Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Ahwp TC
General updates
for Secretariat meeting
@ Riyadh, SA

September 2012

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Chair, AHWP Technical Committee

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Endorsement procedure for AHWP documents

- Endorsement procedure were clarified and discussed

- Presentation slides for endorsement of document to be sent to all chairs and co-chairs and also be put up as reference document on the website

- Points to be brought up to AHWP secretariat:
  - Timeline for endorsement processes
  - Clarification to be sought on:
    - How recommendations made by AHWP in the final documents are binding
    - Whether a list of standards can be recognised

- After the documents are endorsed, a formalised procedure must be put in place to strongly encourage member states to adopt the recommendations

Appointment of TC Advisors

- Name list will be collated from the WGs
- The selection process will be objective and transparent
- The feedback will be brought back to Secretariat

AHWP TC
WORK GROUP UPDATES

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AHWPTC WG1 Pre-Market Submission & CSDT Updates

WG1 - Pre-Market Submission and CSDT

Guidance on Mapping of STED to CSDT

- Summary Technical Documentation (STED):

  GHTF's recommendation as a harmonized template for the documentation of evidence of conformity to the Essential Principles of safety and performance

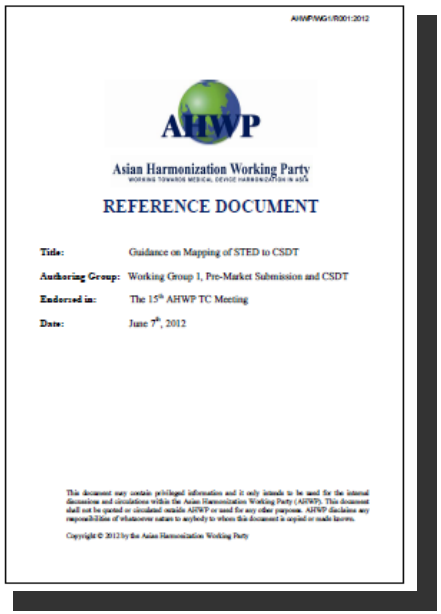
- Common Submission Dossier Template (CSDT):

  Endorsed by the ASEAN Member States MD Regulatory Authorities as the common template for the submission of device information

→ CSDT contains elements of the STED.

AHWPTC WG1 Pre-Market Submission & CSDT Updates

Guidance on Mapping of STED to CSDT


AHWP/WG1/R001:2012

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REFERENCE DOCUMENT

Title: Guidance on Mapping of STED to CSDT

Authoring Group: Working Group 1, Pre-Market Submission and CSDT

Endorsed in: The 15th AHWP TC Meeting

Date: June 7th, 2012

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- To map the sections of STED to CSDT and provide a brief comparison of the requirements in the two dossier templates
- To strengthen understanding of the similarities and differences between the two templates and to facilitate the bi-lateral transposition of STED and CSDT product dossiers

→ *The document is intended to provide non-binding guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development.*

The guidance of mapping of CSDT to STED will be circulated and posted on AHWP website for comments and proposed for adoption in the next meeting.

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AHWPTC WG1 Pre-Market Submission & CSDT Updates

- Comparison of the revised GHTF definition of medical device and with the adopted definition and present an impact analysis of the changes
- Maintaining a list of applicable standards for medical-related software and explore training on software validation

AHWPTC WG1a IVDD Updates

WG1a - IVDD

- To coordinate with WG6 on IVD-related training
- To work closely with WG1 on the comparison between CSDT and STED, with practical experience from countries that are implementing the formats (e.g. Singapore and Chinese Taipei)

AHWPTC WG2 Post-Market Surveillance & Vigilance Updates

WG2 – Post-market Surveillance & Vigilance

- Survey on the adoption of post-market forms (e.g. AE electronic forms) by member economies is required as some extent of national level infrastructure needs to be present before implementing these initiatives
- Maintaining the list of member economies' contact points
- Encouraging communication with all AHWP member economies to strengthen SADS system

AHWPTC WG3 Quality Management System Updates

WG3 – Quality Management System

- Study the application of QMS to domestic small-medium manufacturers and low-risk device manufacturers
- Look into documents to guide domestic manufacturers on how to implement QMS
- To work with WG6 to provide training to increase awareness for domestic manufacturers on QMS
- AHWP may need the help of accreditation bodies such as IAF to refine the requirements for auditing

AHWPTC WG4 Quality System Audit Updates

WG4 – Quality System Audit

- To work more closely with WG3 and tap on the WG3 members for inputs
- To encourage convergence, consider sharing audit reports to reduce repetition in audits between member economies
    - Definition of the scope of audits is required

AHWPTC WG5 Clinical Safety/Performance Updates

WG5 – Clinical Safety/Performance

- A draft survey form from WG5 was presented on framing of guidance documents to be obtained from member economies
  - Survey form will be sent out 10 June and it will be sent out to AHWP members by 15 June
  - Other work groups can suggest on relevant survey questions
- Encourage countries doing active clinical trials (e.g. India, China, Korea) to join WG5
  - TC Chair and Co-Chair will speak to AHWP Chair on whether this can be facilitated
- Mapping of the differences between the old and new versions of ISO 14155 is underway

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AHWPTC WG6 Capacity Building & Regulatory Training Updates

WG6 – Capacity Building and Regulatory Training

- To encourage training, links to relevant online course providers and privileged pricing for AHWP members can be put on AHWP website
  - Timeline to be set
  - To work with Tran Quan to discuss on relevant courses for online training programs

- Priority training areas:
  - WG1: Borderline products
  - WG1a: Personalised disease measurement
  - WG2: Implementation of AE/FSCA
  - WG3: Basic training on QMS with emphasis on domestic manufacturers, importers and distributers
  - WG4: To split up the topics and suggest one topic to focus on. Need to advise on whether any of the topics need to be covered in the Taipei meeting
  - WG5: Introduction to ISO14155
  - WG6: May get relevant trainers

AHWPTC STG(N) Medical Device Nomenclature Updates

STG (N) – Medical Device Nomenclature

- The next GMDN board of trustees meeting will be held on 20th June in Singapore
- AHWP is represented in both the GMDN BOT and PAG
  - The regulatory authorities of AHWP have access to GMDN codes
- STG (N) will check whether membership to IMDRF-UDI group is still open for interested members
  - Information to be sent to chair

THANK YOU

http://www.ahwp.info/

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