AHWP TC WG1
Pre-market Requirements

November 8, 2011

AHWP Annual Meeting, Bali

Summary of WG1 work 2010

- Chair: Hui Fen Bai, HSA, Singapore
- Co Chair: Daphne Yeh, Industry
- Members (active): 23 from AHWP members
- Members (active): 2 from US and EU
- Accept members openly but monitor participation in Monthly t-con and project
- 5 Subgroup projects:
  - CSDT v.s. STED
  - Def of Manufacturer
  - Labelling
  - Classification
  - Combination products

AHWP WG1 Subgroup: STED and CSDT

Nov 2011

Leader: Bai Huifen

Volunteers: Huifen, Daphne, Laleetha, Kitty Mao, Jacqueline, Woei Jiuang

Objectives

1. To make recommendations on pre-market submission dossier template based on:

- the comparison and mapping results of CSDT with STED
- experience of implementing a common dossier template

2. To establish AHWP WG1 as a platform for good understanding of CSDT.

Objective 1:
Recommendations on pre-market submission dossier template

- The use of a common dossier template is beneficial to both regulators and industry.
- If a member economy wishes to adopt CSDT, the endorsed ASEAN CSDT should be considered.
- If a member economy wishes to adopt STED, it should be in line with the GHTF recommendations.

Objective 2:
To establish AHWP WG1 as a platform for good understanding of CSDT.

- WG1 wishes to seek approval to prepare the STED-CSDT mapping as a guidance document for publication on AHWP's website.

- Purpose of document:

  - to map the sections of STED to CSDT.

  - To strengthen understanding of the similarities and differences between the 2 formats.

  - To facilitate industry members who need to prepare both formats for different markets.

Objective 2:

To establish AHWP WG1 as a platform for good understanding of CSDT.

- Status:

"Skeleton of topics" drafted and circulated among WG1 for comments.

- Sections of draft document:
  - Introduction
  - Purpose
  - Scope
  - Overview of Mapping
  - Detailed Mapping

WG01 Draft Guidance_Mapping of CSDT to STED_v1 (2).doc

THANK YOU

AHWP WG1 Subgroup: Definition of Manufacture

November 2011

Daphne Yeh
AHWP TC WG01

Objective

1. Identify Responsibility of Safety for Medical Device
2. Facilitate country registration of products
3. Facilitate import of medical device across countries

Approaches

1. Study of GHTF, EU, Canada, Australia, USA, Japan's Definition of Manufacturer (completed)
2. Comparison of GHTF's member's definitions, ID label and requirements (completed)
3. Benefits of GHTF definitions (completed)
4. Issues commonly met (continuing)
5. Suggestions (continuing)
6. Collection of country practices and sharing (continuing)

GHTF's Definition

- GHTF document **GHTF/SG1/N055: 2009**
- "Manufacturer" means any natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s).

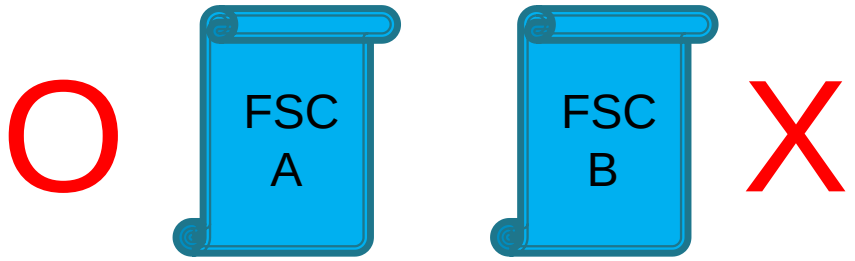
- The manufacturer's responsibilities are described in GHTF guidance documents, including pre-market, post-market and QMS requirements…

Benefits of GHTF's Definition

- Alleviate the issues of confusion caused by several different manufacturers of different key components.
- Control clear product liability throughout product life cycle
- Use with GHTF labeling document to define the legal entity on primary label as the manufacturer
- Similar concept accepted by GHTF Founding Members

Common Issues met in Asia (1) – registering a product with a different actual manufacturing site

- Description of issue:
- Legal manufacturer A in country X
- Actual manufacturing site B in Country Y.
- The product is meant to be registered under legal manufacturer A.
- FSC issued from CA of Country X for A available.
- FSC issued from CA of Country Y for B not available as product is for export only. B did not apply for approval in country Y.



Issues commonly met (2) – importing a product with different actual manufacturers

- Description of Issue
- Legal manufacturer A in country X
- Actual manufacturing site B in country Y
- Product certificate also listed legal manufacturer in country A.
- On ID label, beside legal manufacturer's name and address, country of origin listed as "Made in country B". Is this product certificate acceptable for importing this product?

