



WG4 : Quality System Audit

AHWP meeting in KL, Malaysia, Dec. 4-5, 2013.

Chair: Abdullah A. Al Rasheed(Saudi Arabia)

Co-Chair: E.H.Cho(South Korea)

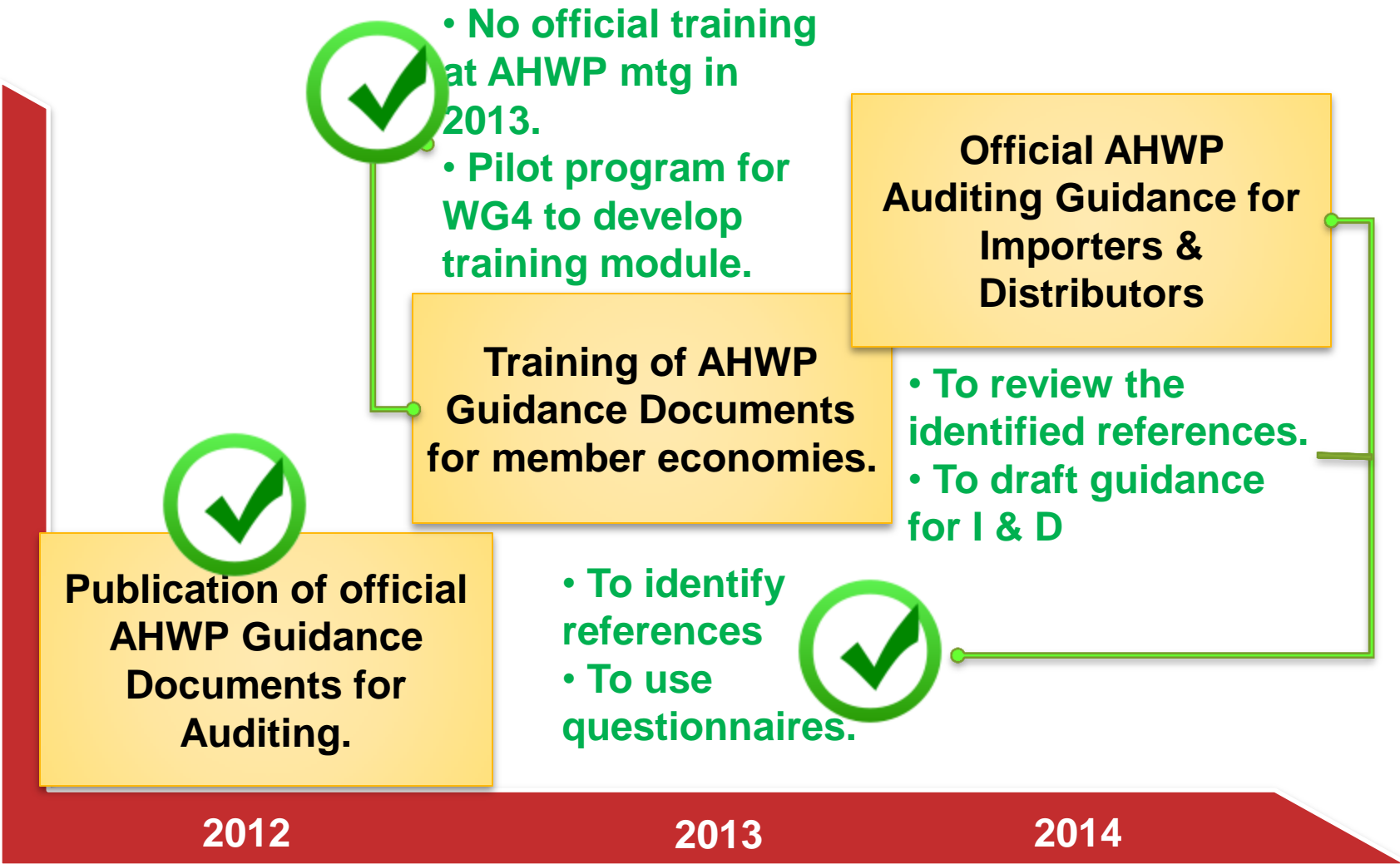
Vision of WG4

To have a Harmonized Auditing Guidance for manufacturers, importers, and distributors to ultimately one audit report works among and beyond AHWP member economies.

WG4 Updates since Taiwan Meeting

- No. of WG members: 19 people from regulators, industry, and notified body.
- Progress
 - Development of Work Plan for 2012-2014.
 - 6 telecons were held.
 - 2 face-to-face meetings; one combined with training & workshop and one combined with AHWP annual meeting.
 - Survey to develop an auditing guidance for importers & distributors among different AHWP ME.

