SG4 / N61-1

GLOBAL HARMONIZATION TASK FORCE
Working Towards Harmonization In Medical Device Regulation

Global Harmonisation Task Force, GHTF, Study Group 4: Auditing Meeting on 19 – 21 May 2004 in Tokyo, Japan

Summary

Location: JFMDA office
Iidabashi Square Bldg., 8F B-zone
2-3, Shimomiyabi-cho, Shinjuku-ku, Tokyo 162-0822, Japan

Wednesday, May 19, 2004 until Friday, May 21, 2004

Interim chair: Prof. Dr. Horst Frankenberger, EUROM VI, Europe (Germany)

17 participants inclusive 3 observers

Goals of the meeting are:

- To review comments to the proposed document: "Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy" (SG4(PD)/N30 R6) and integrate the agreed aspects – including a statement of auditing risk analysis – into the document
- To finish the first draft of the GHTF guidance document: "Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 3: Audit Reports"
- To inform the interested public on activities of GHTF SG4

1. **Welcome by the chairman Horst Frankenberger, by Ms. Fumi Yamamoto for the Japanese government, by Mr. Masato Yoshida for JFMDA and Kenji Aoyama for TUV Rheinland Japan.**

   Roll call of the participants.
   The agenda was adopted. The document on regulatory auditing strategy was given the highest priority.

2. **Review, discussion and decisions on comments to the proposed document GHTF/SG4/N30R6.**

   More than 80 comments were received. – not all are structured as given by the GHTF-"Comments Template".

   Although only a few comments have rationales, all these comments were treated and answers will be sent to the responsible organizations/persons.

Further comments came up, when discussing the document. All accepted comments were integrated into the SG4(PD)/N30 R9.

The proposed document SG4(PD)/N30 R9 implements “Auditing of Risk Management” as required by the Steering Committee. This was agreed unanimously.

At the end the content was agreed upon.

After partly linguistical and editorial control, the document became the SG4(PD)/N30 R10. GHTF-SG4-members have to check and complete this document until end of July. It was decided to send the document SG4(PD)/N30 R11 after compiling all comments by the secretary to the Steering Committee for adopting it as “Final Document” after the next meeting in September.

3. Discussion on the first draft of the GHTF guidance document: “Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 3: Regulatory Audit Reports“ (SG4/N33 R4).

To the working document SG4/N33 R4 the following comments were received:
- Definition of “Regulatory Audit Report”
- Examples of audit reports from European Notified Bodies
- Remarks from the Notified Bodies meeting in Brussels
- Audit report by the Australian Government
- Table of he structure of “Common Data”

The definition of “Regulatory Audit Report” was revised and implemented into the document SG4/N33 R4. This led to the document SG4/N33 R5.

The audit report which is based on the European directives was explained. There is no general differentiation between a regulatory or a non-regulatory report.

On the basis of the structure of common data it was started to check the positions of the matrix (N339) in view of their necessity and their belonging to the relevant part of the audit report – until position 21. This led to the document N339 R3.

Until end of August this work will be finalized.

4. **Revision of the “Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 1: General Requirements (GHTF/SG4/N28R2:1999)” and its supplements - planning of the work steps.**

This item was postponed. The review will start after the strategy document is finalized.

5. **Next meetings**

For 2004 already fixed:

27 until 29 September	Canberra, Australia There will be no seminar after the meeting

Proposal for 2005:

9 – 11 March or	Taipei, Taiwan or alternatively
16 – 18 March	Feedback by members until 15 June 2004!
14 – 16 September or	Boston, USA
21 – 23 September	The chair will ask Tim Missios for the convenient date

The relevant dates have to be checked.

6. **Miscellaneous**

- The working documents should have the lines numbered.
- It was decided, that the minutes of the meetings are for internal use only and the summary will be posted on the web-site. Both were released by the secretary.
- The observer of the meeting will present proposals for improval of the GHTF procedures concerning the handling of the GHTF Comments Template to the Steering Committee.
- Andrew Muir will send to the GHTF SG 1 the proposal that the STED document (SG1 N011 R17) should include risk management.

7. **Closure**

The chair closed the meeting with warm thanks to the Japanese ministry MHLW, Ms. Fumi Yamamoto and Mr. Ichiro Tsunoi, as well as to the association JFMDA, Mr. Yoshida Masato and Mr. Kenji Aoyama for the organisation and the excellent hospitality.

8. **Training Seminar**

In the afternoon of 21 May 2004 a GHTF training seminar was held in the rooms of JFMDA with more than 20 participants from medical devices industry and government. Information on GHTF in general as well as on Study Group 4 documents was presented. This was accompanied by an intensive discussion.

Tokyo, 21 May 2004

Horst Frankenberger	Dierk Bellwinkel
Interim-Chair	Secretary