Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Work Group 3
Quality Management System

Riyadh

27 November – 1 December 2010

Ali Al Dalaan , MBA-IT
Vice-Chairperson AHWP TC
Chairperson AHWP WG3
Director Technical Support and
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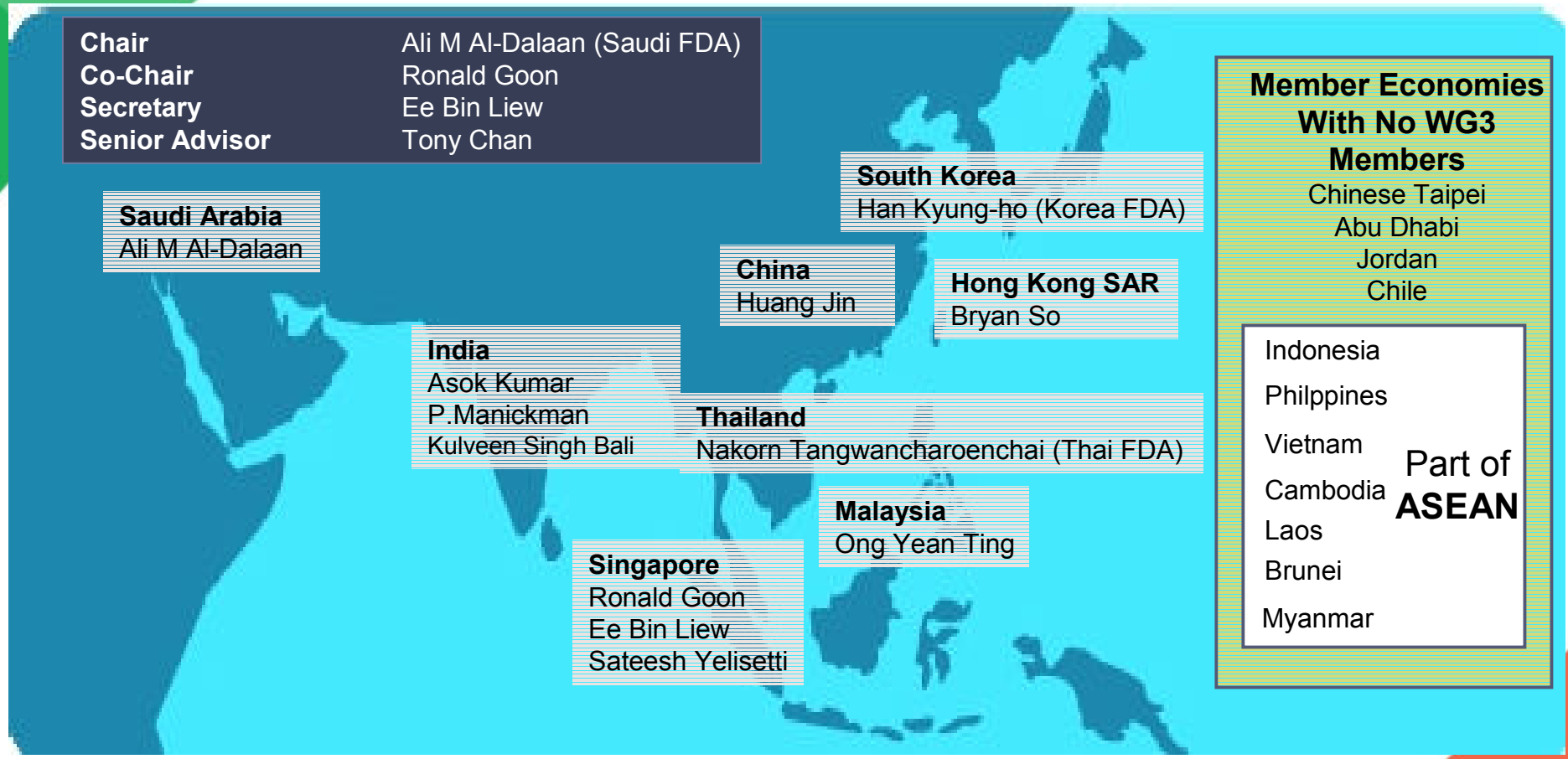
Co-Chairperson AHWP WG3
Director, Quality & Compliance
Worldwide
Johnson & Johnson

AHWP WG3 Membership



- We aim to have at least 1 regulatory authority **and** 1 industry representative per member economies
- We need your participation and support!

