**Common Submission Dossier Template (CSDT)**

# Summary Report from TC WG01

By : Daphne Yeh
Date: Nov 5-6, 2008
Location: New Delhi, India

## Discussions on Future Work Items (1)

- a work item entitled "Adopting the Principles and Elements of Conformity Assessment for Medical Devices" and implementation phases and timelines for WG01's work items. WG01 requested Member Economies to: (Alfred Kwek)
  - Reach consensus on adopting the principles of conformity as a fundamental;
  - Adopt the proposed elements of conformity assessment for MD; and
  - Have the commitment to share experience regulating medical devices

# Discussions on Future Work Items (2)

- Compare CSDT and STED, (e.g. Come out with Guidance of submitting STED plus CSDT variations.)
- The definition of manufacturer
- UDI (Unique Device Identifier)
- Format of Certificate
- Questionnaire for economy (Experience study on CSDT)
- Special Import process
- Counterfeit MD / IVD (could be special task)
- Mutual recognition of pre-market approval

- Best practice sharing among economies (reference to the presentations made in the "Update from Economy on Harmonization)

- Reference to GHTF SG1's projects and select AHWP focused topics

## Update from SG1 Meeting
## Date: July 8-11, 2008, Buenos Aires

**Final Document**

- SG/N044:2008 of February 21st, 2008: *Role of Standards in the Assessment of Medical Devices* has been endorsed as a Final Document by the Steering Committee.

- SG/N011:2008 of February 21st, 2008: *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)* has been endorsed as a Final Document by the Steering Committee.

- SG/N045:2008 of February 19th, 2008: *Principles of Classification of In Vitro Diagnostic Medical Devices* has been endorsed as a Final Document by the Steering Committee.

- SG/N046:2008 of February 26th, 2008: *Principles of Conformity Assessment of In Vitro Diagnostic (IVD) Medical Devices* has been endorsed as a Final Document by the Steering Committee but discussion continues as reported above.

## Update from SG1 Meeting
## Date: July 8-11, 2008, Buenos Aires

**Proposed Document**

- SG1/N055R6 of 26th February, 2008 *Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer* has been endorsed by the Steering Committee as a Proposed Document and is on the GHTF website for public comment. Comments will be accepted until early December.

- SG1/N065R05 of 26th February, 2008: *Registration of Manufacturers and other Parties and Listing of Medical Devices* will be discussed later in this meeting. Comments on the document have been received, consolidated and circulated to SG1. These will be discussed later in this meeting.

## Update from SG1 Meeting
## Date: July 8-11, 2008, Buenos Aires

**Document Under Revision**

- Comments received for consideration when SG1 revises its guidance entitled *Essential Principles of Safety and Performance of Medical Devices* later in this meeting. A list of consolidated comments has been circulated. These will be discussed later in this meeting.

- Comments received for consideration when SG1 revises its guidance entitled *Information Document Concerning the Definition of the Term "Medical Device",* at a future meeting, have been circulated.

- Comments received for consideration when SG1 revises its guidance entitled *Labelling for Medical Devices,* at a future meeting, have been circulated.
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## Update from SG1 Meeting
## Date: July 8-11, 2008, Buenos Aires

**New SG1 Document Work Items**

GHTF SG1 has proposed two new work items and noticed to AHWP TC WG01 .

- - Change management
- - Technical Documentation for Medical Devices

AHWP TC WG01 has replied to GHTF SG1 the support of these new work items. Also WG01 input as follows:

- - Separate guidance of "change management" for IVD and non-IVD products (or dedicating a specific section to IVD).

## Update from SG1 Meeting
## Date: July 8-11, 2008, Buenos Aires

**Purpose of GHTF Study Group 1 modified on GHTF website**

**Previous:**… Pre-Market…

**Modified:**

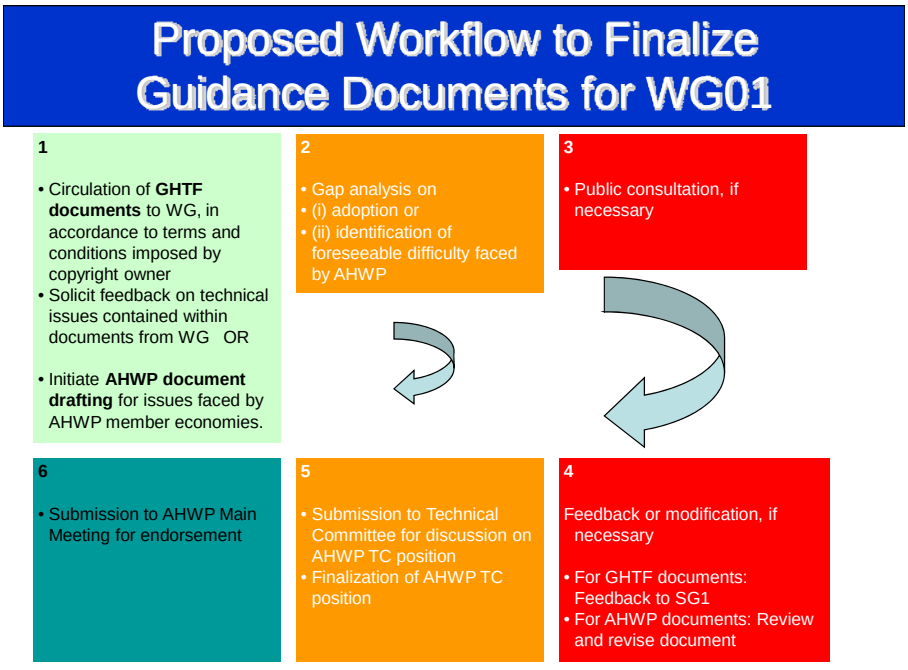
**Purpose of Study Group**

- SG1 has been charged with supporting convergence of medical device regulatory systems through the development of harmonized guidelines on elements of a global regulatory model. These elements include definitions of key terms such as 'medical device' and 'manufacturer'; essential principles of safety, performance, and labelling; principles of classification and conformity assessment; and recommendations for summary technical documentation.
- In developing these guidelines, SG1 collaborates with other GHTF Study Groups in creating a global regulatory framework. It has additionally welcomed the contribution to its work of regulators and industry in other parts of the World.

## Update from SG1 Meeting
## Date: July 8-11, 2008, Buenos Aires

**Milestones for the future (Latin America):**

- Need for industry participation in the Latin America working party.
- Seek both industry and regulator participation in all GHTF SGs.
- Seek ways to make AHWP WG6 work (training group) available to Latin America.
- Reinforce PAHO Resolution on Medical Devices to develop regulations, promote Latin American & Caribbean participation in GHTF & promote use of GHTF guidance.
- Speed up the translation process of the GHTF documents.
- Improve document control e.g. version control between published documents versions and the translated documents.



Thank you for your attentions!