



## **Asian Harmonization Working Party**

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

# **Asian Harmonization Working Party WG01**

## **Work Plan**

**20 Dec 2008**

**Wu Zhou Guest House  
Shenzhen, China**

# AHWP WG01 Work Items

## (1) CSDT topic:

### 1. Where we are:

1. ASEAN adopted CSDT as requirement for product submission. Singapore HSA also come out with guidance document on how to submit CSDT. CSDT requirement will be implemented in Singapore from April 2009.

### 2. Where GHTF are:

1. New STED document announced in April / May 2008
2. Japan still use previous version of STED
3. Healthcare Canada will promote to use New STED

# AHWP WG01 Work Items

## (1) CSDT: Possible WG01 items

1. Comparison of GHTF new STED and ASEAN CSDT
2. Come out a finalized CSDT document, propose to AHWP member economy for adoption or propose the adoption of STED
3. Invite non-ASEAN countries to pilot implement the CSDT (or STED) requirements
4. Share the experience in Singapore of implementing CSDT requirement with other detailed guidance rule surrounding product submission.

Measurement:

No. of AHWP countries adopt and pilot implement CSDT (STED)

# AHWP WG01 Work Items

## (2) Definition of Manufacturer (importer, authorized Rep.)

### 1. Where AHWP are:

1. Diversified definitions in member economies about manufacturers.
2. To cope with the trend of OEM manufacturing and multinational manufacturing, it is beneficial to work out a harmonized definition of manufacturers.
3. Each member economy may have their own definitions of manufacturer in the legal system and it may conflict with the GHTF proposed definitions.
4. The label of “country of origin” may conflict with the GHTF Def.

### 2. Where GHTF are:

1. There is near finalized GHTF guidance document on this topic.
2. This SG1 document is also used and input by other SGs. (SG3)

# AHWP WG01 Work Items

(2) Definition of Manufacturer:

Possible WG01 items on

1. Study and input on GHTF guidance document
2. Come out with AHWP guidance document based on GHTF definitions
3. Guidance on the issuing of “country’s free sale certificate” or “country’s export certificate”
4. Successful story sharing in AHWP countries on adopting GHTF definitions.

Measurement:

No. of AHWP countries adopting the GHTF’s guidance document.

# AHWP WG01 Work Items

- (3) Grouping of Medical Device for registration
- (4) Change Management (Requirements of registration for new product or partial change of product)
- (5) Others SG01 work items

To be finalized by Jan. 2009.

# AHWP WG01 Work Items

(3) Possible fTf Meeting, Telecon, discussions of WG01:

1. Annual AHWP planning meeting (End or Beginning of year)
2. Annual AHWP formal meeting (Nov. 2009, 2010, 2011)
3. Bi-monthly WG01 t-con
4. Ad hoc t-con
5. E:mail
6. Participation of GHTF SG1 Meeting in 2009
  1. Jan 19-24, 2009 in Sydney, Australia
  2. May, 2009 in Toronto, Canada

Any questions, please contact: AHWP WG01 Chair: Elaine Tan  
Co-Chair: Daphne Yeh, Secretary (2): To be decided

# Thanks