AHWP WG3 Update

Historical Link with GHTF-SG3

- June 2008, **GHTF-SG3 membership**
- Oct 2008 **Ottawa meeting, Reviewed comments during Development on N17 (SG3 guidance document)**
- Oct 2008 **AHWP India meeting WG3 Chair election and establishment of AHWP-WG3**
- **Finalized WG3 work plan for 2009-2011**
- Feb 2009, **WG3 Co-chair gained SG3 membership**

WG3 2010 Update

Collaboration between WG3 and GHTF SG3

- WG3 Chairperson and SG3 Chairperson discussed the value and benefits of the AHWP and GHTF collaborating on **common** projects related to the harmonization of medical device regulations
  - One or more members of the AHWP WG3 to join the GHTF SG3 as permanent member(s)
  - Enable WG3 members to provide their opinions and comments in the development of SG3 guidance documents and ISO standard for QMS – reduce duplication of work
  - Encourage increased understanding on the benefits of harmonization

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WG3 2010 Update

Collaboration between WG3 and GHTF SG3

- Formal invitation from GHTF SG3 Chairperson for WG3 Chairperson and Co-chairperson to be members of SG3
- WG3 Co-chairperson participated in February 2009 meeting of SG3 in Tokyo, Japan
- Participated in the review and drafting of SG3 guidance documents
  - N17
  - N18
  - N19

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WG3 2010 Update

Achievements:

- Active engagement with GHTF SG3 to provide AHWP input and perspective in development of GHTF guidance documents
  - Actively participated and reviewed and finalized GHTF N17 guidance document
  - Actively participated in development of GHTF N18 guidance document
  - Currently working on development of N19

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AHWP WG03 Work Items

Participated and REVIEWED GHTF SG3 documents

- N17 Quality management system – Medical Devices – Guidance on the control of product and services obtained from suppliers
- N18 Management System – Medical Devices – Guidance on corrective action and preventive action
- New Work Item Proposal N19 - Quality Management System - Medical devices - Criteria for characterizing the significance of QMS deficiencies

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GHTF N17

Setup comments format

AHWP WG3: Quality Management System

Document number: GHTF/SG3/N17:2008

& Title: Quality Management System – Medical Devices –

Guidance on the Control of Products and Services Obtained from Suppliers

Submitted by (name): Jin Huang Economy Member / Industry: China / Shenzhen Association of Medical Devices On: 25/02/2009

Comment number	Economy Member / Industry (e.g. SFDA)	Page / Section / Line	Editorial or Technical	Comment	Proposed revised text	WG3 Decision (& date)
1	/ Shenzhen Association of Medical Device	Page 5 / Section 1.0 / Line 14~16	Technical	Internal audit scope should not be only criterion to identify whether the supplier operates under a separate quality management system. The reason is as following: For example, some organization has several manufacturing sites (might be in different countries). But they are under same quality management system. One of manufacturing sites might be chose as the manufacturer of some medical devices, and the other manufacturing sites provide sub-assembling to the manufacturer. If the management review scope of this organization includes all of these manufacturing sites or external audit scope includes all of these manufacturing sites, all of these manufacturing sites should be considered under the same quality management system.	Change the line 14~ Page 5 to: For example, if the supplier is neither a part of the manufacturer's internal and external audit scope nor within a same management review scope, then the supplier is under a separate quality management system and is considered an internal supplier.	
2	/ Shenzhen Association of Medical Device	Page 14 / Section / Line 10	Technical	Regarding "intellectual property", the controls should not only include "Protection of intellectual property", but also manufacturer should ask the supplier to disclose requested information to regulatory authorities for approval of medical devices for commercial sale and distribution. Usually this kind of requirements could be clearly defined in a contractual agreement.	Add the following information under Line Page 14. ●Disclose requested information to regulatory authorities for approval of medical devices for commercial sale and distribution	

GHTF N17

Overview of N17 Contents

1. Scope
2. Definitions.
3. General Principles
4. Planning

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GHTF N17

1. Scope

- provides guidance for medical device manufacturers on the control of products and services obtained from suppliers.
- For the purposes of this document:
  - a product or service is one.
  - a supplier is anyone that is independent from the manufacturer's quality management system.
    - **example,** if the supplier is not a part of the manufacturer's internal audit scope, then the supplier is under a separate quality management system and is considered an internal supplier.
- Corporations or companies that have corporate quality policies and procedures do not necessarily place all divisions or groups under the same quality management system.
- Manufacturers are required to define and document the type and extent of controls applied to suppliers and to maintain objective evidence that products and services meet predefined specifications.
- Applicable to combination products

