

GLOBAL HARMONISATION TASK FORCE

STUDY GROUP 5 – CLINICAL EVIDENCE

Minutes of Meeting Tuesday 8 May to Wednesday 9 May 2007

**US FDA Los Angeles District Office
19701 Fairchild Rd., Irvine, California, USA**

A meeting of the Global Harmonisation Task Force (GHTF) Study Group 5 was held at the US FDA Los Angeles District Office, Irvine, California, USA on 8-9 May 2007.

Attendees at the meeting were:

Greg LeBlanc, MEDEC, CANADA
Barbara Westrum, AdvaMed, USA
Guy Hibbins, TGA, AUSTRALIA
Herbert Lerner, FDA, USA
Atsushi Tamura, PMDA, JAPAN
Johan Brinch, MIAA, AUSTRALIA
Peter Rattke, COCIR, AUSTRIA
Yoshihiro Noda, JFMDA, JAPAN
Maria Carballo, Health Canada, CANADA
Isabel Scuntaro, Swissmedic, SWITZERLAND
Christophe Bailleul, Eucomed, BELGIUM

Item 1 Welcome and Introductions

The meeting was convened by Greg LeBlanc, who, as vice-chair, agreed to chair the meeting due to Dr. Susanne Ludgate's absence. All members were thanked for their attendance.

Item 2 Adoption of Agenda

There were no changes to the draft agenda circulated in advance of the meeting. Thus, the following agenda was adopted:

1. Welcome and Introductions
2. Adoption of Agenda
3. Discussion of Minutes from Previous Meeting and Matters Arising
4. Discussion of Clinical Investigations Document
5. Discussion of New Work Item – Post-Market Clinical Follow-Up
6. Other Business

7. Next Meetings

It was also confirmed that a small subgroup from SG5 would be meeting with members of the SG1 IVD Subgroup on Thursday, 10 May to discuss how to address the planned document regarding Clinical Evaluation for IVD medical devices (minutes to be attached as Appendix).

Item 3 Discussion of Minutes from Previous Meeting and Matters Arising

No significant issues or “matters arising” were brought forward or discussed. The minutes had been previously circulated and accepted via e-mail.

Item 4 Discussion of Clinical Investigations Document

The comments brought forward on the document to date were reviewed and considered. Additionally, the comments presented by the Steering Committee based on their preliminary review of the document at their most recent meeting were discussed. It was concluded on the basis of the combined comments that a small subcommittee consisting of SG5 members would convene to review and amend the document. It would then be circulated to the full committee membership in order to examine the changes and approve the document for re-circulation to the Steering Committee for another preliminary review.

Item 5 Discussion of New Work Item – Post-Market Clinical Follow-Up

A discussion of the New Work Item approved by the Steering Committee – a document discussing Post-Market Clinical Follow-Up was undertaken. A skeletal structure for the new document was drafted, and it was agreed that Greg LeBlanc would take that structure and flesh it out into a preliminary working draft in time for the next meeting of the committee.

Item 6 Other Business

Communication with ISO TC 194 WG4 re: ISO/ICH MoU

An update was provided by Susanne Ludgate via written documentation that official channels of communication with WG4 had been re-established after some confusion following the recent change in Chairmanship of SG5 and departure of some members. Communication is ongoing regarding areas of mutual interest.

Upcoming GHTF Conference

There was a brief discussion regarding the upcoming GHTF Conference to be held in Washington and plans surrounding it. It was noted by some members that costs for

industry seemed particularly high and there was agreement that this should be brought forward as a concern to the Steering Committee.

Item 7 Next Meetings

The current schedule for upcoming meetings is as follows:

- Washington, DC, USA, 1-2 October 2007
- Europe (location TBD) 29-30 January 2008

The meeting was closed by the Chair with thanks to all for their participation in what was a very productive meeting.

APPENDIX

Meeting Notes from Joint SG5 / SG1 IVD Subgroup Meeting

Thursday 10 May 2007

**US FDA Los Angeles District Office
19701 Fairchild Rd., Irvine, California, USA**

A joint meeting between members of GHTF Study Group 5 and the IVD Subgroup of Study Group 1 was held to discuss how to address Clinical Evaluation for In-Vitro Diagnostic medical devices.

The meeting commenced with an overview of the current SG5 N2 Document that discusses Clinical Evaluation for medical devices. A consideration of how the concept of Clinical Evaluation might apply to the IVD medical devices situation then took place. It was agreed that this concept would really only apply in situations where there is a clinical claim being made for the device and if claims center only around performance and specificity from an analytical standpoint, then clinical evidence would not necessarily be required. Discussion then centered around how best to extrapolate the current SG5 document to address the situation for IVD medical devices.

It was agreed that the IVD subgroup of SG1 would consider the current SG5 document and develop a working draft for consideration. This would then be brought forward for further discussion at a future meeting.

The meeting was then closed with thanks to all participants.