Suggestions (1)

Considering that the GHTF's definition of manufacturer is adopted widely, WG1 suggested:

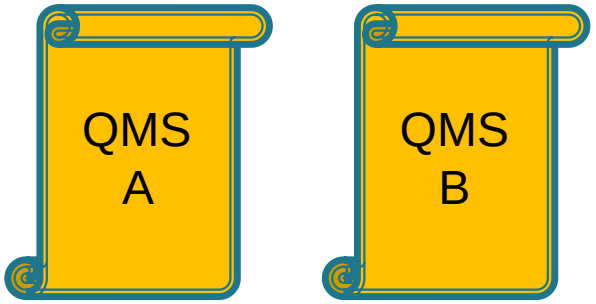
1. Allow the use of legal manufacturer (entity on the ID label) as manufacturer for product registration.

2. For smooth import of product, on product certificate, suggest to list both legal manufacturers and also actual manufacturing sites.

Suggestions (2)

3. For the actual manufacturer site, suggest to consider the requirements for the OEM manufacturer. through the legal manufacturer's supply chain control process in the quality management system.

4. For a product to have a manufacturing site change, suggest to deem this as a change of site instead of a new product submission.



Suggestions (3)

6. Consider to have a common format of Free Sale Certificate for legal manufacturer among AHWP members (Suggested Project for next WG1.)

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AHWP WG1

Labeling Subgroup Report

Ed Woo

Oct 2011

Report

Scope

- Manual and IFU (Phase I)
- Package Label (Phase II)

Members

- Meshal A. Al-Amri, Saudi FDA
- Huifen Bai, HSA
- Devi Laleetha, Kimberly Clark
- Kitty Mao, GE
- Jacqueline Monterio, MDT
- Woei Jiuang Wong, Ciba Vision
- Ed Woo, MDT
- Daphne Yeh, Phillips

Objective

- To advocate the acceptance of web-based eLabeling to satisfy local regulatory requirement for local manual/IFU

Next steps

- Review and provide comparison of e-labeling requirements of GHTF member economies (US, EU & Canada) by end of CY 2011
- Determine applicability of these requirement to formulate proposal for AHWP members.

Study Material:

1. European (draft) legislation, 2011

2. Letter of GUIDANCE from FDA on e Labeling dated March 2003

3. Canadian Notice on e Labeling dated Nov 9 2010

THANK YOU

CURRENT REGULATORY STATUS OF MEMBER ECONOMIES

S/N	Member Economy	MD Classification , similar to GHTF rule based, 4 levels of risk system (Y/N), List differences	MD Definition, similar to GHTF's (Y/N), List differences
1	Hong Kong	Yes	??
2	Indonesia	??	??
3	Malaysia	??	??
4	Saudi Arabia	Yes	Yes
5	Singapore	??	??
6	Thailand	??	??
7	Cambodia	??	??
8	China	China Catalogue, 3 levels	??

CURRENT REGULATORY STATUS OF MEMBER ECONOMIES

S/N	Member Economy	MD Classification , similar to GHTF rule based, 4 levels of risk system (Y/N), List differences	MD Definition, similar to GHTF's (Y/N), List differences
9	Chinese Taipei	Similar to FDA classification	??
10	India	??	??
11	Korea	??	??
12	Philippines	??	??
13	South Africa	??	??
14	Chile	??	??
15	Brunei	??	??
16	Laos	??	??

CURRENT REGULATORY STATUS OF MEMBER ECONOMIES

S/N	Member Economy	MD Classification , similar to GHTF rule based, 4 levels of risk system (Y/N), List differences	MD Definition, similar to GHTF's (Y/N), List differences
17	UAE	??	??
18	Jordan	??	??
19	Myanmar	??	??
20	Pakistan	??	??
21	Vietnam	??	??
22	Yemen	??	??

GHTF'S PRIMARY RECOMMENDATIONS ON CLASSIFICATION

- Regulatory Authorities should work towards the establishment of a global classification system.
- This system should consist of four risk classes. Based on experience of GHTF Founding Members, this is sufficient to accommodate all medical devices and allows an efficient and graduated system of conformity assessment controls.
- The initial determination of class should be based on a set of rules derived from those features of devices that create risk. In most cases the initial rules based classification will also be the final classification.
- These rules should be sufficiently clear that manufacturers may readily identify the class of their medical devices, subject, as required, to final classification by the Regulatory Authority.
- The rules should be capable of accommodating future technological developments.
- The manufacturer should document its justification for placing its product into a particular risk class, including the resolution of any matters of interpretation where it has asked a Regulatory Authority and/or Conformity Assessment Body for a ruling.
- Decisions on final classifications, which deviate from the initial rules-based classification, should be weighed against the disadvantages of disharmonized international classification.

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GHTF'S DEFINITION OF MEDICAL DEVICE

`Medical device' means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:

a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

· diagnosis, prevention, monitoring, treatment or alleviation of disease,
· diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
· investigation, replacement, modification, or support of the anatomy or of a physiological process,
· supporting or sustaining life,
· control of conception,
· disinfection of medical devices,
· providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body;

and

b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function

The end
Welcome your inputs!