



SG4 / N63 - 1 d

GLOBAL HARMONIZATION TASK FORCE
Working Towards Harmonization In
Medical Device Regulation

**Global Harmonization Task Force, GHTF, Study Group 4:
“Regulatory Auditing”
Meeting on 27 – 29 September 2004 in Canberra, Australia
with
GHTF-SG4 Training Seminar on 30 September 2004 in Sydney**

Summary

Location for GHTF-SG4 meeting: Therapeutic Goods Administration, TGA
136 Narrabundah Lane
Symonston, ACT

Location for Training Seminar: Mercure Hotel
194 Pacific Hwy, St Leonards
Sydney

Monday	September 27, 2004	09.30 to 17.00
Tuesday	September 28, 2004	09.00 to 19.00
Wednesday	September 29, 2004	09.00 to 17.30
Thursday	September 30, 2004	14:00 to 17:30 Training Seminar

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

Participants:
10 participants; 9 members and 1 observer

**1. Welcome by the chairman Horst Frankenberger
Roll call of the participants, adoption of the agenda**

Horst Frankenberger for the Study Group 4 and Andrew Muir for the TGA welcomed the participants, especially Shigetaka Miura as a new member. All participants introduced themselves. The agenda was adopted.

2. Information on results of the GHTF Steering Committee meeting (June 2004)

Horst Frankenberger informed about the following results:

- The GHTF-chair moved from Japan to Europe. Cornelis Brekelmans from the Commission is the chair, Maurice Wagner from industry (EUCOMED) is the vice chair.
- Reports on the update of main developments in founding members regulatory systems (see also records on GHTF Steering Committee website)

- The SC asked GHTF-SG4 for not delaying the audit report (N 33). We should try to present a working draft to the Steering Committee for the next SC-meeting in 2005.
 - SG 3 and SG 4 proposed a joint meeting in March 2005 in Boston. The task is to develop a guidance document of how to integrate a risk management system into a quality system (based on ISO 13485:2003) and develop criteria for auditing risk management. One aim of the guidance document is to keep ISO 14971 as flexible as possible. SG 3 develops for the moment a document on risk management for educational purpose only, not for auditing purpose. Horst Frankenberger will draft a proposal for the scope of the joint SG3/SG4 meeting.
 - The SC has installed a new study group SG 5 “Clinical Evidence”. Chair is Graeme Harris.
- 3. Decision on the splitting of the proposed document GHTF/SG4(PD)/N30R10 into “Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 2: General Remarks on Regulatory Auditing Strategy” and “Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 2: General Remarks on Regulatory Auditing Strategy” Supplement 1: The regulatory auditing of risk management aspects within quality management system audits.**

The document “Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 2: General Remarks on Regulatory Auditing Strategy” contains the quality system strategy requirements and additional requirements, as e. g. for risk management. Supplements to the Part 2 document will be established, when the guidance document mentioned in 2 (guidance document of how to integrate a risk management system into a quality system (based on ISO 13485:2003) and develop criteria for auditing risk management) is available.

In praxis quality system and risk management are handled in one system: Both are process orientated, both require management responsibility and risk management is part of the quality system. The first joint SG3/SG4 meeting is planned for April 2005 in Boston. Further supplements can be established for further requirements, like for software and others. This procedure was agreed unanimously.

Facit:

The document “Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 2: General Remarks on Regulatory Auditing Strategy” will remain as it is structured for the moment. It was decided to add a rationale and minor editorial revisions based on the work done by John Worroll and Robert Turocy. Auditing of risk management will become supplement 1 to the Part 2 document.

- 4. “Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 2: General Remarks on Regulatory Auditing Strategy” (SG4/N30). Preparing of a final document.**

This part 2 was reviewed and reformatted, the rationale added and became R 13. It will be circulated on October 3, 2004 to the members with short time for checking (until October 20, 2004). After that it will be sent to the Steering Committee to be accepted as Final Document GHTF/SG4/N30RXX:2004.

- 5. Finishing 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“ (SG4/N33) under consideration of the work of Markus Zobrist and Karen Coleman

The matrix on “Common Data” was reviewed, became no. N 339 R4 and is the basis for the drafting of the document on “Regulatory Audit Report” N 33 R 6. All items in conformity among all GHTF founding members are marked yellow and will become part of the document N 33. The items handled differently are in white and have to be discussed continuously for bringing them in line.

Depending on the matrix “Common Data” Japan announced several changes with the new Pharmaceutical Affairs Law, PAL, which will come into force in April 2005.

6. Miscellaneous

GHTF SG4 Training Seminar in Sydney

The Australian association MIAA, Mr. Brian Vale and Ms. Penny Adams have organised this Training Seminar for interested persons from the medical devices industry. With about 50 participants it was a success. (Agenda enclosed).

Next GHTF SG 4 meetings:

Monday April 4, 2005 until Wednesday April 6 2005 in **Boston** / NATICK

Monday April 4: joint meeting with SG 3

April 5 and 6, 2005 SG 4 meeting

April 7, 2005: Training Seminar on demand of US industry.

September 12 – 16, 2005 meeting with all Study Groups in Gaithersburg / Washington on invitation of FDA.

February 2006 Taipei – proposed, dates to be agreed.

End of June 2006 Luebeck, Germany – together with the GHTF Conference.

7. Closure

Horst Frankenberger closed the meeting with warm thanks to the Australian administration TGA and thanks to Andrew Muir for the organisation and the excellent hospitality. He also thanked Mr. Brian Vale and Ms. Penny Adams for the preparation of the successful training seminar.

Luebeck, November 11, 2004

Horst Frankenberger
Chairman

Dierk Bellwinkel
Secretary



Agenda

Training Seminar: Results from GHTF SG 4 “Auditing” Sydney, September 30, 2004

- 14:30 – 15.00 **Opening remarks**
Andrew Muir and Brian Vale: Welcome
Horst Frankenberger, Chair GHTF Study Group 4 –
Auditing: Opening remarks, overview and objectives of GHTF
- 15.00 – 15:30 **Guidelines for regulatory auditing of quality systems of
medical device manufacturers – Part 1: General
requirements** (Final document)
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)
Dierk Bellwinkel, EUROM VI, FIDE
- 16.00 – 16:30 **Guidelines for regulatory auditing of quality systems of
medical device manufacturers – Part 2: Regulatory Auditing
Strategy** (Proposed document)
Robert Turocy, Philips
- 16:30– 17.00 **Guidelines for regulatory auditing of quality systems of
medical device manufacturers - Part 3: Regulatory Auditing
Reports** (Working draft)
Andrew Muir, TGA
- 17:00 – 17.30 **Discussion**

Horst Frankenberger
Chair GHTF SG4
August 9, 2004