

GLOBAL HARMONISATION TASK FORCE

STUDY GROUP 5 – CLINICAL EVIDENCE

Minutes of Meeting Tuesday 3 October and Wednesday 4 October 2006

**Pantages Suites Hotel and Spa
200 Victoria Street, Toronto, Ontario, CANADA**

A meeting of the Global Harmonisation Task Force (GHTF) Study Group 5 was held at the Pantages Suites Hotel and Spa on 3 and 4 October 2006.

Apologies were received from the Chair of the group, Dr. Graeme Harris, as well as Klaus-Dieter Willamowski, Yoshihiro Noda, Mary Anne Hinkson, Maria Carballo, Christophe Bailleul, Kazuhiro Sase and Wolfgang Ecker. Attendees at the meeting were:

Greg LeBlanc, MEDEC, CANADA (acting chair)
Patricia Garvey, AdvaMed, USA
Guy Hibbins, TGA, AUSTRALIA (for Graeme Harris)
Herbert Lerner, FDA, USA
Atsushi Tamura, PMDA, JAPAN
Johan Brinch, MIAA, AUSTRALIA
Peter Rattke, COCIR, AUSTRIA
Susanne Ludgate, MHRA, UNITED KINGDOM
Mitchell Krucoff, Duke University Medical Center, USA

Item 1 Welcome and Introductions

The Acting Chair welcomed everyone to the meeting. It was noted that Dr. Harris is still on leave from the group, and the group continues to wish Dr. Harris a speedy return.

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. Clinical Investigations Document
5. Discussion of Clinical Evaluation for IVDs
6. Other Business
7. Next Meetings

Item 3 Discussion of Minutes from Previous Meeting and Matters Arising

No significant issues or “matters arising” were discussed. The comment period for the Key Definitions and Concepts (N1) and Clinical Evaluation (N2) documents continues. The chair informed the group that no comments had been received to date; however, this was not surprising given that there are still several months to go in the comment period.

The chair also mentioned that due to Keith Butler’s retirement, as mentioned at the last meeting, a new representative from Health Canada had been named to SG5. Maria Carballo has been designated in this capacity; however she was unable to attend this meeting.

Item 4 Clinical Investigations Document

The group discussed and edited a rough draft working document which was circulated prior to the meeting. It was agreed that the draft would act as the basic working document for the discussions. The group then proceeded to edit the document, making changes where it was felt they were necessary. In the end, the group agreed that they were very pleased with the draft output, and felt that the next step would be to prepare to circulate it for jurisdictional comments when appropriate.

Item 5 Discussion of Clinical Evaluation for IVDs

The current status of the plans for addressing the Clinical Evaluation process for IVDs was discussed. The group was told that things were moving slowly at this point due to the fact that SG1 was going to be meeting at approximately the same time as the SG5 meeting was occurring, and therefore a joint subgroup meeting would not be feasible. However, plans continue to go ahead for a joint meeting to be held in conjunction with the next SG5 meeting. Greg LeBlanc will be in contact with Nancy Shadeed of Health Canada, the chair of the IVD subgroup of SG1 in order to make arrangements and determine the composition of the joint subgroup. Thus far, volunteers from SG5 include Greg LeBlanc and Wolfgang Ecker, with other volunteers still being sought. It was pointed out that the expertise expected from SG5 would predominantly be in the area of Clinical Evaluation, and therefore a background in IVDs was not necessary to participate.

A draft of some wording that was proposed by Dr. Harris to be included in the original Clinical Evaluation document was circulated by Guy Hibbins for the group’s consideration going forward.

Item 6 Other Business

Discussion of “other business” included:

- Exposure of SG5 Documents
- The Steering Committee Glossary Project
- Letter from Dr. Ziegler of ISO TC194 WG4

The first item centered on whether it was felt that the majority of constituents within each jurisdiction represented at the meeting were aware that SG5 had the two proposed documents out for comment. The general consensus was that in many instances, this was probably not the case. Therefore, it was agreed that all of the members should go back to their respective organizations and try to find a mechanism to disseminate this information to the organizations' membership at large as appropriate.

The second item involved a project currently being undertaken by the Steering Committee involving the harmonization of definitions and terms across the various Study Groups. The initiative is being led by Hiroshi Ishikawa, and they are requesting representatives from each SG to act as leads for the project. The chair asked for volunteers to represent SG5, and Johan Brinch agreed to act on behalf of the SG.

The final item involved the circulation of a letter that was forwarded to Kimber Richter by Dr. Ziegler, the Convenor of ISO TC194 Working Group 4 in Dr. Richter's capacity as liaison person between the two groups. The letter seemed to indicate that ISO TC194 is hoping to work with the ICH with a view to a revision of the ICH GCP (E6) Guideline. It was agreed that Greg LeBlanc would draft a letter to Dr. Ziegler on behalf of the group asking for clarification of the matter in order to help determine its impact on SG5.

Item 7 Next Meetings

The current schedule for upcoming meetings is as follows:

- Honolulu, Hawaii, USA, 5-7 February 2007
- Irvine, California, USA, May 2007
- Bethesda, Maryland, USA, September 2007

The meeting was closed with the chair thanking everyone for coming and for their participation in a very productive meeting.