

## **Mission Report for Sub-Project 1.g.1**

### **I. Introduction**

**Submitted by:** Jack Wong  
**Date:** 12 Aug 08  
**Dates of mission:** 14-18 Jul 08  
**Places visited:** Bali, Indonesia

### **II. Objectives and expected results**

The objective of the sub-project is to support the ACCSQ – Medical Devices Products Working Group (MDPWG) in the implementation of regional regulations and procedures for Medical Devices in line with other global initiatives such as the Global Harmonisation Task Force (GHTF) and learning from other regional initiatives such as the Medical Devices Directive of the EU.

The main expected results of the Workshop, participants were better informed of European and GHTF approaches to the standardisation of medical devices regulations practices, and the MDPWG encouraged to agree a set of ASEAN harmonised regulations for Medical Devices, in line with international best practice, that enhance patient safety and increase access to safe, effective and clinically beneficial medical technologies in a way that is trade facilitating both within ASEAN and in relation to third country trade.

### **III. Activities and Results**

The main task performed by the ISTE Jack Wong was presentation covering the following topics:

- Global Regulatory trend
- Comparison of key markets regulatory system
- MDD Vs CSDT (opportunities for harmonization)

The main results of the workshop and dialogues with the participants are as follows:

#### **ASEAN Medical Device Directive (AMDD)**

- Asean Medical Devices Directive (AMDD) was developed based on the experience of ASEAN Cosmetic Directive and European Medical Devices Directive (MDD)
- AMDD will cover registration of medical devices, registration of dealers of devices

The work time table to finalize the AMDD is as follow

- Singapore to revise the draft and circulate the draft by 30 July 2008
- Member states to review and submit comment by 30 September 2008
- Singapore to collect the input and revise the draft and to be circulated by 31 October 2008
- Member states conduct public consultation on the draft by 30 April 2009
- MDPWG to review and endorse the draft during 10<sup>th</sup> meeting in July 2009
- Final draft of AMDD to be presented to ACCSQ at 34<sup>th</sup> meeting in August 2009
- Signing of finalized AMDD in 2009
- Transposition into National Legislations if necessary in 2010

#### **Common Submission Dossier Template (CSDT)**

- Common Submission Dossier Template was developed based on STED (from SG1 in GHTF)
- Guidance document draft by Singapore HSA was presented.

- 2<sup>nd</sup> draft to be presented at 9<sup>th</sup> MDPWG meeting in January 2009 by Singapore
- Plan to include CSDT in AMDD at 10<sup>th</sup> MDPWG meeting in July 2009

BSI was invited to present the comparison between CSDT and MDD. It was also mentioned that abridged evaluation will be arranged for products already got CE Marking.

Industry also share their problems on CSDT e.g. what document need legalization or notarization (Answer: it is up to country specific requirement), detail of raw material specification require (Answer: it depends on product and difficult to make it specific), regulator needs narrative or flow chart format for manufacturing process (Answer: both will be good), and registration fee is also an issue to local industry

A STED Working Group (A voluntary group of representatives from the medical device industry, international regulatory authorities, and trade associations) in US was formed. BSI was invited to be the member and detail of the STED Working Group will pass to Technical Committee as well.

#### **In-Vitro Diagnostic Devices classification (IVD)**

- GHTF issued Principles of IVD Medical devices classification (SG1(PD)/N045R12)
- MDPWG adopt the IVD medical device risk-based classification rules proposed by GHTF

### **III. Recommendations and Discussions**

The main recommendations following the workshop are the following:

#### **EU-ASEAN Cooperation**

- Maintain regular communication between Europe and ASEAN e.g. form a regulatory expert panel and meet regularly with ACCSQ-MDPWG (ASEAN Consultative Committee on Standards and Quality, Medical Device Product Working Group).

#### **Training needs**

- MDPWG stressed they need training in many aspects.
- MDPWG will collect the training needs from ASEAN Member States
- US FDA also contact ASEAN secretariat and very keen to provide training to ASEAN Member States

### **IV. Conclusions and Future Planning**

The workshop seems to be very useful for MDPWG and ISTE are invited to provide new regional training session during next ASEAN meeting on January 2009.

### **V. Appendices**

- Annex 1 Presentations