Global Harmonization Task Force
Working Towards Harmonization in Medical Device Regulation

SG4 / N65-3

Global Harmonization Task Force, GHTF, Joint Meeting of Study Group 3 and 4 Meeting on 4 – 5 April 2005 in Boston, MA, USA

Meeting Summary

Location for this meeting:		Boston Scientific Ltd. One Boston Scientific Place Natick, MA 01760-1537 United States of America
Monday	April 4, 2005	09.30 to 17.30
Tuesday	April 5, 2005	09.00 to 12.30

Chair:
Mrs. Kimberly Trautman, FDA, USA fo r GHTF-SG 3
Prof. Dr. Horst Frankenberger, EUROM VI, Europe for GHTF-SG 4

Participants:
SG3: 8 members and 2 observers
SG4: 12 members and 2 observers

Goals of the joint SG3/SG4 meeting:

Develop a guidance document 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.

In the joint meeting the structure of the two parts of the guidance document should be harmonized.

1. **Opening**
   The chairs of
   - GHTF-SG3: Kim Trautman and
   - GHTF-SG4: Horst Frankenberger
   welcomed the participants to the first joint meeting of the two Study Groups. All the participants introduced themselves. The agenda for the joint GHTF-SG3/SG4 meeting was adopted.

2. **Information on the proposed documents**
   Kim Trautman informed on the proposed document of GHTF-SG3: *"Implementation of Risk management Principles and Activities within a Quality Management System",SG3/N15R8.* This document is final but not yet on the

GHTF web-site.

Horst Frankenberger informed on the document of GHTF-SG4: *"Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 2: Regulatory Auditing Strategy" SG4/N30R14*.

With the enclosed folios (attachment 1) he explained the background, the development and the proposed integration of risk management.

When looking through the document SG4/N30R14, some editorial changes were done which led to the document SG4/N30R14A (attachment 2). For the continuation of this document the following alternatives were discussed:

1. a) Issue the SG4/N30R14 document with editorial changes as SG4/N30R14A as a final document in May 2005. The editorial changes consist in taking out some aspects of risk management.
   b) Issue in a second step a document where the risk management requirements as given in the document SG3/N15R8 are integrated. The incorporation of risk management requirements as given in the document SG3/N15R8 into SG4/N30R14 will be done in the revision document based on SG4/N30R14A. The revised document will be ready in 2006 and will replace the document described under 1a).

2. a) Issue the SG4/N30R14 document with editorial changes as SG4/N30R14A as a final document in May 2005. The editorial changes consist in taking out some aspects of risk management.
   b) Issue a supplement to SG4/N30R14A where the auditing of risk management requirements will be treated. This supplement can be ready in 2006.

3. a) Withdraw SG4/N30R14
   b) Revise SG4/N30R14 and integrate the auditing of risk management requirements into the revised document. Alternative 3 is estimated to be ready in 2006.

After discussion the group decided with majority for alternative 1 (13 persons). For alternative 3 voted 6 persons and for alternative 2 voted 4 persons. The rationale for this decision is:
- Since the risk management requirements are an integral part of the quality management system, there should be only one document – no separation as proposed in alternative 2.
- Since there is a high demand for an audit strategy dealing with the auditing of quality management systems there should be no delay for the document given to the Steering Committee as final document.

Result:
The group decided to follow proposal 1 and to propose this result to the Steering Committee at the May meeting in Seville.

3. **Joint work on how to integrate risk management requirements from ISO 13485:2003 into the SG4/N30R14A document**

The first considerations on how to integrate risk management into the audit strategy document led to the working draft as a new document (attachment 2). Attention: During the meeting this document got the number SG4/N30R14B which has to be changed into SG4/N30R16 because of new tasks.

Study Group 3 determined 15 requirements from ISO 13485:2003 how risk management has to be treated. These requirements were assigned to the 8 subsystems of the table 1 “Subsystems and associated clauses” in N 30 R 14 .

SG 3 will have a look through the document SG4/N 30R14B for harmonizing the documents of both of the study groups.

4. Resumee

The main document SG4/N30R14A does not include the auditing of risk management requirements. The auditing of risk management requirements will be included into the document SG4/N30R14B which will be a working draft which has to pass all the steps indicated by the Steering Committee. The participants agreed to check the consistency of the new document in a second joint meeting in September 2005.

5. Closure of the Joint Meeting

Kim Trautman and Horst Frankenberger thanked all participants for their active participation. Both of them declared this meeting as a successful experience which will be repeated at the next meeting in Gaithersburg for one day. The chairs also thanked Boston Scientific for hosting the joint GHTF-SG3/SG4 meeting.

Kim Trautman	Horst Frankenberger	Dierk Bellwinkel
Chair SG 3	Chair SG 4	Secretary SG 4