

Status Report on GHTF - SG4 Activities and Work Plan: 2006 - 2008

1. [Area of work](#)
2. [Structure of GHTF-SG4 "Regulatory Auditing" Documents](#)
3. [Membership](#)
4. [Current status](#)
5. [Work plan and meetings 2006 – 2008](#)

1. Area of work

The area of work of GHTF SG 4 is guidance on „Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers“ with three main topics:

- General requirements
- Regulatory auditing strategy
- Regulatory audit reports

It is understood that the regulatory auditing of quality systems includes the auditing of risk management systems, if this is a regulatory requirement.

2. Structure of GHTF-SG4 "Regulatory Auditing" Documents

The documents worked out in GHTF-SG4 "Auditing" are "Guidelines for Regulatory Auditing of Quality Management Systems of Medical Devices".

The documents are structured as follows:

- Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – **Part 1: General Requirements**
- Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – **Part 2: Regulatory Auditing Strategy**
- Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – **Part 3: Regulatory Audit Reports**

3. Membership

Active members consist of representatives from all founding members. CAs, CABs and industry representatives are present from Australia, Canada, Europe, Japan Taiwan and USA.

Chair of GHTF-SG 4 is Markus Zobrist – Swissmedic

Secretary: Jan Welch – FDA

4. Current status

Table 1: Final documents published			
Document	Name of document	No.	Stage
Part 1	Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers – Part 1: General Requirements	SG4 (99) 28	Final (now under revision)
Part 2	Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers: – Part 2: Regulatory Auditing Strategy	SG4/N30R20: 2006	Final
Supplement 1	Audit Language Requirements	SG4 (99) 14	Final
Supplement 2	Estimation of Audit Duration		Cancelled

Supplement 3	Training Requirement for Auditors	SG4 (00) 3	Final
Supplement 4	Compilation of Audit Documentation	SG4-N(99) 24R3	Final
Supplement 5	Report on Observation of Audits by SG4		Cancelled
Supplement 6	Observed Audits of CABs	SG4- N26R1:2001	Final (now under revision)

Guidelines for Regulatory Auditing of Quality Systems of Medical Devices Manufacturers – Part 1: “General requirements” is a basic guidance document which is followed by supplements giving more detailed guidance information mainly to the regulatory auditing organization and to the manufacturer.

According to the work plan agreed by the Steering Committee, SG 4 is preparing a guidance document on „Regulatory Audit Reports“. SG 4 proposes to introduce this document as Part 3: Furthermore, SG4 is revising the document Part 1: General Requirements.

Table 2: Work in progress			
Document	Name of document	No. SG 4 /	Stage
Part 3	Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers: – Part 3: Regulatory Audit Reports	N 33:R13	Submitted to SC for Stage 4
Part 1 (Revision)	Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers: – Part 1: General Requirements	N 28 R2	Document development started in February 2006

5. Work plan and meetings 2006 – 2008

5.1 “Part 3: Regulatory Audit Reports”

The purpose of this document is to enable auditing organizations to prepare a report following a standard format which could fulfil the needs of multiple regulatory authorities and/or conformity assessment bodies. The report would provide all essential details of the audit, the quality management system and its documentation/records evaluated, the auditor’s 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, analyzed and as appropriate used for regulatory decisions and/or conformity assessment purposes. In addition, the data might be used in support of bilateral agreements.

GHTF-SG 4 started this work in September 2003 in Bern. This work has the highest priority. It is expected that the proposed document will be available for consultation in stage 5 after November 2006. The final document is expected to be available in 2007

5.2 Review of final documents

The review of Guidelines for Regulatory Auditing of Quality Systems of Medical Devices Manufacturers – Part 1: “General requirements” (GHTF/SG4/N 28 R2) and the existing supplements is necessary. Some supplement documents have also to be streamlined and adjusted or incorporated according to the new structure and content of Part 1.

Rationale

The revision is necessary because these SG4 guidance documents are based on and refer to a set of outdated ISO standards such as ISO 10011:1990 and the quality systems of ISO 9000:1994 and ISO 14000:1996 series. The revision will now take into account the ISO 9000:2000 series standards, ISO 13485:2003, ISO 19011:2002 and the new ISO 17000 series standards on conformity assessment which include provisions for auditing as well.

Proposal

The review project has started February 2006 and it was soon realized that structure and content the document Guidelines for Regulatory Auditing of Quality Management Systems of Medical Devices Manufacturers – Part 1: “General Requirements” need to be reengineered completely and therefore will need more time than initially estimated.

5.3 Summarized work plan and meetings of SG4

(Plan of approved work items.)

Table 3: Summarized work plan and meeting plan								
Year	2006		2007				2008	
Quarter	III	IV	I	II	III	IV	I	II
Part 1	Stage 2	Stage 2		Stage 3	Stage 4		Stage 5	Stage 6
Part 3		Stage 4	Stage 5	Stage 5		Stage 6		
SG4 Meetings		October 11-13 Berne		May 7 – 11 Los Angeles	Sept. Washington DC			

Markus Zobrist, Chair SG4
October 3, 2006