# Survey on Auditing in AHWP member economies

Progressive Report of WG4

AHWP meeting, Riyadh, Saudi Arabia

# Background of Survey

- Action items for WG4 had unclear objectives or guidelines.
- So going back to the starting point, working group members proposed to survey the demands of each member economy for auditing.

- Purpose :
  - WG4 provides a reference to the auditing for AHWP member economies.
  - WG4 identifies more feasible key working items to focus on.

- Member Economies who provided feedback :

  China, Chinese Taipei, Hong Kong, Korea, Malaysia, Saudi Arabia, Singapore, Thailand. (alphabetical sequence)

# Progress Update

| Action item | Due |
|---|---|
| After TC meeting in Singapore, WG4 members proposed a survey in June. | June, 2010. |
| Developing Questionnaires | July. 2010 |
| Questionnaires review meeting via Telcon. | Aug. 2010 |
| Finalizing Questionnaires. | Setp.24 |
| Gathering answers from both Industries and Regulators. | Oct.-Nov.2010 |

# Major Questions of Survey

- Total 16 Questions.
  - Regulatory status for auditing
  - Improvement areas in current auditing.
  - Recommendation for future auditing.
  - Recommendable guidelines for auditing.
  - Timelines for corrective actions for non-compliance.
  - Advisable audit scope.
  - Who is to be audited.

# Survey Results

**Q1. Do you have audits by regulators or notified body?**

**Q2. Do you have regulations on audit by regulators/notified bodies?**

**YES : total 7 member economies**

China, Chinese Taipei, India, Korea, Malaysia, Saudi Arabia, Singapore

* Singapore has external audit by CAB.

**Q3. What's the area to be improved and/or harmonized in auditing in your country? (No.of answerers)**

- **Auditor (5)**
- **Audit Guidance (4)**
- **Audit Report (4)**
- **Audit Process (1)**

# Survey Results

**Q4. Why do you see marked areas for Q3 should be improved?**

**Audit Guidance**

- On time update of guidance is required.
- To have fairness audit and to apply the accurate process.
- To raise up the market standard.

**Auditors**

- The Regulated and Regulator need to clearly know, without ambiguity, what the Regulated need to comply with, without overkill.
- Consistency in auditor qualification and required training is very important in harmonization and mutual acceptance of audit results.
- To foster the learning of auditors on the design and manufacturing technologies.

**Audit Reports**

- Presently audit reports from one Certification body differs significantly to the next.

# Survey Results

Q5. **What's your recommendation for the improvement for Q3?**

**Audit Guidance**

- To get harmonized with GHTF guidance.
- Adoption of ISO 13485 and ISO 14971 along with the Essential Safety Requirements
- Audit Checklist for Regulators (who may not be familiar with ISO 13485) with variable risk proportional requirement for Class A,B,C,D devices.

**Auditors**

- To have a certified training program for auditors.
- That there be defined requirements on those who wish to be medical device auditors in terms of education, background, training and experience.
- To establish the requirements of auditor qualification and training by following GHTF/SG4/N28 Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers.

**Audit Reports**

- Audit reports are standardized.

# Survey Results

**Q6. If there's no audit requirement, is there any plan for audit in the future?**

- **Hong Kong, Thailand.**

**Q7 & 8. What guidelines do you recommend for future regulations on audit and Why?**

- **ISO and GHTF guideline**
  - It's more common & most of the RA/notified bodies reps. are familiar with the ISO standard for the audit.
  - ISO standard is well understood and implemented in many companies in medical device industry. It's a universal standard.
  - ISO is the widely recognized standard commercially.
  - GHTF may be good approach in public organization perspective. Regulator's adopting of well established guidelines would help local system standardized internationally which will ease the cooperation among regulators. It will also benefit private sector resource management.

# Survey Results

**Q9. Business Impact of future audit?**

- **Cost and Resource.**

**Q10. As a regulator, what action would be taken for non-compliance found during audit?**

- **Enforcement action**
- **Corrective action**

# Survey Results

Q11. What is the general timeline for corrective action for non-compliance during the audit? – (1)

| Country | Gap: | Timeline | Country | Gap: | Timeline |
|---|---|---|---|---|---|
| **China** | 1) Critical | 15 working days | **Korea** | 1) Critical | Immediate |
| | 2) Major | 4 weeks | | 2) Major | 4 weeks |
| | 3) Minor | 12 months | | 3) Minor | Noted in the report |
| **India** | 1) Critical | Usually 3 weeks | **Malaysia** | 1) Critical | 60 days |
| | 2) Major | Usually 2 weeks for response of planned action | | 2) Major | 60 days |
| | 3) Minor | Usually 2 weeks for response of planned action | | 3) Minor | 60 days |

