ASIAN HARMONIZATION WORKING PARTY

WG8: Standard

(formerly WG7-Standard)

- Chair: Mr. Lupi Trilaksono

  MoH of Republic Indonesia
- Co-Chair: Mr. Tonny Low

  TUV - Malaysia
- No. of WG members: 4
  - Covers member economies: Indonesia, Malaysia, Singapore and India
- WG8 was formed in 2013, during the AHWP annual meeting 2013 in Kuala Lumpur - Malaysia

2014-2016
Vision of AHWP WG8

- Encourage a harmonized **Approach** within AHWP member economies with regards to Selection, Interpretation and Use of Standards to demonstrate the Safety & Effectiveness of Medical Devices

Objectives of AHWP WG8

- In general support the Role and Use of Standards by Regulators & Industry through:
  - Encourage the adoption of international consensus standards by Regulatory Authorities for medical devices to demonstrate compliances.
  - Encourage manufacturers, importers, distributors to comply with appropriate standards.
  - Encourage Regulatory Authorities of AHWP member economies to adopt a mechanism for the Role of Standards to evidence EPSP

2014 Achievements

- Collaboration with WG2 to proposed document “Role of Standards in the Assessment of medical device”

AHWP WG8 Proposed Documents

Doc. No.	Title	Status
AHWP/WG8-WG2/D001:2014 (in collaboration with WG2) Guidance document	Role of Standards in the Assessment of Medical Devices	▪ Have gone through TC and public consultation ▪ To be endorsed by AHWP

AHWP WG8 Standard - Training, November 19, 2014

- The meeting was held in Seoul - Korea and was attended by 10 participants
- Training topics covered :
  - The role of standard in the assessment of medical device, based on GHTF SG1/N044 2008 and GHTF/SG1/N68:2012
  - Alternative to using voluntary consensus standards in meeting “Essential Principles”

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Work Plan

No	Work Items	Deliverables	Action plan & Time Line
1.	Identify vision and mission of WG8	Identification of areas what are to be achieve in WG8	Completed in 10 May 2014
2.	Develop work plan and programs	Identification of work plans for 3 years ahead	
3	Guidance document on identifying role of standards & application of standards	Obtain endorsement from AHWP member economies on Guidance on Role of Standards in the Assessment of Medical Device's based on GHTF-SG1-n044	Proposed document in 18 November 2014
4	Awareness presentation on GHTF-SG1-n044 and pilot standard	• Identify standard as pilot– scope of the standard, role of the standard, to meet its objective of patient safety • Assessment on success of training with developed indicators (Clarify and identification the role of standard in supporting the efficient regulatory framework)	Held in Seoul – Korea 19 November 2014, during the AHWP Meeting in Korea, Forum was attended by regulatory affairs and regulatory authority of member economies to learn a harmonized understanding & approach in the use of Standards.

Phase 1 – by end 2014

- Role of Standards based on GD (SG1 n44) to be adopted by AHWP member economies through proposed the AHWP document

Phase 2 – by end Q1 2015

- Selection of Standards For Pilot (e.g. ISO (DIS) 13485:2014/2015; ISO 14971; ISO 14155; IEC 60601, etc.)

Phase 3 – by beginning Q2 2015

- Launch Pilot (ISO 14971) with 6 to 9 months target completion

Phase 4 – by end 2015

- Review Pilot and work with WG on training to AHWP RA on the Interpretation of these Standards incl. addressing National Deviations, etc.

Phase 5 – Q12016 onwards

- 2nd Standard (ISO 13485 + others) – 9 months
- Review & publish results by Q4

AHWP/WG8-WG2/D001:2014 Role of Standards in the Assessment of Medical Devices

- Scope of paper:
  - This document applies to all products that fall within the definition of a medical device that appears within the GHTF document *Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'*.
- Objective of paper:
  - To:
    - encourage and support the development of international consensus standards for medical devices that may serve to demonstrate conformity with the *Essential Principles of Safety and Performance of Medical Devices*;
    - encourage manufacturers to conform with appropriate standards;
    - persuade Regulatory Authorities to introduce a mechanism for recognising standards that provide manufacturers with a method of demonstrating conformity with the Essential Principles;
    - support the concept that in general, the use of standards is voluntary and manufacturers have the option to select alternative solutions to demonstrate their medical device meets the relevant Essential Principles.
- Summary:
  - The present guidance services as recommendation to Regulatory authorities, Conformity Assessment Bodies and Industry on the principle of appropriate use of standards in the assessment of medical devices from the development of recognition of standards, the use of these standards during and after the transition period, revision of standards, and thereby the changes of the status, status of devices designed using recognised standard before the end of transition period and alternatives to recognised standards.

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THANK YOU