

**REPORT OF THE SG1 IVD subgroup MEETING HELD ON  
November 16-19, 2009 – San Jose, California**

**Attendees**

Acting Chair – Shelley Tang  
Secretary – Benny Ons

**North America**

Francis Kalush – FDA, USA  
Regina O’Meara – Advamed, USA  
Matt Gee - Medec

**Europe**

Marie-Lise Miguères – Affsapps, Europe  
Celine Bourguignon – EU Commission, Europe  
Petra Kaars-Wiele – EDMA  
Michael Thein - EDMA

**Asia/Australasia**

Yoko Ikeda – JACRI, -Japan  
Masaki Sugiura – PMDA, Japan  
Kazutoshi Yamagishi - JFMDA – Japan  
Peter Harman – IVD Australia - Australia  
Abdulrahman Al Gifari – AHWP, Saudi Arabia

**Observer**

Irena Prat – WHO, Switzerland

**Apologies**

Nancy Shadeed – Chair  
Maria Carballo – Health Canada  
Coles Jillyanne – MIAA, Australia  
Jeffrey Chern – AHWP, Taiwan  
Essam Mohammed Y. Al-Mohandis – AHWP, Saudi Arabia

**1 Welcome to the meeting and introduction of delegates**

Shelley Tang, acting, chair of SG1 IVD subgroup (Nancy Shadeed could not make it to the meeting due to language training requirements in Health Canada), welcomed the members and observer to the SG1 IVD subgroup meeting. She also welcomed Abdulrahman Al Gifari to the meeting representing AHWP as a replacement for Essam Mohammed Y. Al-Mohandis. The meeting was held at the BD San Jose, CA facilities. Benny Ons welcomed the participants to the BD facilities.

Apologies were reported as shown above.

## **2 Approval of the meeting minutes of June 2009**

The meeting minutes were approved with the following addition in section 5 of the following paragraph:

There was consensus in the IVD Subgroup that GCP does not apply to studies for IVD medical devices and therefore the reference to ISO 14155 was taken out in the IVD document.

## **3 Adoption of Agenda and discussion of procedures for this meeting**

The Agenda was agreed as attached.

## **4 STED update**

The STED document is out for public comments until beginning of January. The comments will be reviewed during the March 2010 meeting.

## **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 will not be dealt with in this meeting and most likely also not in the March 2010 meeting. Probably the June meeting will be dealing with this document.

### **4.2 Labelling**

The IVD subgroup received the document from the main SG1 study group. The IVD subgroup was expected to create the IVD medical devices specific section for this document.

Because of the discussions around the term 'Labelling' and the fact that the document does only contain guidance for the label and the Instructions for Use, the main study group has currently renamed this guidance document to 'Label and Instructions for Use for Medical Devices'.

The IVD subgroup worked through this document in this November meeting and provided a final draft to SG1 for their review. The IVD subgroup preferred to have a dedicated general principles section in addition to IVD medical device specific content for the label and the Instructions for Use.

Upon the review by SG1, the labelling document will be forwarded to the Steering Committee with the request to let this move forward to public comments.

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

The IVD subgroup continued its work on the documents related to clinical evidence (key concepts and definitions and clinical evidence).

During the meeting there was an emerging need to create a third document that would describe the actual studies. All the text that was currently contained in the clinical evidence document but which covers carrying out a study will therefore be transferred to this third document that still needs to be created.

It was agreed that work on the clean-up of the clinical evidence document would continue after the meeting.

Matt agreed to work on a first draft for the third document (related to clinical performance studies) for discussion within the IVD subgroup, most likely in the June 2010 meeting.

## **7 Document in progress and timetable**

Work in progress is as follows:

<b>WORK ITEM</b>	<b>REF.</b>	<b>CURRENT STATUS</b>	<b>TARGET FOR COMPLETION</b>
<i>Summary Technical Documentation for Demonstrating Conformity to the Essential Principles for Safety and Performance (STED)</i>	SG1/N063	Proposed document	Final document 2010 /
<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 2010/Q2

## **8 Date and place of next meeting**

- Next meeting will be March 23-26, 2010..  
This meeting will be hosted by the FDA in the Double Tree hotel at Bethesda, Washington..
- The June meeting will be in Sydney, Australia from June 7-10, 2010.

