

Global Harmonization Task Force

Working Towards Harmonization in Medical Device Regulation

Study Group 4 “Regulatory Auditing“

Summary

SG3/SG4 Joint Meeting

Location: Hilton Washington DC North Gaithersburg
620 Perry Parkway
Gaithersburg, Maryland 20877
United States

Monday	September 12, 2005	09.00 to 12.30	SG4 Meeting
Monday	September 12, 2005	13.30 to 17.30	SG3/SG4 Joint Meeting
Tuesday	September 13, 2005	09.00 to 17.30	SG3/SG4 Joint Meeting
Wednesday	September 14, 2005	09.00 to 17.30	SG3/SG4 Joint Meeting
Thursday	September 15, 2005	09.00 to 12.30	SG3/SG4 Joint Meeting (If necessary, or SG4 alone)
Thursday	September 15, 2005	13.30 to 17.30	SG4 Meeting
Friday	September 16, 2005	09.00 to 17.00	Joint Meeting of all Study Groups

Goals of the joint SG3/SG4 meeting:

Develop guidance of how

- to integrate a risk management system into a quality system (based on ISO 13485:2003) – mainly a task of SG3 – and
- to audit the risk management requirements within the quality system including the links – mainly a task of SG4.
- The document SG4 N30 "Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 2: Regulatory Auditing Strategy" has to be finalised and has to be sent SG4 N 30 to the Steering Committee on 22nd September latest!

Chairs:

For SG 3 : Alain Prat, AFSSAPS, France, Europe

For SG 4 : Dr. Markus Zobrist, Swissmedic, Zwitterland, Europe

Participants:

From SG 3: 12 Participants and 1 Guest

From SG 4: 14 Members and 2 Guests

1. Opening

Welcome by the chairs of

- SG3: Alain Prat and

- SG4: Markus Zobrist

Roll call of the participants

Adoption of the agenda for the joint SG3/SG4 meeting

2. Briefing about the goal of this meeting

Information on the document of SG3 N15 R6: *“Risk management as an integral part of the quality management system“*

(Alain Prat)

Information on the modification of the document of SG4 N30: *“Guidelines for regulatory auditing of quality systems of medical device manufacturers – Part 2: Regulatory auditing strategy“*.

Markus Zobrist pointed out the task given by the Steering Committee as its meeting in London in May 2005: To implement the requirements to audit the risk management by only a few modifications and without rewriting the whole document. This task was done by the Drafting Team 1:”SG3 / 4: Implementing the requirements for risk management into the document N 30”

(Markus Zobrist)

3. Development of the Final Draft of the document N 30

Discussion and consequences for the SG 4 work item SG4 N30 *“Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 2: Regulatory Auditing Strategy“*.

The following documents were sent in advance to both of the Study Groups:

- N 30 R 15 as the result of the SG 4 Drafting Team 1 for implementing risk management into the document N 30
- N 30 R 15A as proposal from SG 3 to modify the document N 30.

The group decided to follow the document N 30 R 15 as a basis for the further discussion. It was furthermore decided to follow the ISO 13485:2003 as a standard for regulatory purposes and to put specific regional requirements into an appendix. In that way the scope was assimilated, but not changed. The table 1 and chapter 7 references to ISO 13485:2003 only. The new appendix 3 shows the ISO 13485:2003 plus the relevant legal requirements from the FDA and Japan.

The table 1 with the 8 subsystems in the chapter 6.2 “Auditing Quality Management Systems and Subsystems” will remain, but some headlines were modified. It was not supported to eliminate the subsystems 6 until 8.

Several termini were assimilated to other documents of the GHTF.

4. Closure of this meeting

The joint meeting took place over two days (Monday 12th afternoon until Wednesday 14th lunch). Both of the chairmen thanked the participants for the fruitful contributions. This document has to be finalised at this meeting in Gaithersburg by SG 4 and has to be delivered to the Steering Committee 22nd September latest.

Markus Zobrist
Step-in Chair GHTF SG 4

Dierk Bellwinkel
Secretary GHTF SG 4

Gaithersburg, September 15, 2005