Work Plan for 2012 - 2014



Survey to develop I&D guidance

- **Background :**
 - **AHWP ME dependency on importing : Ave.70%(min.30%-China, max 90%-SaudiArabia)**
 - **MEs see the necessity to have QMS and Auditing for I & D.**
 - **WG4 needs to identify the available references.**
- **Current regulatory audit for I&D within AHWP ME :**
 - **Regulatory Audit : Saudi Arabia, China, Malaysia, *Korea(No certifying audit)**
 - **Audit criteria : SFDA regulations, CFDA regulations, MFDS regulations, Malaysia GDP,**
- **Next Plan : Review the audit criteria and identify the commonalities & differences to reflect on WG4 auditing guidance for I&D.**

Training for WG4 Guidance Docs

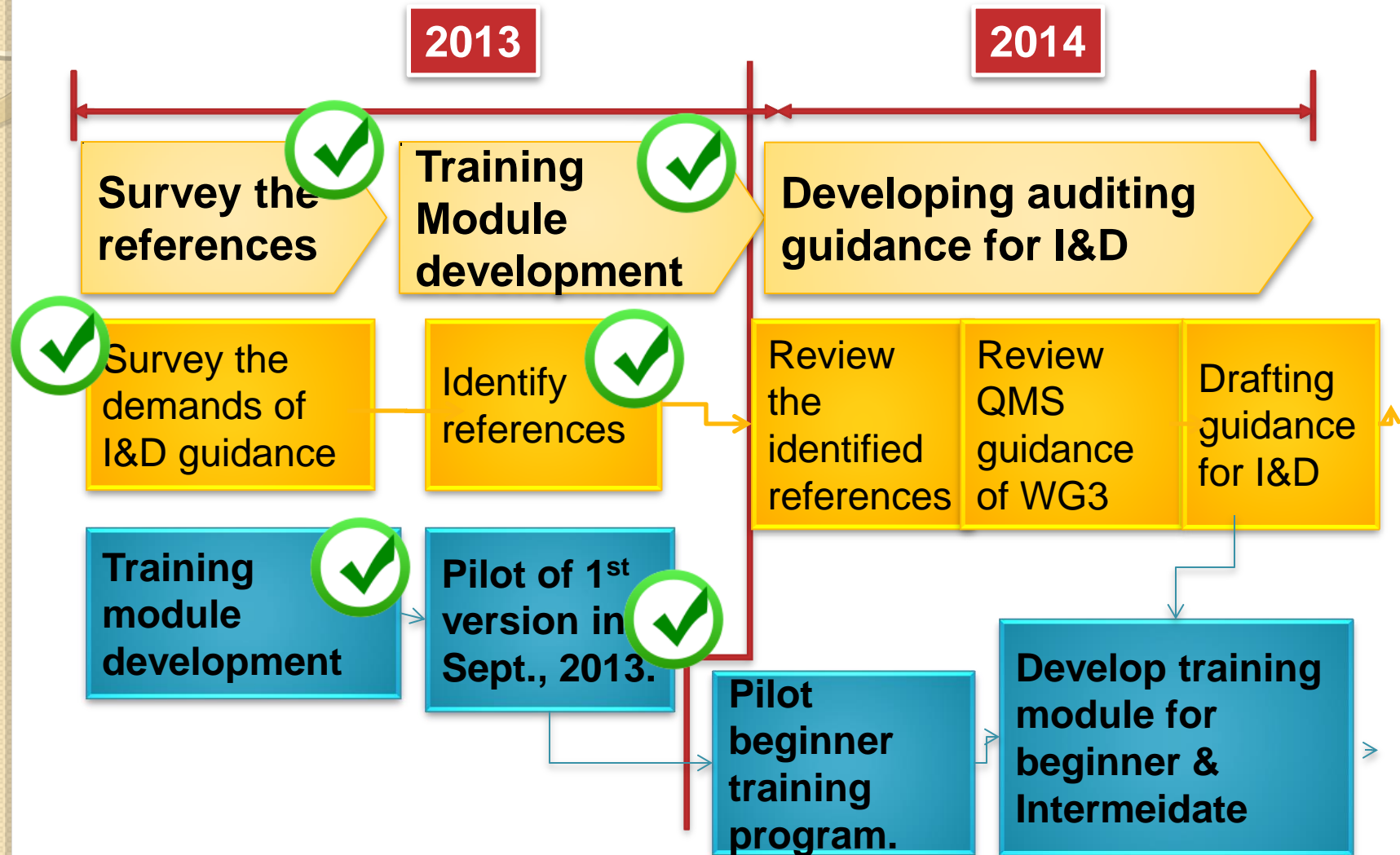
- **Background :**
 - **To make the official guidance doc. used more valuable docs.,, understanding of guidance docs is the first.**
 - **To understand guidance docs, a training is necessary for AHWP.**
 - **Pilot program for WG4 members.**
- **Pilot training program : Singapore, Sept.9-10, 2013.**
- **Trainers : Albert Li & Vincent Lam (Experienced auditors and WG4 members)**
- **Agenda :**
 - **Training on guidance docs of GHTF SG4 by instructors.**
 - **Workshop on each guidance.**
 - **Case sharing with each other.**



Feedback on Pilot Training

- All the attendants agreed that the program and the contents were so packed in a positive way.
- Compared to ISO training programs, WG4 training was way beyond the expectation. It's priceless.
- Experienced auditors and experienced auditees could interact in a productive way and made the workshop more valuable.
- It was the most worthwhile and recommendable training to attend.
- It's better to share the training program with WG4 members and the rest of AHWP attendants. Development of training module will be one of the valuable deliverables.
- Next Plan : Development of training module for WG4 guidance docs. For AHWP meeting attendants to get benefit.

WG4 Updates





Thank You !