Global Harmonization Task Force
Working Towards Harmonization in Medical Device Regulation

SG4 / N 65-4

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

Meeting Summary

Location: Boston Scientific Ltd.
One Boston Scientific Place
Natick, MA 01760-1537
United States

Tuesday	April 5, 2005	13:30 to 17:30 h
Wednesday	April 6, 2005	09:00 to 17:30 h
Thursday	April 7, 2005	08:30 to 12:30 h

Chair: Prof. Dr. Horst Frankenberger, EUROM VI, European Industry

Participants: 12 members and 3 observers

The GHTF-SG4 meeting followed the joint GHTF SG3 / SG4 meeting (see the minutes SG 4 N65 – 1).

Goals of the SG4 meeting:

- To finish the first working draft of the GHTF guidance document: *"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

Horst Frankenberger welcomed the participants and observers – especially Jan Welch from FDA as a new member of GHTF-SG4. As a résumé from the joint GHTF SG3 / SG4 meeting he pointed out:
The joint meeting
- was a very good impact from and for both sides and
- has brought further clarification for the document SG4N30R14.

The roll call of experience with this joint meeting showed that it was very efficient – especially with the subject of integration of risk management into the quality management system. The exchange of experiences is considered to be helpful for the work to be done by GHTF – also in the cooperation between different study groups.

Due to the preceding joint GHTF SG3 / SG4 meeting a review and assessment of

this meeting was added to the agenda including the following topic: “Drafting the implementation of Risk Management into the document SG4 N30 R14**”**.

The agenda was adopted.

2. Report on GHTF Meeting in Brussels

The EU Commission called for a meeting to rework the GHTF procedural documents on 7 and 8 February 2005. Horst Frankenberger reported:

- There was a reorganization within the EEC. Mr. Keith Brekelmans left the medical devices sector. He is succeeded by Mr. Abraao Carvalho (Portugal) as head of unit, responsible for Pharma, Biotech, Human Tissue, Medical Devices and Cosmetics. The final decision on organization is outstanding.
- Mr. Antonio Lacerda continues in the medical devices sector.
- The Steering Committee will meet
  18 – 20 May 2005 in Seville
  and the study groups will meet
  12 – 16 September 2005 in Gaithersburg.
  13 – 15 September 2005 there is the meeting of all Study Groups in Gaithersburg; MA; on 12 Sept. meets only SG 5.
- In June 2006 the GHTF - Conference will take place in Luebeck:
  25 – 28 June 2006 Study Groups
  29 – 30 June 2005 GHTF - Conference with Plenary

The European Commission has established a web-site with all information for medical devices:
http://europa.eu.int/comm/enterprise/medical_devices/index.htm

3. **Drafting the implementation of Risk Management into the document SG4 N30 R14**

For implementing “Risk Management Requirements” into the document SG 4 N 30 R 14 several tasks were done and planned. It was decided to integrate the auditing of risk management requirements into a document based on SG4 N30 R14.

It was decided <u>not</u> to make a new document, but to stay with N 30 and continue with the Revision numbering: N 30 R….

A first draft of this document was started. It is expected that this draft will become a proposed document in 2006.

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

The document N 33 R 6 from September 29, 2004 was reviewed. It was updated and got the number R7. For chapter 7.0 ”Main points for a regulatory audit report” the structure of the matrix (R 339 R 5) was taken. Several tasks were planned.

The discussion led to the conclusion that this document has to be a core document and not a summary of all existing requirements. The fundamental questions are:

- How is a regulatory audit report structured (This is not only one report, but a collection of many reports – not all of them are available to the manufacturer)
- “What are the essential topics regulatory audit reports have to contain?
- In what detail they should be covered?”

If it should be necessary to have specific regional requirements they have to be mentioned on regional level.

On the basis of task no. 13, a comparison will be drafted. CDN and Japan are asked to join.

5. Update of SG 4 Work Plan

The work plan was updated and got the number N 43 R 3 (attachment 1)

6. Résumé

The joint meeting with SG 3 was a good experience and will be repeated.
The document N30 R14 has been sent to the SC for adoption as a final document.
A first working document for auditing the risk management requirements – based on N30 R14 – was drafted. Since the risk management requirements are an integral part of the quality management system it was decided to draft one document for auditing the quality management system and the risk management requirements.
The document N33 R8 will combine all comments on R7 and will be circulated before the next meeting in September.
The document N 33 has the highest priority; a working draft should be finished at the September meeting.

7. Miscellaneous

6.1 Next meetings

12 – 16 September 2005	Gaithersburg together with all SGs,
14 – 16 February 2006	Taipei, Taiwan
25 – 27 June 2006	Luebeck, Germany in the frame of the GHTF Conference until 30 June 2006

6.2 Farewell to Christine Nelson
Horst Frankenberger und Robert Turocy thanked Christine Nelson for her utmost contribution since 1995 in the GHTF Study Group 4. Since this was her last meeting with GHTF-SG4 all participants expressed their best wishes for Christine.

6.3 Closure
Horst Frankenberger thanked Tim Missios and the company Boston Scientific for the excellent hospitality and Katy for the excellent help.

Boston, April 7, 2005

Horst Frankenberger	Dierk Bellwinkel
Chair	Secretary