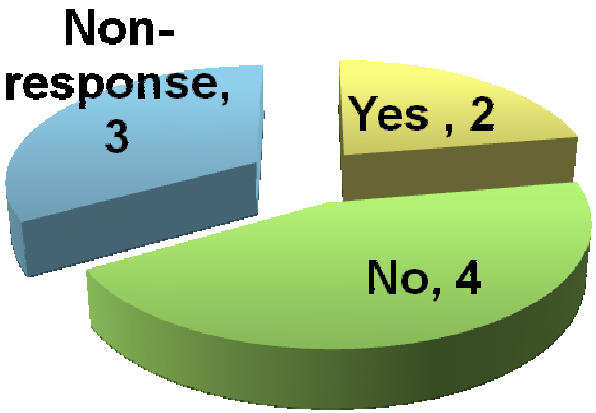
# Survey Results

Q11. What is the general timeline for corrective action for non-compliance during the audit? – (2)

| Country | Gap: | Timeline | Country | Gap: | Timeline |
|---|---|---|---|---|---|
| **Saudi Arabia** | 1) Critical | 2 weeks | **Chinese Taipei** | 1) Critical | 2-3 months |
| | 2) Major | 4-8 weeks | | 2) Major | 10 days |
| | 3) Minor | A follow up visit on renewal | | 3) Minor | Noted in the audit report |
| **Singa-pore** | 1) Critical | NA | **Hong Kong / Thailand** | 1) Critical | - |
| | 2) Major | Initial 1 month, subsequent extension allowed. | | 2) Major | - |
| | 3) Minor | Initial 1 month, subsequent extension allowed. | | 3) Minor | - |

# Survey Results

Q12. Does your audit covers risk management?




***Yes,*** **Malaysia / Chinese Taipei/ Korea**

***No,*** **China / India / Saudi Arabia / Singapore**

Q13. If yes, do you adopt ISO14971 as standard for risk management?

- **Korea**
- **Malaysia**
- **Chinese Taipei**

# Survey Results

Q14. How would you define the audit scope?

| | |
|---|---|
| **China** | - Physical location<br>- Organizational activities such as manufacturing/distribution |
| **India** | - Physical location<br>- Organizational activities such as manufacturing/distribution |
| **Korea** | - Organizational activities, manufacturing/distribution/marketing /users |
| **Malaysia** | - Physical location<br>- Organizational activities such as manufacturing/distribution |
| **Saudi Arabia** | - All of the above |
| **Singapore** | - Applicable requirement by GHTF |
| **Chinese Taipei** | - All of the above |

# Survey Results

Q15. What kind of audits are carried out by government/notified body?

| | | | |
|---|---|---|---|
| **China** | • Partial Audit<br>• Physical Audit<br>• Document Audit | **Korea** | • Full Audit<br>• Partial Audit<br>• Document Audit |
| **India** | • Full Audit<br>• Partial Audit<br>• Physical Audit<br>• Document Audit | **Malaysia** | • Full Audit<br>• Document Audit |
| **Saudi Arabia** | • Full Audit<br>• Physical Audit<br>• Document Audit | **Singapore** | • Full Audit<br>• Physical Audit<br>• Document Audit |
| **Taipei** | • Full Audit<br>• Physical Audit<br>• Document Audit | **Hong Kong** | • Document Audit |

# Survey Results

Q16. Who are qualified to be audited in your country?

| | | | |
|---|---|---|---|
| **China** | • Importers<br>• Conformity assessment bodies | **Korea** | • Manufacturers<br>• Importers<br>• Medical Institutes |
| **India** | • Manufacturers<br>• Importers<br>• Distributors<br>• Users/Hospitals/Clinics | **Malaysia** | • Manufacturers<br>• Conformity assessment bodies |
| **Saudi Arabia** | • Importers<br>• Distributors | ***Singapore** | • Conformity assessment bodies |
| **Taipei** | • Manufacturers | **Hong Kong** | • Conformity assessment bodies |

# Next Plan

| Action item | Due |
|---|---|
| Feedback on survey results | Dec.2010. |
| Identify & prioritize key action items for WG4 to focus on. | Jan.2011 |
| Project planning for key action item. | Feb. 2011 |
| Project kick-off | Mar. 2011 |
| Project management | Mar.2011~ |
| Delivery the outcome in 16th. AHWP meeting | TBD |

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