

**Global Harmonization Task Force
Study Group #3**

**Meeting Summary
May 25-27, 2004
Ottawa, Canada**

GHTF SG#3 met in Ottawa, Canada, from May 25th through 27th, 2004.

The agenda was revised as follows:

1. Welcome and Introduction to new member and guest Experts
2. Review Old Business and San Francisco Steering Committee information
3. Report of TC 210 WG#1 meeting in Sydney Feb. 2004
4. Proposed Risk Guidance Document – Review comments, revise text and record disposition of comments per new Steering Committee directive
5. Discuss status of Risk Document and course of action
6. Discuss any items to be presented to the Paris June Steering Committee Meeting
7. Discuss any new work item proposal
8. Discuss the EU notified body oversight group (NBOG) document on auditing of subcontractors
9. Any other business
10. Plans for next meeting

Adjournment

1) WELCOME AND INTRODUCTION TO NEW MEMBERS AND GUEST EXPERTS

Kim Trautman opened the meeting at 9am with logistical comments, followed by introductions.

In attendance were:

- Alain Prat (EU Gouvernement- Agence Francaise de Securite Sanitaire des Produits de Sante – Direction de l’inspection et des etablissements)
- Althea Lawrence (Canadian Industry- Medical Devices Canada - Becton Dickinson Canada)
- Dr. Harvey Rudolph (TC 210 JWG Liaison - UL)
- Ed Kimmelman (TC 210 WG#1 Liaison - Consultant)
- Egan Cobbold (Canadian Government - Health Canada Medical Devices Bureau)
- Erin Keith (US Government - Risk Manangement Guidance Project Manager - FDA)

- Geetha Rao (Risk Management Expert - Macronus Inc.)
- Gunter Frey (US Industry - NEMA – GE)
- Joep van Lieshout (EU Industry - European Diagnostic Manufacturers Association - bioMérieux bv)
- John Gams (Canadian Industry - Medtronic of Canada, Ltd)
- Ken Kopesky (US Industry - AdvaMed - Medtronic)
- Ken Nicol (Australian Industry - MIAA - St. Jude Medical)
- Kim Trautman, Chair, (US Government - FDA)
- Nancy Shadeed, (Canadian Government – GHTF SG#1 -Health Canada Medical Devices Bureau)
- Shigetaka Miura (Japanese Industry – JFMDA – GE retired)
- Tony Chan (Risk Management Expert – Virginia Polytechnic Institute and State University)
- Victor Dorman-Smith (EU Industry – EUCOMED – Abbott retired)
- Werner Schoenbuehler (EU Industry – COCIR - Siemens Medical Solutions)
- Yasushi Murayama (Japanese Industry – JFMDA - TUV Product Service)

2) REVIEW OLD BUSINESS AND SAN FRANCISCO STEERING COMMITTEE INFORMATION

General Comments:

Kim Trautman and Werner Schoenbuehler reviewed the minutes and events of the last Steering Committee Meeting held in San Francisco in the Fall of 2003. SG#3 was informed that a Clinical Investigation group has been formed (currently under SG1), however, it will be determined at the next Steering Committee Meeting if this group will remain as part of SG1 or forms a separate Study Group.

Comments were made from a few members that the Global Harmonization effort needed to go beyond documents and requirements but needed to extend to the differences in interpretations and practices.

Regional Updates:

Canada - Egan Cobold updated the group on the transition status of ISO 13485:2003 in Canada. Health Canada has assessed 16 third parties.

Australia - Ken Nicol updated the team on the developments in Australia. Australia is about 18 months into the new regulatory framework. The biggest issue that has arisen is one of backlog in conformity assessment. Should TGA utilize third party assessors? If third parties are not used and TGA hires more assessors, this would be an additional resource burden on industry since the TGA is a fully fee funded organization. Implementation of third party assessment will require a change in legislation. New IVD regulations are expected to be published in the not too distant future, essentially based on the European directives with a “down under” flavor.

