WG6
Quality System Audit & Assessment

AHWP meeting in Seoul, Korea, Nov. 20, 2014

Chair: Abdullah Al Rasheed

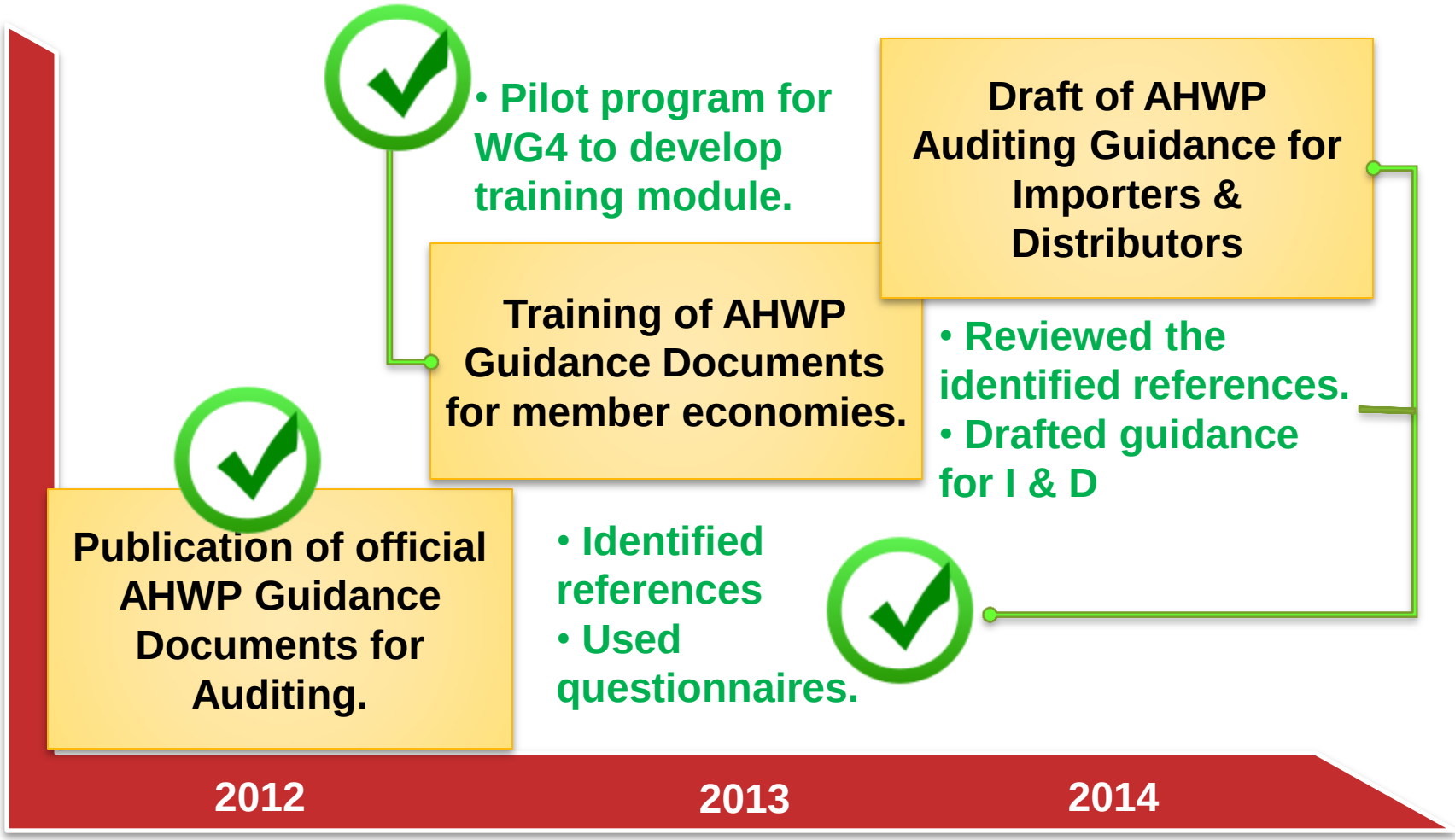
Co-Chair: E.H. Cho

Advisor: Albert Li & Vincent Lam

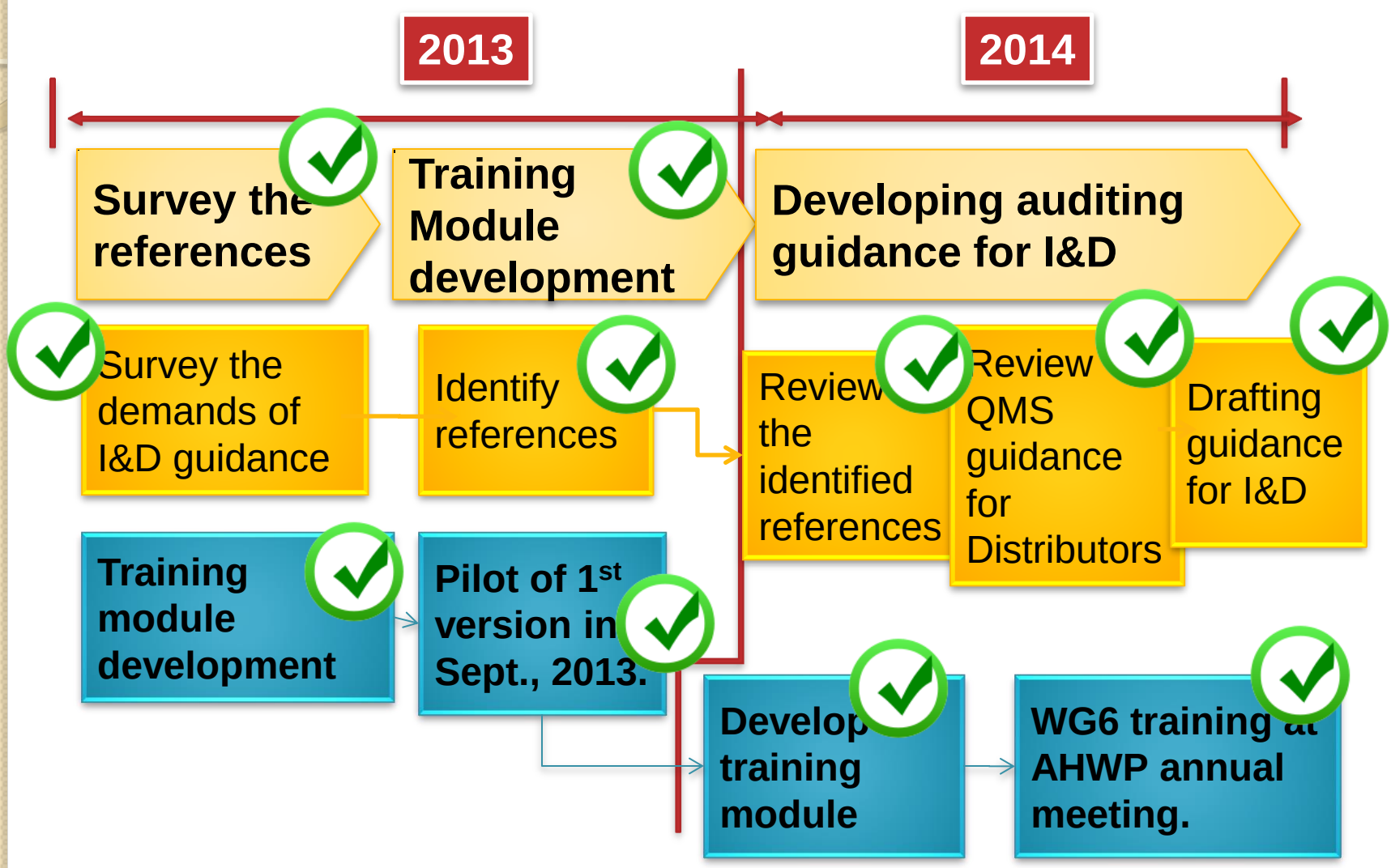
WG6 Updates since KL Meeting

- 7 telecons were held
- Review of the 5 countries(Saudi Arabia, Korea, Singapore, Taiwan, and China) documents
- Revisit adopted auditing guidance and identify which one to include, exclude, and add to the guidance for I&D
- Forming 5 sub groups to provide us with the required comments that enable us to develop the audit guidance for Distributors.
- Drafted a guidance for I&D and now on “call for comments”.
- Training slot on Nov. 19 during annual meeting in Seoul, Korea.