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GHTF N17

2. Definitions

- Supplier
- Product
- Process
- Objective evidence
- Manufacturer

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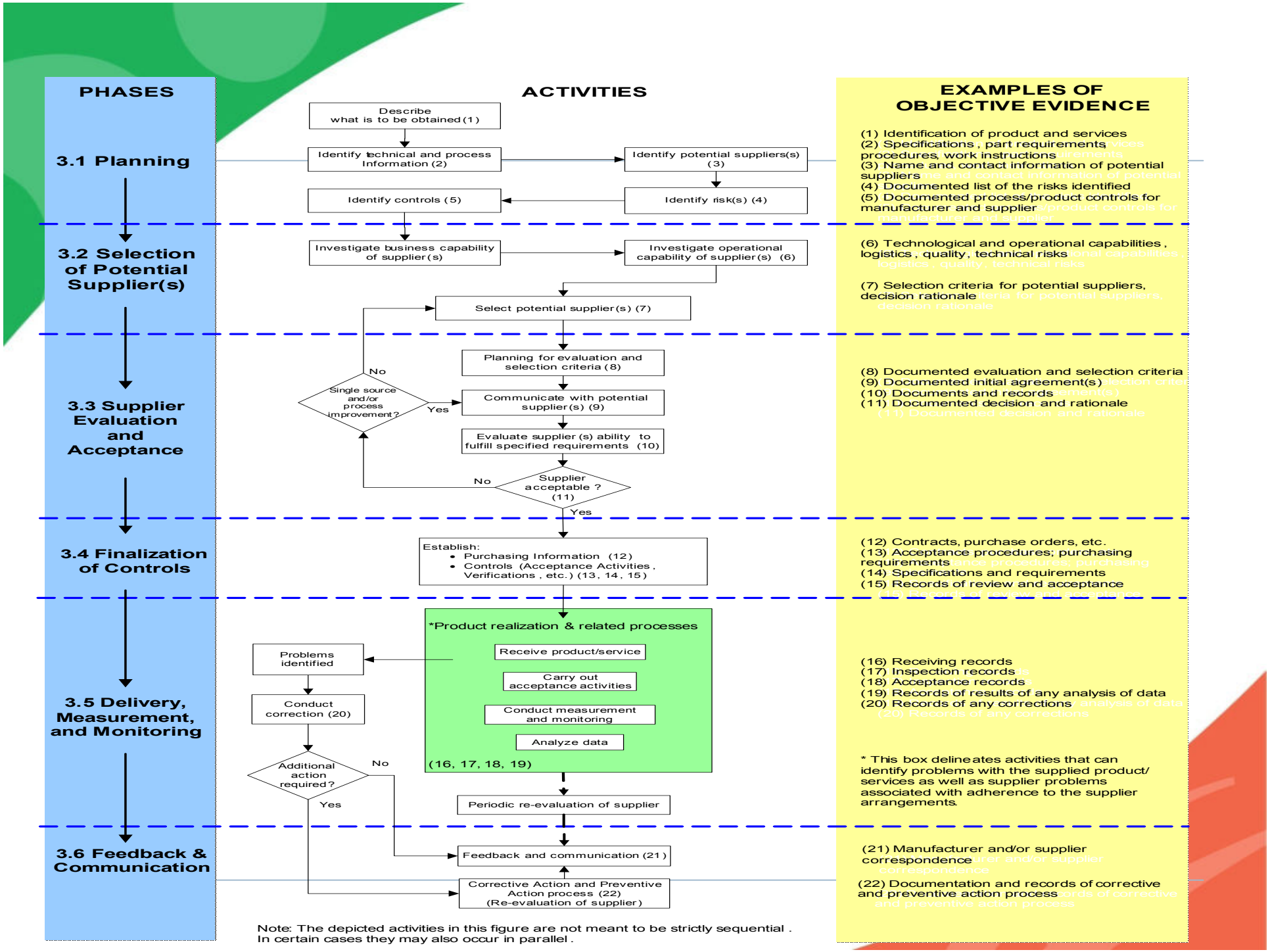
3. General Principles

The process of establishing controls for products and services obtained from suppliers typically comprises six phases, which include:

- Planning
- Selection of potential supplier(s)
- Delivery, measurement and monitoring
- Supplier evaluation and acceptance
- Finalization of controls
- Delivery, measurement and monitoring
- Feedback and communication, including Corrective Action and Preventive Action process


PHASES
3.1 Planning
3.2 Selection of Potential Supplier(s)
3.3 Supplier Evaluation and Acceptance
3.4 Finalization of Controls
3.5 Delivery, Measurement, and Monitoring
3.6 Feedback & Communication
ACTIVITIES
Describe what is to be obtained (1)
Identify technical and process Information (2)
Identify potential suppliers(s) (3)
Identify risk(s) (4)
Identify controls (5)
Investigate business capability of supplier(s)
Investigate operational capability of supplier(s) (6)
Select potential supplier(s) (7)
Planning for evaluation and selection criteria (8)
Single source and/or process improvement?
No
Yes
Communicate with potential supplier(s) (9)
Evaluate supplier (s) ability to fulfill specified requirements (10)
Supplier acceptable ? (11)
No
Yes
Establish:
Purchasing Information (12)
Controls (Acceptance Activities, Verifications, etc.) (13, 14, 15)
*Product realization & related processes
Receive product/service
Carry out acceptance activities
Conduct measurement and monitoring
Analyze data
(16, 17, 18, 19)
Problems identified
Conduct correction (20)
Additional action required?
No
Yes
Periodic re-evaluation of supplier
Feedback and communication (21)
Corrective Action and Preventive Action process (22) (Re-evaluation of supplier)
EXAMPLES OF OBJECTIVE EVIDENCE
(1) Identification of product and services
(2) Specifications, part requirements, procedures, work instructions
(3) Name and contact information of potential suppliers
(4) Documented list of the risks identified
(5) Documented process/product controls for manufacturer and supplier
(6) Technological and operational capabilities, logistics, quality, technical risks
(7) Selection criteria for potential suppliers, decision rationale
(8) Documented evaluation and selection criteria
(9) Documented initial agreement(s)
(10) Documents and records
(11) Documented decision and rationale
(12) Contracts, purchase orders, etc.
(13) Acceptance procedures; purchasing requirements
(14) Specifications and requirements
(15) Records of review and acceptance
(16) Receiving records
(17) Inspection records
(18) Acceptance records
(19) Records of results of any analysis of data
(20) Records of any corrections
* This box delineates activities that can identify problems with the supplied product/ services as well as supplier problems associated with adherence to the supplier arrangements.
(21) Manufacturer and/or supplier correspondence
(22) Documentation and records of corrective and preventive action process
Note: The depicted activities in this figure are not meant to be strictly sequential. In certain cases they may also occur in parallel.

3. General Principles

3.1 Planning

- ✓ Product or service to be obtained from supplier.
- ✓ Technical and process information.
- ✓ Identification of potential supplier(s).
- ✓ Identification of risk(s).
- ✓ Identification of controls.

3. General Principles

3.2 Selection of potential suppliers

- ✓ Supplier business capability
- ✓ Supplier operational capability
- ✓ Selection of potential supplier

3. General Principles

3.3 Supplier evaluation and acceptance

- ✓ Planning for evaluation and selection criteria.
- ✓ Communicate with potential suppliers
- ✓ Evaluation of potential supplier's ability to meet selection criteria
- ✓ Supplier acceptance

3. General Principles

3.4 Finalization of Controls

The list below shows other typical areas that should be considered for finalizing the agreement between the manufacturer and its supplier.

- ✓ Acceptance and verification activities
- ✓ Complaint handling
- ✓ Root cause analysis
- ✓ Corrective action and preventive action
- ✓ Product risk management
- ✓ Design
- ✓ Labelling/traceability requirements
- ✓ Technical documentation (of the supply)
- ✓ Handling of non-conformities
- ✓ Change control requirements
- ✓ Creation and retention of documents and records
- ✓ Supplier audits
- ✓ Product recall
- ✓ Periodic evaluation or re-evaluation (supplier's product, service and/or data)

3. General Principles

3.5 Delivery, measurement and monitoring consist of:

- ✓ Receiving product/service
- ✓ Carrying out acceptance activities (e.g. inspection or test, review certificates of conformity/analysis)
- ✓ Conducting measurement and monitoring
- ✓ Analyzing data using valid statistical techniques

3. General Principles

3.6 Feedback and communication

a) Provisions for CAPA related activities performed by suppliers are defined in the manufacturer's QMS.

b) Based on the products provided by a supplier, all CAPA specific activities to be performed and data/information to be provided by that supplier are identified (e.g. related to the extent of control necessary at the supplier).

c) The supplier's obligations related to CAPA activities are communicated to the supplier and clearly defined in a contractual agreement (e.g. in the contract itself or a quality assurance agreement).

d) The supplier fulfils his contractual obligations in relation to the CAPA activities (e.g. timely processing of corrections).

e) Documentation and records related to a supplier's CAPA activities are controlled and readily available.