As of July next year a Trans Tasman Agency will be set up, including New Zealand. New Zealand will be catapulted from being virtually unregulated in medical devices to a highly regulated system. New Zealand is predominantly a country of distributors with very limited manufacturing. Overseas manufacturers can easily apply for inclusion of devices for distribution in New Zealand through subsidiary companies.

European Union - Alain Pratt updated the group on some EU efforts and discussed the EU notified body oversight group (NBOG) document on auditing of subcontractors - OEM device.

Japan - Miura-san provided a brief update on the new Japanese regulations. The new regulations do not require ISO 13485:2003 certificate, however the compliance to the requirements of ISO 13485:2003 will be mandatory Spring 2005.

USA - Kim Trautman provided an update on recent FDA developments. 15 Third Party Auditing Organizations were selected late fall 2003. Training occurred in January 2004, similar to EU FDA MRA training with the addition of an evidence development training module. This is the biggest difference to the prior training. Certification by FDA is tied to the individual representative from the recognized organization. If only one individual has been qualified, and subsequently leaves the recognized organization, the recognized organization while remaining to be recognized cannot perform audits for FDA until such time as one (or more) additional auditors have been qualified. Third party audits can only be request from the agency if the manufacturer exports. Upon meeting all pre-requisites, FDA provides a list of recognized third parties to the manufacturer from which a recognized third party can be chosen.

3) REPORT OF TC 210 WG#1 MEETING IN SYDNEY FEB. 2004.

Ed Kimmelman reported on the Sydney meeting. Key meeting objective was to review and resolve comments received on Technical Report 14969. All comments received were addressed and as of March 22, 2004 the document has been sent to the committee to be published as a technical report. Working Group 1 of TC210 has completed it's work for the time being. WG1 will most likely go dormant for the near future.

TC210 has accepted the Software Requirements standard document and Human Factors/Useability standard document as work items for JWG. SG3 members are asked to also provide comments on these documents. TC210 JWG3 received over 700 comments on the Software Requirements standard (CD2). JWG3 is compiled of members from TC210 and IEC 62A.

Issue : There are no regulatory requirements currently that mandate ISO14971. However, there is potential for ISO 14971 to become a regulatory requirement if it remains as a normative reference in the Software Standard or other standards. It was brought to the attention of the members the existence of document N243 ISO/CD 62366 which currently includes normative references to ISO13485, ISO14971, and IEC 601-1-6. This is problematic because making such ISO standards normative may

in effect take away certain regulatory options that the industry currently has available to them.

The working group discussed this issue to some length and decided that a strong proposal was to be drafted for the Steering Committee meeting in Paris. One proposal would be for GHTF to issue a letter to Standards Organizations that develop medical device standards and draw their attention to the problem of normative references and request that these standards organizations refrain from making basic management system standards directly or indirectly as normative references thereby limiting regulatory options.

Issue: There was concern expressed that after the San Francisco Steering Committee meeting, which assigned SG#4 the task of drafting a guidance document on auditing risk management activities that the work item has not been accurately translated to SG#4. Further, additional concern was voiced that this item would not be worked on immediately due to other work assignments in SG#4. Members of SG#3 felt that this guidance was needed immediately upon the completion of the SG#3 Guidance document. The members requested that a proposal be made to the Steering Committee that a small work group of approximately 6 members from both SG#3 and SG#4 be formed to initiate the drafting of this document.

<i>ACTION ITEM</i>		
Responsible Party	Issue	Closure
Kim Trautman. Ed Kimmelman, Ken Kopesky	Raise to the GHTF Steering Committee (at the Paris meeting), ISO (TC210) and IEC the issue and implications of including normative references (example a medical device incorporating softwareaffecting the regulatory scheme	
Kim Trautman	Raise to the GHTF Steering Committee (at the Paris meeting) Auditing of risk management (SG4)	

4) PROPOSED RISK GUIDANCE DOCUMENT – REVIEW COMMENTS, REVISE TEXT AND RECORD DISPOSITION OF COMMENTS PER NEW STEERING COMMITTEE DIRECTIVE

Alain Pratt presented to the members a compilation of additional comments received from the UK MHRA (Medicines and Healthcare products Regulatory Agency).

