

**SG4****Study  
Group 4**

### SG4 Atlanta Meeting Summary

Location: Atlanta, Georgia, USA  
 Philips Sales and Service Office

Date:	Monday	February 2, 2004	09.30 until 17.00 h
	Tuesday	February 3, 2004	09.00 until 17.00 h
	Wednesday	February 4, 2004	09.00 until 17.00 h

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

10 participants inclusive 2 observers

#### Goals of the meeting were:

- To review comments to the proposed document: “Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy”
- To develop the first draft of the GHTF guidance document: “Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 3: Audit Reports”
- To discuss the development of a new guidance document for audits of risk management as an integral part of audits of the quality management system.

#### 1. Development of GHTF

Horst Frankenberger reported about the meeting of the Steering Committee on 5 until 6 November in San Francisco. The official report is available on the GHTF web-site.

#### 2. Review and discussion of comments on the document SG4 N30 R6 “Regulatory Auditing Strategy”

This document was put onto the GHTF web-site as a proposed document on 25 Nov. 2003. Comments are expected until 25 February 2004. At the Tokyo meeting all comments will be treated. This document will be finalised at the next meeting.

#### 3. Development of the first draft of the GHTF guidance document: “Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 3: Regulatory Audit Reports”

“The purpose of this document is to enable auditing organisations to prepare a report to a standard format providing all essential details of the audit carried out, the quality system and its documentation/records evaluated, the auditors observations and conclusions on the manufacturer's compliance status. The

report has to be in a format that may be electronically stored and capable of being reviewed, analysed and as appropriate used by regulatory bodies for regulatory decisions. In addition, the data might be used in support of bilateral agreements“.

Several comments were received from the members which were looked through. The table of contents of document N 33 was reviewed. The chapters 1 – 5 (without “references” and “definitions”) were drafted.

In addition the matrix “Common data and regulatory requirements and comparison of reporting practices” was drafted. Several actions have been decided to be done until indicated times.

**4. Discussion on the development of a new guidance document for audits of risk management as an integral part of audits of the quality management system. This project is initiated by the GHTF Steering Committee at the San Francisco meeting. The discussion should respect the following GHTF document: SG3 N15 Rev 6: “Risk Management as an integral part of the Quality Management System”**

The result of the discussion is:

Q: Should SG 4 develop Risk Management audit guidance as an integral part of the Quality Management System?

The analysis of this question lead to the following 2 questions and answers:

Q: In which regions are Risk Analysis (RA) and Risk Management (RM) regulatory requirements?

Country / Region	RA regulatory requirement	RM regulatory requirement
Canada	Product related ISO 14971 is a recognised voluntary standard, but manufacturer can use other	as part of Quality System (QS) requirements (ISO 13485)
USA	Product related 820.30(g)	Implied in part 820 preamble, FDA recognises ISO 14971. If manufacturer adopts 14971 or other RM as a standard operating procedure (SOP), FDA may audit conformity with SOP
EU	Product related as required in MD directives	ISO 13485 and implied in MD directives
Japan	Product related under revised PAL (Pharmaceutical Affairs Law)	New GMP and PMS regulations?

Australia is asked to complete this list.

Q: What are the advantages and disadvantages of integrating RM auditing guidance in QS audit strategy?

Advantages:       - Easy for auditors to conduct effective audit of both the Quality System and Risk Management activities  
                      - Helps auditor and auditee understand the role of Risk Management in the Quality System

Disadvantages:   - Not all GHTF members require a full risk management system  
                      - Having risk management audit guidance incorporated in QS auditing guidance may confuse auditors as to which audit objectives concern mandatory requirements and which audit objectives are not mandatory requirements.  
                      - Industry may object to having risk management, which is not mandatory in all regions, as part of QS audit strategy.

### **Conclusion:**

The principles of the Regulatory Auditing Strategy document (SG4 N 30) should apply to the auditing of Risk Management as an integral part of the Quality Management System. SG 4 will integrate the guidance document for audits of risk management as an integral part of audits of the quality management system into SG4 N 30 “Regulatory Auditing Strategy”.

### **5. Planning of the next meeting in Tokyo in May 2004**

From Japan was given an overview on the new Japanese legislation which will become effective on 1 April 2005.

At the 3<sup>rd</sup> day of the forthcoming GHTF SG4 meeting in Tokyo (19 until 21 May 2004) a training seminar will be held. The agenda for this seminar was drafted:

### **Agenda**

#### **Training Seminar: Results from GHTF SG 4 “Auditing” Tokyo, 21 May 2004**

- |               |  |
|---------------|--|
| 14:30 – 15.00 | <b>Opening remarks</b><br>Masato Yoshida, JFMDA<br>Fumi Yamamoto, MHLW<br>Horst Frankenberger, Interim Chair GHTF Study Group 4 – Auditing                                 |
| 15.00 – 15:30 | <b>Guidelines for regulatory auditing of quality systems of medical device manufacturers – Part 1: General requirements</b> (Final document)<br>Markus Zobrist, Swissmedic |

- 15:30 – 16.00      **Guidelines for regulatory auditing of quality systems of medical device manufacturers – Part 1: General requirements – Supplements** (Final document)  
Christine Nelson, FDA
- 16.00 – 16:30      **Guidelines for regulatory auditing of quality systems of medical device manufacturers – Part 2: Regulatory Auditing Strategy** (Proposed document)  
Kenji Aoyama, JFMDA
- 16:30– 17.00      **Guidelines for regulatory auditing of quality systems of medical device manufacturers - Part 3: Regulatory Auditing Reports** (Working draft)  
Tim Missios, CDN Industry

17:00 – 17.30      **Discussion**

Horst Frankenberger  
Interim Chair SG4  
Atlanta, 4 February 2004  
Revision by Japan 10 February 2004

**6. Miscellaneous**

No items were raised.

**7. Next Meetings**

19 – 21 May 2004	Tokyo, Japan
27 – 29 September 2004	Canberra, Australia

**8. Closing of the Meeting**

On behalf of all participants Horst Frankenberger thanked Robert Turocy (who was unfortunately unable to participate) and the company Philips Medical Systems. The GHTF SG4 is very grateful to Mr. Fred Wyatt for having hosted the meeting and to Ms. Trish Schmidt for the excellent services given during the meeting and the hospitality offered to each participant.

Horst Frankenberger  
Interim Chair

Dierk Bellwinkel  
Secretary