

GLOBAL HARMONISATION TASK FORCE

STUDY GROUP 5 – CLINICAL EVIDENCE

Minutes of Meeting Tuesday 27 June and Wednesday 28 June 2006

**Dräger Medical
Moislinger Allee 53-55, Lübeck, GERMANY**

A meeting of the Global Harmonisation Task Force (GHTF) Study Group 5 was held at the Dräger Medical facility in Lübeck, Germany on 27 and 28 June 2006.

Apologies were received from the Chair of the group, Dr. Graeme Harris, as well as Klaus-Dieter Willamowski, Mitchell Krucoff, Patricia Garvey, and Susanne Ludgate. Attendees at the meeting were:

Greg LeBlanc, MEDEC, CANADA (acting chair)
Barbara Westrum, AdvaMed, USA (for Patricia Garvey)
Yoshihiro Noda, JFMDA, JAPAN
Guy Hibbins, TGA, AUSTRALIA (for Graeme Harris)
Herbert Lerner, FDA, USA
Atsushi Tamura, PMDA, JAPAN
Johan Brinch, MIAA, AUSTRALIA
Peter Rattke, COCIR, AUSTRIA
Mary Anne Hinkson, NEMA, USA
Keith Butler, Health Canada, CANADA
Christophe Bailleul, Eucomed, BELGIUM
Kazuhiro Sase, Juntendo University Medical School, JAPAN
Wolfgang Ecker, Federal Ministry of Health and Women, AUSTRIA

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. Discussion of plans for adaptation of Clinical Evaluation Document – SG5/N2R7 to IVDs
5. Discussion of Clinical Investigation Requirements
6. Other Business
7. Next Meeting

Item 3 Discussion of Minutes from Previous Meeting and Matters Arising

No significant issues or “matters arising” were discussed beyond the submission of the Key Definitions and Concepts (N1) and Clinical Evaluation (N2) documents to the Steering Committee. The group was informed by the Acting Chair that at the previous day’s Steering Committee Meeting, the Steering Committee had agreed to move both documents forward unchanged as Proposed Documents. The standard timeframe for posting of new Proposed Documents is approximately three weeks from the Steering Committee decision.

Item 4 Discussion of Plans for Adaptation of Clinical Evaluation Document (SG5/N2R7) to IVDs

The group discussed, in general terms, plans for moving forward with a parallel document to the Clinical Evaluation document (N2R7) that would address IVDs. It was noted by the Acting Chair that a proposal was put forward at the Steering Committee meeting that a joint task force including members of SG5 and the IVD Subgroup of SG1 could work together on the issue. The group agreed that this sounded reasonable, and arrangements were made for a meeting with Nancy Shadeed, the Chair of the SG1 IVD Subgroup, and Maria Carballo, a member of the SG1 IVD Subgroup, to discuss the issue (see below).

The group proceeded to draft a Work Item Proposal for submission to the Steering Committee, and Wolfgang Ecker volunteered to draft a basic outline of a potential document structure. The Acting Chair indicated that the Work Item Proposal would be submitted to the Steering Committee for their consideration.

During the informal meeting with the SG1 IVD Subgroup members, the topic of a joint task force was discussed and ideas on the structure and function of the task force were exchanged. It was agreed that the task force would continue to work under the auspices of SG5, with the SG1 Subgroup members providing expertise on the subject of IVDs and the SG5 members providing their expertise and experience on working with the original Clinical Evaluation document. It was also agreed that Nancy Shadeed and Greg LeBlanc (and/or the Chair of SG5) would work together to gather volunteers to serve on the task force and form an appropriate balance of expertise and perspectives.

Item 5 Discussion of Clinical Investigation Requirements

The group discussed, in general terms, plans for the development of a document on clinical investigation requirements, specifically on when a clinical investigation would be necessary as per the phase two terms of reference.

The group proceeded to draft a Work Item Proposal for submission to the Steering Committee along with a basic outline of a potential document structure to serve as a template for future work. The Acting Chair indicated that the Work Item Proposal would be submitted to the Steering Committee for their consideration.

Item 6 Other Business

It was revealed at the meeting that Dr. Keith Butler from Health Canada will be retiring shortly and that this would be his final meeting with the group. The group expressed its thanks for his valuable participation and wished him well in his retirement.

No other significant business was raised beyond the discussion of the timing of subsequent meetings, including the planned meetings to be hosted by the FDA in May and September of 2007 (see below).

In closing the meeting, the Acting Chair thanked everyone for their attendance and participation in a productive meeting.

Item 7 Next Meetings

- Toronto, Ontario, Canada, 3 and 4 October 2006
- Honolulu, Hawaii, USA, 5-7 February 2007
- Irvine, California, USA, May 2007
- Bethesda, Maryland, USA, September 2007