

**Global Harmonization Task Force
Study Group 3**

**Meeting summary
September 14th / 16th, 2004
Erlangen, Germany**

1) Welcome and Introduction to new member and guest Experts

Kim Trautman, as chairman, opened the meeting .

In attendance were :

- Alain Prat (EU Gouvernement- Agence Française de Sécurité Sanitaire des Produits de Santé – Direction de l’inspection et des établissements)
- Gunter Frey (US Industry - NEMA – GE)
- Ken Kopesky (US Industry - AdvaMed - Medtronic)
- Ken Nicol (Australian Industry - MIAA - St. Jude Medical)
- Kim Trautman, Chair, (US Government - FDA)
- Shigetaka Miura (Japanese Industry – JFMDA – GE retired)
- Tony Chan (Risk Management Expert – Virginia Polytechnic Institute and State University)
- Werner Schoenbuehler (EU Industry – COCIR - Siemens Medical Solutions)
- Hideki Asai (Japanese Industry – JFMDA – Hitachi High-Technologies)

2) Approval of the agenda

The agenda is approved as followed :

1. Welcome and Introduction to new member and guest Experts
2. Review Old Business and Paris Steering Committee Meeting
3. Proposed Risk Guidance Document – Review comments, revise text and record disposition of comments per new Steering Committee directive
4. Discuss status of Risk Document and course of action
5. Discuss any items to be presented to the Seville May Steering Committee Meeting
6. Discuss any new work item proposal
 - a. Registration and Listing
 - b. Electronic Medical Devices and Wireless Technology: Electromagnetic Compatibility (EMC) and Data Integrity in Medical Device Quality Systems
7. Status of the EU notified body oversight group (NBOG) document on auditing of subcontractors - OEM device
8. Status of SG#3/SG#4 Ad Hoc Writing Group for Auditing Risk Management
9. Set date and location of next meeting

3) Steering Committee Meeting in Paris – June 2004

Kim Trautman raised the concern of the study group 3 on the way to reference quality system and risk management system standards normative in other medical device related standard.

Kim asked all members of the group to go to each representatives/contacts in Technical Committee to sensitize them to this problem. She asked also for some example in the EU.

Action (s) :

- Kim to draft a white paper on normative reference to communicate it to all member of the group
- Alain Prat and Ken Nicol for providing example from their regulation

SG3 wished to express concern on the length of time between GHTF plenary meetings and lack of information on the others study group. There is the possibility to have a joined meeting of all the members of the four study group in a year.

The steering committee agreed with the proposition of an ad hoc joined working group on risk management auditing (see further for more info).

- Steering Committee discussed the chairmanship of the four study group. In particular for the study group 3, the SC invites Alain Prat to take over the Chair from Mrs. Kimberly Trautman as of May 2005.

4) Risk Management as an integral part of the Quality Management System (SG3/N15R6)

During the meeting the members reviewed the second half of the publics comments and many revision were made to the text and the annexes.

The group recognized that the first review in Ottawa in May 2003 and the second review in Erlangen are not completely consistent as regards the wordings used.

The group agreed to decide that another meeting will be necessary in order to review from the beginning to the end the all document with the same approach in the explanation.

Action (s) :

- All member of the study group have to review the entire document with regard to consistency, also the writing of the diagrams with the consolidated text.
- Our Japanese colleagues will provide the group with a new annex C : Example of risk management summary table.

5) New work items proposals

a) Registration and Listing

Kim Trautman explained that an item on registration and listening has been forwarded to the study group 3 for consideration. The initial decision of the group is to set a table of comparison of data required by the four different registration systems of each GHTF members. In general however, study group 3 did not feel this subject was an appropriate work item under the Quality System Requirements and Guidance study group.

Action (s) :

- All members to send the data required by each regulation to fill in the spread sheet drafted during the Erlangen meeting ;
- Gunter Frey to compiled the document.

Further works will be discuss during the next meeting.

b) Electronic Medical Devices and Wireless Technology

Kim Trautman expressed also the interest of a technical group of FDA colleagues on the subject of Electromagnetic Compatibility (EMC) and wireless technology in Medical Device Quality Systems. A proposal paper was distributed to each member of the group in order to look at the needs of this technical group and to evaluate the interest of such new item. It was decided that this topic was too specific and the study group did not necessarily have this specific technical expertise for this specific type of guidance document.

6) Steering Committee Meeting in Seville – May 2005

The group agreed to propose the document on Risk Management as an integral part of the Quality Management System as a final document for the next steering committee in Seville.

7) EU Document on auditing of subcontractors - OEM device

The working group on designation and surveillance of EU notified body (Notified Body Oversight Group – NBOG) is working on a document on auditing subcontractors. The next meeting of this group is planned for October 2004. Alain Prat will keep the study group 3 updated with the works on this subject.

8) Ad Hoc joined Writing Group for Auditing Risk Management

The SG3 agreed to send to the ad hoc joined working group between SG 3 and /SG 4 four or five member to work on the risk management auditing guidance. Kim Trautman ask for member participation.

This ad hoc group should meet for the first time before or after the next SG4 meeting schedule probably in March 2005 in Boston.

9) Any Others business

- The group agreed that the document on Design Controls should be removed from the GHTF web site. The group recognized that there is a need to revise it but did not consider this a priority and did not assign any projected revision date.
- Our Japanese colleagues expressed their concern on the new standard on medical device software. Members of the group agreed that Study Group 3 can provide comments on this standard.

Action (s) :

- Kim Trautman will circulate this standard for comment
- All members to provide their comments

10)Set date and location of next meeting

- next study group meeting planned in January in Europe (Paris or other proposition from Ken Kopesky)

- meeting of the ad hoc group on auditing risk management in Boston, tentative March, 2005