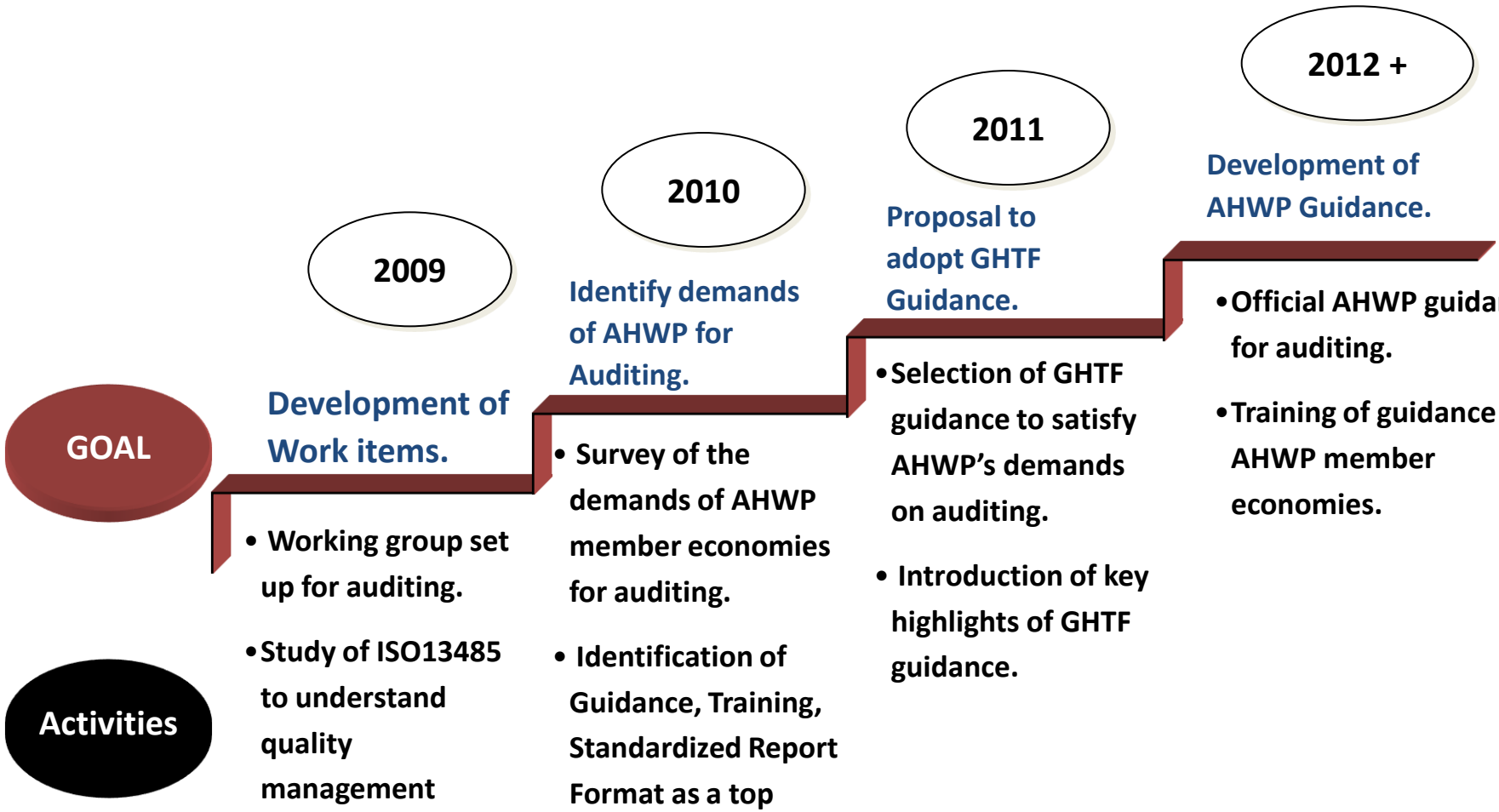
Asian Harmonization Working Party
Technical Committee

Progress of WG4



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WG 4

Work Item :	**Development of AHWP Guidance Documents for Auditing. (Audit by Regulator/ Auditing organizations for Medical Devices Manufacturers)**
Current status:	Review of GHTF Guidance (Part 1, Part 2, Part 3, Part 4, and Part 5).
Conducted with inputs from GHTF?.	Yes. Leverage GHTF Guidance Documents.
Nov. 2011 (Bali meeting).	Proposal to adopt GHTF guidance by AHWP member economies.
Steps forward	Development of “AHWP Guidance Documents”.

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Inputs from GHTF

GHTF guidance document: Working group4 reviewed the available guidance documents.

- Part1. General Requirements.
- Part 2. Regulatory Auditing Strategy.
- Part 3. Regulatory Audit Reports.
- Part 4. Multiple Site Auditing.
- Part 5. Audits of Manufacturer Control of Suppliers.

GHTF joint meeting & mentors: SG4/GHTF completed their work in 2009. No more active working for SG4 now so that joint meeting is not feasible.

