospitality offered to each participant.

Horst Frankenberger	Dierk Bellwinkel
Interim Chair	Secretary