

**REPORT OF THE SG1 IVD subgroup MEETING HELD ON
March 23-26, 2010 – Washington**

Attendees

Nancy Shadeed – Chair
Secretary – Benny Ons

North America

Francis Kalush – FDA, USA
Maria Carballo – Health Canada (by phone)
Regina O’Meara – Advamed, USA
Matt Gee - Medec

Europe

Marie-Lise Miguères – Affsapps, Europe
Celine Bourguignon – EU Commission, Europe
Thomas Mall - EDMA

Asia/Australasia

Shelley Tang, TGA Australia
Coles Jillianne – IVD Australia, Australia
Yoko Ikeda – JACRI, -Japan
Kentarou Azuma – MHLW, Japan
Kazutoshi Yamagishi - JFMDA – Japan
Jeffrey Chern – AHWP, Taiwan
Essam Mohammed Y. Al-Mohandis – AHWP, Saudi Arabia

Observer

Irena Prat – WHO, Switzerland

Apologies

Petra Kaars-Wiele – EDMA
Michael Thein - EDMA
Masaki Sugiura – PMDA, Japan

1 Welcome to the meeting and introduction of delegates

Benny Ons, acting chair until Nancy arrived at the meeting welcomed the members and observer to the SG1 IVD subgroup meeting.. The meeting was held at Bethesda and was hosted by the FDA. The FDA had also set up teleconferencing capabilities to allow Maria to participate by phone. Apologies were reported as shown above.

Lillian Gill from FDA welcomed the IVD subgroup to the meeting in Bethesda. She underlined how important the work of GHTF is for FDA and wished the IVD subgroup a successful meeting.

2 Approval of the meeting minutes of November 2009

Unfortunately the meeting minutes were only distributed just before the meeting – participants were invited to provide written comments after the meeting. One comment was received. Japanese industry suggested to remove the post meeting note related to the clinical evidence – for approval at the June meeting.

3 Adoption of Agenda and discussion of procedures for this meeting

The Agenda was agreed as attached.

4 STED Document and review of the public comments received.

During the public consultation we received around 300 comments on this document – several purely editorial while others were more substantial technical comments.

EDMA had suggested a reorganization of the section about product verification and validation as well as splitting this section into quantitative and qualitative tests. The reorganization comment was accepted however there was no agreement to split that section into a quantitative and qualitative part.

The entire meeting was dedicated to review and discuss these 300 comments – the subgroup succeeded in reviewing all of them – for the resolution decisions of the comments we refer to the comments table.

It was agreed to circulate the document with all of its changes back to the IVD subgroup for a final review. Comments received were incorporated into the document and the document was forwarded to the main SG1 for their approval. The SG1 will discuss this document during their May meeting in Tokyo.

5 Essential Principles and labelling document update

4.1 Essential principles of safety and performance for medical devices.

This document has been reviewed by the main study group and is awaiting review by the IVD subgroup. However given the current workload of the IVD subgroup this document was not dealt with in this meeting. However a start of the discussion on the future format of the document took place. The question to be resolved is whether we want to split this document also in two sections, one for the medical devices and one for the IVD medical devices, similarly to what has been done for the labelling document. There are different opinions around the table and therefore the IVD subgroup agreed to do an analysis during the next meeting on each of the essential principles whether they are applicable to IVD

medical devices or not. The outcome of this exercise will allow the subgroup to further discuss the best path forward for the EP document.

4.2 Labelling

The IVD subgroup was informed about the discussions that took place in the main study group.

While the main study group did not want to change any of the specific IVD medical device language it found it desirable to align the text as much as possible with the section of medical devices. One of the other significant comments and changes made was to create a common general principles section (the content of the common section was build using existing MD text while incorporating sections of the IVD medical device revision).

The IVD subgroup requested to have some better understanding of the process of moving documents for revision between the main study group and the IVD subgroup. Nancy and Benny will discuss with the chair of the main study group.

6 Clinical evidence for IVD medical devices – work undertaken by the IVD subgroup for SG5

It was agreed with the IVD subgroup that there would be two rounds of comments on the first two documents (“key concepts and definitions” and “what is clinical evidence”). The first round of comments would include SG5 and other direct stakeholders – the IVD subgroup would look to the comments during its fall meeting of 2010. Then the documents would be going to SG5 for approval to move them to the SC. Upon agreement by the SC the documents would then be posted as a proposed document for public comments.

During the Washington meeting there was no time left to address the third document that would describe the actual studies. Matt Gee had volunteered in the November meeting to create a first draft of this document. The IVD subgroup would look at this document during its June 2010 meeting.

7 Document in progress and timetable

Work in progress is as follows:

WORK ITEM	REF.	CURRENT STATUS	TARGET FOR COMPLETION
<i>Summary Technical Documentation for Demonstrating Conformity to the Essential Principles for Safety and Performance</i>	SG1/N063	Proposed document	Final document 2010 /

<i>(STED)</i>			
<i>Essential Principles of Safety and Performance for medical devices</i>	SG1/N045	Working draft Revision	Proposed document 2010 / Q4
<i>Labelling of Medical Devices.</i>	SG1/N046	Working draft	Proposed document 2010 / Q1
<i>Clinical Evidence for IVD medical devices</i>	SG5/XXX	Working draft	Proposed document 2011/Q2

8 Date and place of next meeting

- Next meeting will be Sydney, Australia from June 7-10, 2010 organized by IVD Australia at the Siemens Healthcare facility in Sydney.
- The fall meeting will from December 6-9 and will be hosted by Beckman Coulter at their facility close to Los Angeles.(pending confirmation by Beckman Coulter).