The chair expressed concern over the lack of comments from industry and industry organizations, despite the fact of having published the request for comment in the FDA docket and having placed it on the GHTF website.

There as a brief discussion as to whether this was due to industry’s ignorance to the topic, lack of communication, incomplete communication, communications not received by all appropriate parties, etc.? It was suggested that this may be due to

differing levels of understanding the topic at hand, a lack of understanding the role of GHTF guidance documents, etc.

5) DISCUSS STATUS OF RISK DOCUMENT AND COURSE OF ACTION

During the meeting the members reviewed and dispositioned approximately half of the comments received and made appropriate revisions to those sections of the Risk document. It was decided on the last day that two more meetings would be required to finalize the document before forwarding it to the Steering Committee as Final in Spring/Summer 2005.

The group decided upon a meeting in late September 2004 in Erlangen, Germany and a March 2005 meeting in the Netherlands in order to have the document final in time to submit to the next Steering Committee meeting.

6) DISCUSS ANY ITEMS TO BE PRESENTED TO THE PARIS JUNE STEERING COMMITTEE MEETING

Purpose and Scope of documents MUST be very clearly and precisely stated. Proposal for auditing risk management (see Florence position paper) example 14971 is not part of a regulatory scheme, but is being audited to by many auditors as though it were mandatory. SG4 has been asked to develop a guidance document on how to audit Risk management aspects within the context of Quality Management Systems. This task may require assistance from SG3, as there appeared to be confusion within SG4 as to the purpose and scope of the task.

Propose project specific smaller joint subgroup or SG3 complete initial drafting and forward to SG4 as basis for their work.

Discussed rotation of study group chairmanship based on three year terms.

Electronic labeling (User manuals, etc.) was brought up at the last Steering Committee meeting – Medtronic is currently conducting pilot program (agreed to by the EU) in Europe and is to report out at the next Steering Committee. Concerns from regulators included: Australia did not advocate electronic labeling, FDA uncertain as to whether this would require a change in US laws, Canada believed this would require change in Canadian laws, etc.

Some members expressed concern that the GHTF Plenary Conference (one in a three year period) is viewed as too few to effectively drive GHTF visibility. Regional meetings (such as AHWP and PAHO) could be considered in addition to other options but members expressed concern about the fact that the study groups have not had opportunities to share work and work item concerns in recent years with the extended periods between plenary sessions of GHTF.

Steering committee meeting schedule (as published) is of concern if indeed documents can only be advanced at steering committee meetings – ask for possibility of intermediate meeting between Paris and Sevilla meetings (if necessary or as a matter of operating mechanism).

How can GHTF ensure that an effective communication platform be re-instituted and maintained (such as the plenary meetings), with the intent to promulgate GHTF to the public? This was discussed and proposed to be an item of discussion at the Steering Committee meeting.

<i>ACTION ITEM</i>		
Responsible Party	Issue	Closure
Kim Trautman	Steering Committee Presentation on SG#3 Items	

7) DISCUSS ANY NEW WORK ITEM PROPOSAL

No new work item was proposed, outside of the proposal to join efforts with SG#4 on drafting a document on Auditing Risk Management Activities. See above discussion.

8) DISCUSS THE EU NOTIFIED BODY OVERSIGHT GROUP (NBOG) DOCUMENT ON AUDITING OF SUBCONTRACTORS - OEM DEVICE

Member agreed to review the document, understanding it early deliberations and provide comments back to Alain Pratt. Alain will keep SG#3 informed of the document's time table and comment opportunities.

9) ANY OTHER BUSINESS

See above discussions.

10) PLANS FOR NEXT MEETING

Dates for next meeting in Erlangen, Germany: September 14-16

Meeting was adjourned at approximately 4:30 pm Thursday May 27, 2004.