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

- Publication of official AHWP Guidance Documents for Auditing.
  - Identified references
  - Used questionnaires.

- Training of AHWP Guidance Documents for member economies.
  - Identified references
  - Used questionnaires.

- Pilot program for WG4 to develop training module.

- Draft of AHWP Auditing Guidance for Importers & Distributors
  - Reviewed the identified references.
  - Drafted guidance for I & D
WG6 Updates

2013

- Survey the references
- Training Module development

2014

- Developing auditing guidance for I&D
- Review the identified references
- Review QMS guidance for Distributors
- Drafting guidance for I&D
- 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Draft Guidance for Distributors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.

# Guidance for Distributors vs Mftrs

<table>
<thead>
<tr>
<th>Guidance Docs</th>
<th>Distributors &amp; Importers</th>
<th>Manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scope</strong></td>
<td>Applies to an org. which distributes or imports medical devices.</td>
<td>Applies to an organization which manufactures medical devices.</td>
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<tr>
<td>Part1. General</td>
<td>Y</td>
<td>Y</td>
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<tr>
<td>Requirements</td>
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<td>Part2. Regulatory</td>
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<td>Y</td>
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<tr>
<td>Audit Strategy</td>
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<td>Part3. Regulatory</td>
<td>Y</td>
<td>Y</td>
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<tr>
<td>Audit Reports</td>
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<tr>
<td>Part4. Multiple</td>
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<td>Y</td>
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<tr>
<td>Site Auditing</td>
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<tr>
<td>Part5. Audits of</td>
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<td>Manufacturer control</td>
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<td>of Suppliers</td>
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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.