GHTF
GLOBAL HARMONIZATION TASK FORCE
Working Towards Harmonization In Medical Device Regulation

Global Harmonisation Task Force, GHTF, Study Group 4: Auditing
Meeting on 10 – 12 February 2003 in Rockville, USA

Meeting Summary

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

Participants: 6 from government, 6 from industry and 2 from Notified Bodies, total 14 persons.

Goals of the meeting:

- To finalize a first draft of the GHTF guidance document on „Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 2: Auditing Strategy“
- To provide responses to the suggestions of Dr. Hojo
- To review the work plan of SG 4

Action Plan / To Do List:

For Japan, Makiko Isozaki, Kenji Aoyama for Canada; Anne Marie Coutu, Tim Missios for Australia, Andrew Muir for USA, Karen Coleman, Robert Turocy for Europe, David Marshall, Johann Rader, Markus Zobrist, Philippe Lartigue, Dierk Bellwinkel	For “Audit Report” Compiling existing documents	12 May

All other action points have been done in the meantime.

Structure of the document SG 4 N 30: “Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 2: Auditing Strategy”
The working draft has been sent to the Steering Committee.

Structure of the SG 4 documents
SG 4 has finalized the work on “Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 1: General Requirements”.
The presentation of the SG 4 documents on the GHTF web-site does not follow the logical structure according to their content. SG 4 proposes to the Steering Committee to present the documents in the following order:

Document	Name of document	No. SG 4 /	Stage
Part 1	Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 1: General Requirements	N 28	Final
Supplement 1	Audit Language Requirements	N 14	Final
Supplement 3	Training Requirement for Auditors	N 3	Final
Supplement 4	Compilation of Audit Documentation	N 24	Final
Supplement 6	Observed Audits of CABs	N 26	Final

SG 4 is working for the moment on the Guidance document: "Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 2: Auditing Strategy" SG 4 proposes to introduce this document as Part 2.

Document	Name of document	No. SG 4 /	Stage
Part 2	Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers:– Part 2: Auditing Strategy	N 30	Working Doc March 2003
Supplement XX			

According to the work plan agreed by the Steering Committee SG 4 is preparing a guidance document on „Audit reports". SG 4 proposes to introduce this document as Part 3: "Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 3: Audit Reports"

Document	Name of document	No. SG 4 /	Stage
Part 3	Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers:– Part 3: Audit Reports		First draft during June2004
Supplement XX			

Gap Analysis QSIT and ISO 13485:2003

This topic will be treated at the next meeting. Karen Coleman and Chris Nelson will present a revised paper.

Regulatory Auditing Requirements for QMS in the Regions

This subject will be treated in more detail at the next meeting.
Mori Tanemura has delivered an overview for the Asian region (SG4 / N351 R 1)
Anne-Marie Coutu will prepare a paper until next meeting.

SG 4 Work Plan 2003 – 2004

The work plan has been sent to the Steering Committee.

Implementation of the Document Part 1 (N 28) into national regulations

Europe: Transposed in the European Guideline: MEDDEV 2.10-2 document on designation of Notified Bodies.
USA: Most of the document is implemented in investigation operation procedures.
Australia: Australia has introduced changes to the Therapeutic Goods Act 1989 to align the regulation of medical devices to the principles of GHTF. The system was

implemented in October 2002 and medical device regulation is carried out by the Office of Devices, Blood and Tissues.
Audits of manufacturers are carried out by the Manufacturer Assessment Section and SG4 Guidance documents have been incorporated into SOP's within the Section. These procedures are revised on a regular basis to incorporate SG4 recommendations and SOP 402 Quality System Auditing of Medical Device Manufacturers cross references the SG4 documents.
Canada: This guidance document is referenced in the Canadian Medical Devices Conformity Assessment System (CMDCAS). CMDCAS is the processes and criteria leading for:

- the recognition by Health Canada of third party quality system registrars as being competent to perform an audit of a medical device manufacturer's ISO13485/13488 Quality System;
- the registration activities performed by recognized registrars for the issuance of QS certificates submitted as part of device licensing documentation required prior to sell and/or import for sale a medical device in Canada. The CMDCAS policy uses the guideline in the following ways:

1) As a general reference on how to plan, carry out and document a regulatory audit of a medical device manufacturer. (Note: The guidance given in N28 is based on the principles found in the auditing standards ISO 10011 Parts 1, 2, & 3 which CMDCAS registrars already use to perform quality system audits)
2) As a source of guidance for terms like "nonconformity" and "technical expert" as they would apply to a regulatory audit of a medical device manufacturer's quality system.
3) As criteria for the competency requirements for auditors and audit teams (training, experience and qualifications). Section 10.2 "Audit team competence" of N28 is reproduced in the CMDCAS policy document. All CMDCAS registrars must provide evidence in their application for CMDCAS recognition that their audit team and auditors meet these competency criteria.
Japan: The SG4 document has been translated into Japanese and published since it was officially approved by the GHTF.
The MHLW of Japan has introduced and explained the contents of the document to the manufacturers and the GMP inspectors at a number of the lecture meetings and training program of inspectors held thereafter.
Although not transposed into the national guideline, the document is in use as reference and implemented

Special Part Documents 301 to 306

These documents will be saved in a stand by position for further use as supplements to Part 2.

Next meetings

25 to 27 May 2003 in Tokyo, Japan, starting on Sunday, May 25 in advance at the GHTF Conference
22 to 24 September 2003 in Bern, Switzerland, with Swissmedic

Closure

Horst Frankenberger thanks all for their active participating, especially Chris for the excellent organisation of this meeting. Many thanks to Robert Turocy and the American medical devices industry for organizing the evening meeting of February 10.

Special thanks were given to David Marshall who is a founding member of SG 4 and who is now leaving this group due to his retirement.

Short version of the minutes from SG 4 Rockville meeting
Cologne, 11 March 2003

Interim Chair	Secretary
Prof. Dr. Horst Frankenberger	Dierk Bellwinkel