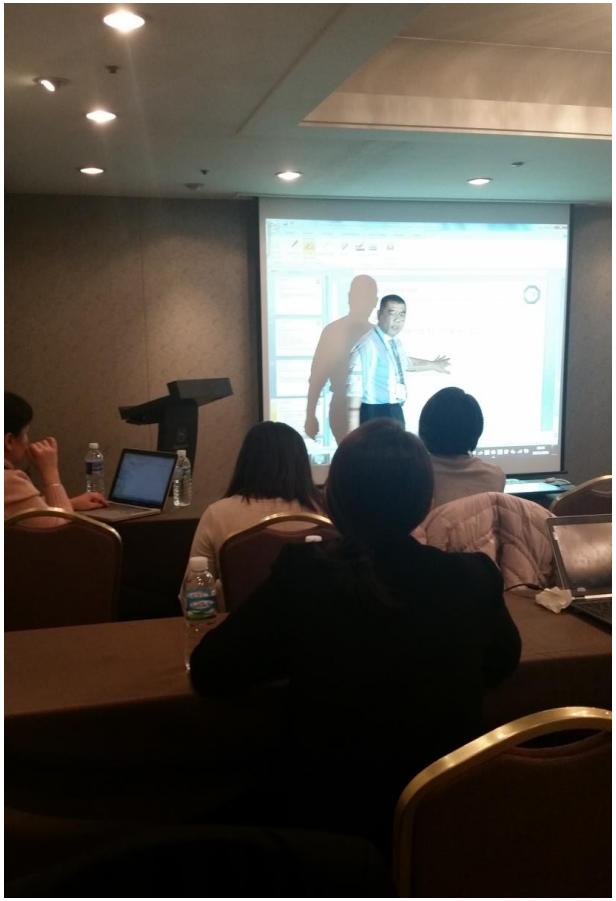
Work Plan for 2012 - 2014



WG6 Updates


2013
2014
Survey the references
Training Module development
Developing auditing guidance for I&D
Survey the demands of I&D guidance
Identify references
Review the identified references
Review QMS guidance for Distributors
Drafting guidance for I&D
Training module development
Pilot of 1st version in Sept., 2013.
Develop training module
WG6 training at AHWP annual meeting.

Snapshot of WG6 Training Nov. 19, 2014



- Topics : How to interpret Guidance docs (Part1~Part5) developed by WG6.
- Attendees : Open to all AHW meeting attendees
- Trainers : Experienced auditors, Vincent Lam & Albert Li
- Format : 3hr interactive workshop with 15 participants.

Draft Guidance for Distributors

- The importance of the role of distributors is ensuring the safety, effectiveness and quality of medical devices marketed in AHWP member economies.
- This guideline is intended to be used by regulators and auditing organizations conducting quality management system audits of medical device distributors based on ISO 13485:2003.
- AHWP/WG6/NxPDRx indicated that the audit should be process-oriented and should preferably follow the workflow processes of the medical device distributor.
- **AHWP References ;** AHWP/WG6/G003:2012: Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers and AHWP/WG7/2014 : Guidance on Quality Management System-Medical Devices Requirements for Distributor.

Guidance for Distributors vs Mftrs

Guidance Docs	Distributors & Importers	Manufacturers
Scope	Applies to an org. which distributes or imports medical devices.	Applies to an organization which manufactures medical devices.
Part1. General Requirements	**Y**	Y
Part2. Regulatory Audit Strategy	**Y**	Y
Part3. Regulatory Audit Reports	**Y**	Y
Part4. Multiple Site Auditing	**NA**	Y
Part5. Audits of Manufacturer control of Suppliers	**NA**	Y

Deviation from Docs for Manufacturers

- The word **Manufacturer** is replaced with **Distributer.**
- **Added** Distributer's definitions ;

  Any natural or legal person that distributes, deliver, install or services medical devices in accordance with the requirements specified by manufacturer according to WG7, QMS for Distributors.
- **Difference from Guidance for Manufacturers**
  - Design and Development
  - Product Documentation
  - Production and Process Controls

  are not applicable for distributors.

***Draft is on website to call for comments.**

Proposal for the next work items:

- To finalize the official Auditing guidance for Distributors.
- To develop auditing of SME(small to medium size enterprise) aligned with WG7.
- To activate auditing training programs to enhance capacity of auditors & auditees of AHWP MEs.
- To share lesson learnt from auditing among AHWP MEs.
- To monitor and evaluate the MDSAP guidance generated by IMDRF.
- To activate the point of contact with IMDRF to explore their updates and the collaboration if required.

THANK YOU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Tan Hwee Ee


Sumati Randeo


Hailey Chu


Vidyashankar


Li, Xiaohua