Global Harmonization Task Force (GHTF)
Study Group 3 (SG 3)
Meeting Summary
January 31 to February 2, 2005
Paris, France

GHTF SG 3 met in Paris, France, from January 31st through February 2nd 2005. The following represents the meeting summary.

The agenda was revised as follows:

1. Welcome and Introduction to new member and guest Experts

2. Review Old Business and Erlangen, Germany Meeting

3. Discuss joint work item with SG#4 and draft proposal for the April 4, 2005 joint meeting in Boston, MA USA.

4. Proposed Risk Guidance Document – Finalize text and finalize disposition of comments for submittal to the Steering Committee by March 2005 for their review at the May Seville meeting.

5. Discuss any additional items to be presented to the Seville May Steering Committee Meeting

6. Discuss any new work item proposal

7. Set meeting for Boston, MA and next proposed 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. No new members or guest experts attended this meeting. Tony Gould (TGA), Ken Kopesky (Advamed) and Shigetaka Miura (JFMDA) were unable to attend this meeting.

In attendance were:

- Hideki Asai (Japan, JFMDA)
- Prof. Tony Chan (Guest Expert, Virginia Polytechnic Institute and State University)
- Egan Cobbold (Canada, Health Canada – Medical Devices Bureau)

- Dr. Victor Dorman-Smith (Europe, EUCOMED)
- Gunter Frey (USA, NEMA)
- Ken Nicol (Australia, MIAA)
- Alain Prat, Vice Chair (Europe, Agence Francaise de Securite Sanitaire des Produits de Sante – Direction de l'inspection et des establissements)
- Werner Schoenbuehler (Europe, COCIR)
- Kim Trautman, Chair, (USA, Food and Drug Asociation)

2) REVIEW OLD BUSINESS AND ERLANGEN, GERMANY MEETING

Briefly discussed the progress made on the proposed risk management guidance document and outlined the work that needed to be accomplished during this meeting on that document.

3) DISCUSS JOINT WORK ITEM WITH SG#4 AND DRAFT PROPOSAL FOR THE APRIL 4, 2005 JOINT MEETING IN BOSTON, MA USA.

Due to logistical and technical difficulties, discussion on the joint work item occurred next. SG 3 discussed SG4 draft proposal (see attached) and have some variations but think it is most appropriate to discuss during the initial part of the joint meeting scheduled for April 4, 2005 rather than drafting proposed changes to the proposal. SG4 is asking for list of SG3 members planning to attend by March 1st.

Boston_AGENDA_SG 4_050113.doc

ACTION ITEM		
Responsible Party	**Issue**	**Closure**
All SG3 members	Inform Kim Trautman of participation at April Boston meeting by no later than March 1st.	
Kim Trautman	Communicate to SG4 Chair SG3 list of attendees	

4) PROPOSED RISK GUIDANCE DOCUMENT – FINALIZE TEXT AND FINALIZE DISPOSITION OF COMMENTS FOR SUBMITTAL TO THE STEERING COMMITTEE BY MARCH 2005 FOR THEIR REVIEW AT THE MAY SEVILLE MEETING..

Discussion ensued around terminology "medical device manufacturers" vs. entities only distributing or developing product – Australia for instance considers distributors to be "sponsors" responsible for reporting post-market surveillance. Ultimately the

finished device manufacturer will be held accountable, but the sponsor plays an important role in this scenario.

Significant discussion arose around the current Section 5 (titled *Product Realization*) wording and the universal replacement of the term "product" with "medical device". It appears as if the section itself predominantly talks to risk management planning rather than actual product realization.

Asai-san informed the group that MHLW is now developing requirement standards for each device. For regulatory submissions the identification of all major risks is now required.

The flowchart depicting the overlay of risk management activities over design and development activities was extensively discussed and revised to reflect the revised wording of this section.

Significant discussion arose around the real challenges regulators are facing with today's increasing trend of outsourcing, leading to the introduction of a chapter summarizing this discussion.

Concern was raised on risk management file definitions proposed in ISOCD3 14971, Section 3.5 (Risk Management file), "NOTE 1 The records and other documents that make up the risk management file can form part of other documents and files required, for example, by a manufacturer's quality management system. The risk management file need not physically contain all the documents relating to this International Standard; however, it should contain at least references or pointers to all required documentation. ***The manufacturer should be able to assemble the information referenced in the risk management file in a timely fashion."***

Although this is merely a note in the standard, individual experiences were that it was clearly indicated that auditors expect to see a risk management file assembled. Some regulators present indicated that this is what they would (and do) expect, while other regulators believe that a separate file is not necessary or beneficial.

The topic of validation/re-validation as a means of being a risk control measure also was extensively discussed. While no doubt, validation and re-validation activities can result in the *identification* of additional risk control measures, it was also argued the periodic re-validation can also *be considered a risk control measure*.

The group spent significant time on the CAPA example given, the benefit and intent, etc.

The risk guidance document was reviewed in its entirety and changes made. The document is to be placed in final form circulated within the Study Group for a brief final review and then to be forwarded to the Steering Committee for final approval.

ACTION ITEM		
Responsible Party	**Issue**	**Closure**
Kim Trautman	Check on proper title of "Do it by Design" http://www.fda.gov/cdrh/humfac/doit.html	
Egan Cobbold and Victor Dorman-Smith	Check on proper title of IEC 19218 Medical Devices - Coding System for Adverse Event Reporting	
Werner Schoenbuehler	Check on proper title of IEC 62366 Medical Devices – General requirements for safety and essential performance-Usability	
Werner Schoenbuehler	Check on proper title of IEC 60601-1-6 2003 Medical Electrical Equipment – Part 6: General Requirements for safety - Usability	
Gunter Frey	Provide Chair with the electronic version of the document resulting from the meeting with the proposed changes incorporated.	
Kim Trautman	Finalize all editorial revision and changes to submit to Steering Committee in order for final approval during the May Seville, Spain meeting.	

5) DISCUSS ANY ADDITIONAL ITEMS TO BE PRESENTED TO THE SEVILLE MAY STEERING COMMITTEE MEETING

No additional items to be forwarded to the Steering Committee, except an inquiry as to the status of the GHTF SG3 statement on ISO 13485:2003 which was suppose to be posted on the website.

6) DISCUSS ANY NEW WORK ITEM PROPOSAL

Ensure that the Steering Committee still concurs with the previously approved work item on a guidance concerning outsourcing and its regulatory obligations.

7) SET MEETING FOR BOSTON, MA AND NEXT PROPOSED MEETING

Monday April 4 through Wednesday April 6, 2005, Natick, MA USA (Boston area) - Joint GHTF SG3 and SG 4 meeting for auditing risk management principles.

June/July 2005 – possible teleconference.

September 2005 Gaithersburg, MD (Washington, DC area) - SG 3 meeting and joint meetings with SG 1 (Conformity Assessment discussion) and SG 4 (Continue work on auditing of risk management principles document).