Update on WG04

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Chair of WG04

Vision & Mission of WG04

- **Environment Overview in Auditing :**

  Basic auditing standard is ISO13485 but the ISO13485 is interpreted in many different ways.

- **Vision :**

  Common understanding and interpretation of ISO13485 in AHWP member economies, government, industry, and notified bodies.

- **Mission :**

  Guidance provision(ISO13485 Handbook) for all stakeholders in AHWP member economies how to interpret ISO13485 in auditing perspective.

Project Background

The basic auditing standard is ISO13485 but there has been different interpretation due to language difference, etc. The GHTF guidance is not also easy to understand for auditors/auditees. To have the same understanding of ISO13485 in each economies, a guideline is required to help the auditors & auditees understand the requirements easily. The ultimate outcome will be a guidance for easy understanding of ISO13485. -By Mr.Mitra-

Why AHWP Guidance

It does not mean that GHTF guidance does not fit AHWP member economies at all. Considering the regulatory development status in AHWP member eocnomies, it is meaningful to have AHWP's own auditing guidance. Especially, many of the regulators in AHWP member economies are from Pharmaceutical field, the ISO13485 handbook would be helpful for regulators to understand medical devices in easy language.

How about Global Harmonization

The AHWP guidance would not be a totally different one from GHTF guidance. The AHWP guidance document should be in aligned with GHTF guidance in principle. Again the handbook is to help the stakeholders to understand the ISO13485 requirement for auditing.

NB's experience & opinion

- WG04 has members from notified bodies. Various perspective from regulators, industry, and notified body are the asset of AHWP. Not only regulators and industry but also NB's active participation in ISO13485 handbook is required.

Working Principle

- The ISO13485 handbook is a to help auditors/auditees understand ISO13485 requirements more easily. However, the handbook should not be too much specific.

Progress

- Completion of identifying the grey area of ISO13485.
- Discussion of the identified areas is going on.

Key Issues of WG04

How to incorporate the AHWP guidance(Handbook) with available guidelines

- ISO13485 for Quality management system - Requirements for regulatory purpose.

- ISO/TR14969 Guidance on the application of ISO13485

- ISO19011 Guidelines for quality and/or environmental management systems auditing.

- GHTF SG4 Guidelines for Regulatory Auditing,

  1. General Requirements

  2.Regulatory Audit Reports

  3. Regulatory Audit Strategy

  4. Training requirements for Auditors