GHTF N17

- SG3/N17/2008: Quality Management System – Medical Devices – Guidance on the Control of Products and Services Obtained from Suppliers
- Final document approved by GHTF Steering Committee on 11 December 2008
- Document posted on GHTF website on 5 February 2009

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GHTF N17

- AHWP WG3 member has reviewed this document and comments and feedback from regulators and industry of AHWP member economies
- No significant issues were raised or identified that required modification of the document for AHWP use
- WG3 recommends that document be adopted by AHWP with no changes

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Overview N18 Contents

1. Scope
2. Definitions.
3. Overview
4. Phases

GHTF N18

1. Scope

- This document provides guidance for establishing adequate processes for measurement, analysis and improvement within the QMS as related to correction and/or corrective action for nonconformities or preventive action for potential nonconformities of systems, processes or products.

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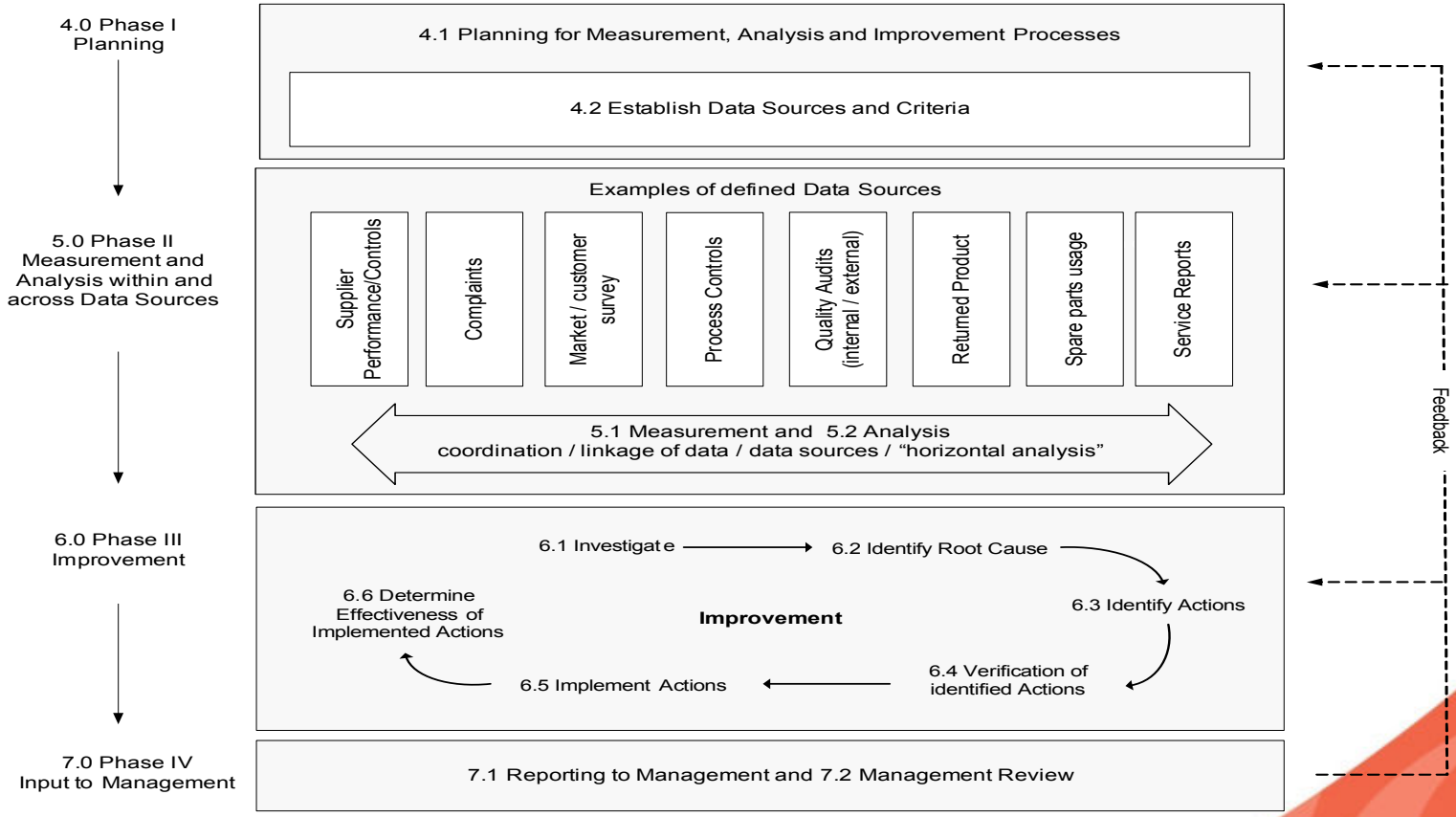
2. Definitions