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Scope of AHWP Guidance for Audit

Intent :
To be used by Regulators & Auditing Organizations to conduct QMS audit of medical device manufacturer based on process approach to QMS requirements (e.g. ISO 13485)

Application:
Applies to Initial & Surveillance Audits & can apply to other Audits defined in GHTF, SG4/N28.

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Part 1: General Requirements

- General requirements of auditing organization
  - Legal responsibility, independence & impartiality, confidentiality, etc.
- Resource, audit team competence, and outsourcing.
- Audit process and type of audit
- Flowchart of typical audit process
- R&R of auditors.
- Language requirements
- Audit team composition.
- Adequacy of audit documentation.
- Follow up activities.

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Benefit of Part1

- Guidance for ; Establishing, Planning, Carrying out, Documenting, follow-up of corrections, CAPA, competence criteria
- Regulators & Auditing Organizations; Guidance to audit device manufacturers.
- Manufacturers; Guidance to prepare for regulatory audit, opportunity to develop global harmonization mechanism.
- Member economies to introduce regulatory system; Reference guidelines
- All ; Regulators, Patients/Users, Auditing org.,etc.; Assurance & Compliance.

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Part 2 : Regulatory Auditing Strategy

- Strategy for regulatory audits.
- Auditing of Quality Management System.
- Auditing Approaches ; Top-down, Bottom-up, Combination, and Product
- Planning of Audits ; Est.audit duration, frequency, targeted on-site auditing time.
- Logistics during an Audit : Change update, Documentation and training at the end of audit, evaluation the internal audit towards end of audit to avoid bias.
- Auditing subsystem of quality
  - Verification of quality manual/policy, management review, quality plan, quality audit procedure, product realization process, internal audits etc.
  - Review of manufacturer organizational structure & related documents.

Benefit of Part2

- Regulators & Auditing Organizations
  → Improved auditing & QMS
  → Greater consistency
  → Greater collaboration
  → Increased Confidence & global harmonization
  → Efficient use of resource
  → Informative to develop strategy.

- Manufacturers
  → Improved auditing to improved QMS and Quality.
  → Greater consistency in audit practice and feedback to manufacturer.
  → Reduction in time.
  → Increased confidence and acceptance of audit by different auditors.

- Patients and Users
  → Higher degree of assurance for safety & efficacy.

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Part 3: Audit Report

- This document is intended to be used for regulators and auditing organization as a guide for writing a report of a regulatory MD QMS audit.
- It's based on ISO13485 and 21CFR 820 requirements
- It is necessary to address the additional national requirements to meet the different needs.
- It describes the detail which can be exchanged between different regulators and audit organizations.

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Benefit of Part 3

Advantages

- Increase consistency
- Increase collaboration
- Will emphasize the harmonization concept.
- Minimum requirement been defined
- Built according to the main quality references
- Reduce cost of audit

Disadvantages

- Doc. Doesn't cover importers & distributors
- Doc. Needs to define the audit types
- No need to mention the GMDN
- In definition we need to add observations
- Auditing of multisite

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Part 4 : Multiple site audit

- Document gives guidance to regulators and auditing organizations conducting audits of quality management systems of medical device manufacturers with multiple sites
- Improved efficiency of an audit of a quality management system of a manufacturer with multiple sites reduced audit time and cost for the auditing organization
- improved understanding of the audit of quality management system of the manufacturer with multiple sites

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Benefit of Part 4

- Improved efficiency of an audit of a quality management system of manufacturer with multiple site.
- Reduced audit time and cost for the auditing organization.
- Provision of guidelines for initial audit, surveillance audit, and special audit of a quality management system of a manufacturer with multiple sites.
- Improved understanding of the audit of a quality management system of the manufacturer with multiple sites.

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Part 5: Audits of Manufacturer Control of Suppliers

- General Principles for CAB to audit
  - Purchasing controls at the Mfgrer (and supplier management/evaluation/control system)
  - Outcome of above plus the degree of incoming inspection, and criticality of product
  - Subsystem like outsourcing of Design & Manufacturing
  - Product or service wherein it can not be verified by inspection (Sterilization services)
- Decision to Audit or Not to Audit Criteria
  - Established Procedures and evidence that product/service meets regulatory requirements.
- Purpose of audit premises
  - Manufacturer supplier control to meet the specified requirements.
  - Supplier's capability for consistency.
- Reporting & Corrective Action (Main report)

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Benefit of Part 5

- Provision of additional information about audit strategy to regulators, auditing organization, and auditors for auditing a manufacturer's purchasing controls and receiving/incoming acceptance activities, as well as on the performance of audits at the manufacturer's supplier(s).
- Promoting consistency in conducting audits - necessity for harmonization and mutual recognition of audit results.

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WG4 strongly proposes to adopt GHTF guidance for auditing for AHWP member economies.

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For Official AHWP Guidance.

- Clarify the debating items
  - Definition of importer and distributor ; Is it required for guidance which is mainly for manufacturers?
  - Multiple sites ; should we include sampling audit of warehouses also ?
  - GMDN for product scope ; Is GMDN an proper example for AHWP member economies?
- Formatting GHTF guidance into AHWP guidance.
- Workshop/Training for AHWP member economies to be familiar with AHWP/GHTF Guidance Documents.

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