- Correction
- Corrective action
- Data Source
- Concession
- Preventive action
- Nonconformity
- Verification
- Validation

3. Overview

The graph below Illustrates typical Phases to be considered when planning, implementing and maintaining effective processes for measurement, analysis, improvement and providing input to management.

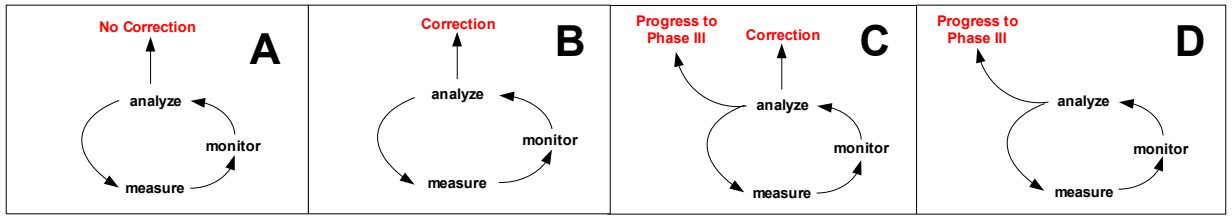


4. Phases

- Phase I: Planning
- Phase II: Measurement and Analysis within and across Data Sources
- Phase III: Improvement
- Phase IV: Input to Management

4. Phases

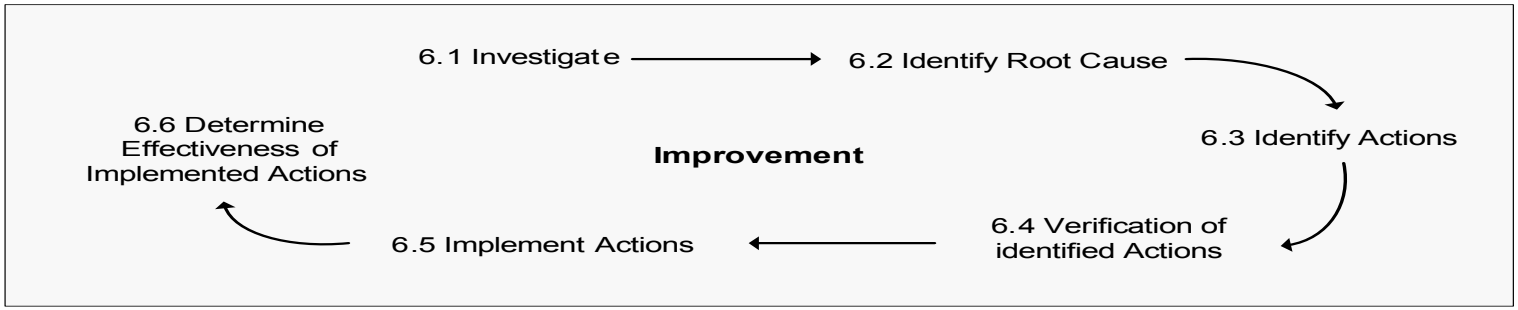
- Phase I: Planning
  - Planning for Measurement, Analysis and Improvement Processes
  - Establish Data Sources and Criteria
- Phase II: Measurement and Analysis within and across Data Sources=
  - Measurement
  - Analysis



This figure show that the outcomes of measurement and analysis

4. Phases

Phase III: Improvement



- Investigate
- Identify Root Cause
- Identify Actions
- Verification of identified actions
- Implement Actions
- Determine Effectiveness of Implemented Actions

Phase IV: Input to Management

- Reporting to Management
- Management Review

GHTF N18

- SG3/N18: Quality management system - Medical Devices - Guidance on corrective action and preventive action and related QMS processes

- Awaiting final approval from GHTF Steering Committee

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GHTF N19

- SG3/N19: Quality Management System - Medical devices - Criteria for characterizing the significance of QMS deficiencies

- Expected publication date of a proposed draft for public comment: **Mid 2011**

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Future Collaboration With SG3

ISO 13485:2003

- Standard published in 2003
- Corrigendum published in 2008
- Based on ISO 9001:2000
- SG3 and TC210/WG1 in discussions on the content and format of next version of ISO 13485
- Joint face-to-face meeting scheduled for April 2011
- Great interest from some stakeholders to add more prescriptive requirements

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Future Collaboration With GHTF SG3

- On August 8, 2010 the Secretariat of TC 210 sent out a call to all members of the international committee requesting comments on the need to revise ISO 13485

"…At the next joint meeting of ISO/TC 210/WG 1 and GHTF/SG 3 which is tentatively schedule for 11-12 April 2011 in Tokyo, members will be discussing whether a revision to ISO 13485:2003 is necessary at this time. If you feel a revision should be initiated, please submit your comments supporting this using the ISO comment template to Ms. Renee Whitehead at rwhitehead@aami.org by 15 December 2010…"

- SG3 encourages all users of ISO 13485:2003 to submit comments via their national standards body

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QMS Survey

WG3 2010 Update

- Survey on QMS requirements in AHWP member economies
- Survey developed and disseminated to member economies

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Objective of the QMS Survey

- To collect data to gain an understanding of the Quality Management System requirements found in each member country within the Asia Harmonization Working Party.

- The results show :
  - which QMS elements were already mostly taken up by the countries, and identify potential elements for harmonization
  - differences between countries in some other QMS elements, then we can investigate the intent of each of these differences per country, and maybe share best practices among them
  - if member economies lack certain guidance on certain aspects, we can attempt to submit a request to GHTF on address some of these gaps, through a new or existing guidance document from SG03

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General Statistics

- Member economies that participated – **11**
- Total member economies in AHWP - **21**

Current Percentage Completion = **52.4%**

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QMS Survey Summary

QMS Requirement	China	Saudi Arabia	Thailand	Chinese Taipei	Hong Kong	Singapore	Malaysia	Laos	Chile	South Korea	Philippines	Total
Importer	Yes	Yes	No	No	No	Yes	No	Yes	No	Yes	No	5
Seller / Distributor / Authorized Rep	Yes	Yes	No	No	No	Yes	No	Yes	No	No	No	4
Finished Device Manufacturer	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes	9
OEM	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No	Yes	Yes	8
Applicable Standards	ISO 13485 ISO 9001 GMP for medical devices	ISO 13485 ISO 9001 US FDA QSR	ISO 13485 Thai GMP 2005	ISO 13485	ISO 13485 Local Stds	ISO 13485 Good Distribution Practice for MD		Local Stds		ISO 13485 Local Stds	ISO 13485 Local Stds	

Conclusions of this QMS Survey

- Some of AHWP members have requirements over distributors/importers, some don't
- All members economy who have QMS requirements, control the local manufacturer, most members economy control the OEM as well, and one for component suppliers
- Common standard used for QMS requirements (especially for manufacturers) is **ISO13485**; but having country-specific requirements were just as common
- GHTF documents proved to be useful at least as a guide - which is its intent

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Possible discussion points to follow up

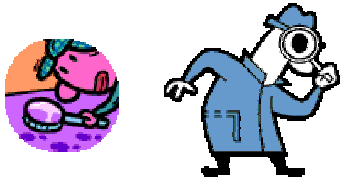
- Should there be QMS requirements for distributors/importers?
- Can we harmonize recertification and surveillance frequencies?
- **Certification requirements – a question on confidence and available resources**

Assessment resources

from local authority vs. 3rd party vs. combo?

Assessment methods

on-site auditing vs. pre-market evaluation?



QMS change control requirements

re-audit vs. written notification?

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QMS Survey Status

- Next Steps
  - Compile responses from **all** member economies
  - Collate and analyze data
  - Present findings
  - Identify opportunities for development (new guidance documents, training, harmonization etc.)

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Thank You