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Asian Harmonization Working Party

WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

WG 3
Quality Management System (QMS)

Ali Al Dalaan, MBA-IT

Vice-Chairperson AHWP TC

Chairperson AHWP WG3

Executive Director, RPS Saudi FDA

History

- WG3 chair joined GHTF-SG3 as a member in June 2008, and participated in the Ottawa meeting, Oct 2008, for the development of N17 (Quality management system – Medical Devices – Guidance on the control of product and services obtained from suppliers).
- Oct 2008, 13th AHWP meeting in India, Delhi WG3 Chair and Vice-Chair elected and establishment of AHWP-WG3 framework.
- finalized WG3 work plan for 2009-2011.
- In Feb 2009, WG3 Vice-Chair Mr. Ronald Goon joined SG3 as a member.
- WG3 Chair and Vice-Chair were actively involved in developing guidance document with SG3.

Membership

Chairperson: Ali M Al-Dalaan
Co-Chairperson: Ronald Goon
Senior Advisor: Tony Chan
Secretary: Ee Bin Liew

South Korea
Han Kyung-ho

USA
Jin Jizhong

China
Huang Jin

Saudi Arabia
Ali Al-Dalaan

Hong Kong SAR
Bryan So

India
Asok Kumar
Kulveen Singh Bali

Thailand
Nakorn Tangwancharoenchai

Malaysia
Ong Yean Ting

Singapore
Ronald Goon
Ee Bin Liew
Sateesh Yelisetti

Member Economies Not Represented in WG3
Abu Dhabi
Brunei
Cambodia
Chile
Chinese Taipei
Indonesia
Jordan
Laos
Myanmar
Philippines
Vietnam

We need your participation and support, as we would like to have at least 1 regulatory authority and 1 industry representative per member country

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Set up of WG3 work

- Developed work plans for 2009 – 2011
- Introduced Comment Form
- Developed & Reviewed comments on N17 (GHTF SG3 guidance document)
- Developed & Reviewed comments on N18 (GHTF SG3 guidance documents)
- Developed & Reviewed comments on N19 (GHTF SG3 guidance documents)

Set up of WG3 work

- **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	

Collaboration between AHWP WG3 and GHTF SG3

- On the organizational side,GHTF- SG3 has strengthened the GHTF's ties with the Asian Harmonization Working Party (AHWP) with the membership of the Chair and Vice-Chair of the AHWP Work Group 3 – Quality Management System .
- Formal invitation from GHTF SG3 Chairperson for WG3 Chairperson and Co -chairperson to be members of SG3.
- WG3 Vice -chairperson participated in February 2009 meeting of SG3 in Tokyo, Japan.
- WG3 Vice -chairperson and SG3 Co-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 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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Collaboration between AHWP WG3 and GHTF SG3

- Participated in the review and development of SG3 guidance 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.

✓ N19 - Quality Management System – Medical devices - Criteria for characterizing the significance of quality management system deficiencies.

- Outcome of collaboration:

✓ Working Draft copies of SG3 guidance documents are shared with AHWP WG3 for their comment.

✓ The Chair of AHWP WG3 does update SG3 from time to time on the work of WP3.

✓ SG 3 met in Riyadh Saudi Arabia Oct. 2010 and jointed meeting with WG 3 anticipated.

✓ WG3 members from either Regulatory Authority or industry activist participated in the development of QMS thru provide their comments and reviewed all documents as Joint work from AHWP WG3 and GHTF SG3.

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SG3 Membership

Ali al Dalaan
Vice-Chairperson AHWP TC
Chairperson AHWP WG3
Director Technical Support and Information Department,
Saudi FDA

Ronald Goon
Co-Chairperson AHWP WG3
Director, Quality & Compliance Worldwide
Johnson & Johnson
Singapore

Canada

Egan Cobbold	HC/MDB (Chair of SG3)
Laila Gurney	MEDEC

US

Kimberley Trautmann	FDA
Gunter Frey	NEMA (Vice-Chair SG3)
Scott S. Sardeson	AdvaMed

Australia

Keith Smith	TGA/OMQ
Ken Nicol	MTAA

European Union

Carlos Arglebe	COCIR Siemens(Secretary)
Dirk Wetzel	EU/BfArM
Emmet Devereux	Eucomed

Japan

Hideki Asai	JFMDA
Munehiro Nakamura	JFMDA
Hirotada Nagai	MHLW
Taishi Nakashima	MHLW
Tsutomu Makino	PMDA
Kneichi Ishibashi	PMDA

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AHWP WG3 & GHTF SG3 – Meeting Summaries

Date			Location		Objective
Day	Month	Year	City	Country	
17-21	October	2011	Alexandria, VA	USA	Revision of the ISO 13485 by ISO TC 210/SG3
10-13	October	2011	Buc	France	1 . Complete “working draft” version of SG3 N19 QMS deficiencies. 2. Prepare for ISO TC 210 meeting in Alexandria, VA, USA, Oct 17-21, 2011 3. Set SG3 meeting location and dates for 2012
13-15	April	2011	Malvern PA	USA	1. Update to SC & SG3 work plan 2. Development of QS related guidance 3. Relationship with AHWP 4. Liaison activities with TC 176 and TC 210 5. Membership 6. Old guidance documents and archived documents.
16-20	October	2010	Riyadh	KSA	Continue design and development of SG3(Draft)N19: QMS deficiencies
7-11	June	2010	Los Angeles California	USA	1.Review public comments on SG3(PD)N18 CAPA and prepare a Final version suitable for submission to SC 2) Continue design and development of SG3(Draft)N19 QMS deficiencies
10-12	May	2009	Toronto	Canada	1) Continue developing working draft of SG3(WD)N18 CAPA 2) Review objectives and framework for SG3(Draft)N19 QMS deficiencies 3) Prepare for teleconference with ISO TC210/WG 1 on draft ISO 13485:20033 Corrigendum 4) Discuss meeting plans for next 12 months
23-27	February	2009	Tokyo	Japan	1) Continue developing working draft of SG3(WD)N18 CAPA 2) Develop draft objectives and framework for SG3(Draft)N19 QMS deficiencies 3) Group discussion and decision on GHTF - Ad Hoc working Group (Combination Products) proposed work items
15-17	October	2008	Ottawa	Canada	1) Review public comments on Draft document SG3(PD)N17R7: Quality management system – Medical devices - Guidance on the control of products and services obtained from suppliers. Revise version N17R7 and prepare a final version for submission to the Steering Committee by mid-December 2008 for their endorsement and approval to publish in February 2009 as a Final GHTF document. 2) Review status of Canberra homework assignments of SG3(Draft)N18 CAPA. 3) Meet with SG1 and SG4 to discuss Work Items of mutual concern

Summary of Collaboration Between WG3 and GHTF SG3

GHTF Guidance Document	GHTF Status	Reviewed by AHWP WG3	Current Status for AHWP
N17 - Quality management system – Medical Devices – Guidance on the control of product and services obtained from suppliers	Publication: 5 Feb 2009	Yes	Adopted by AHWP as guidance document. Previous comments fed back to GHTF for consideration in next revision.
N18 - management system – Medical Devices – Guidance on corrective action and preventive action	Draft	Yes, in process	AHWP comments fed back to GHTF.
N19 - Quality Management System – Medical devices - Criteria for characterizing the significance of quality management system deficiencies	Draft	No	WG3 to provide input on draft.

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Achievements

AHWP WG3 and GHTF SG3

- Active engagement with GHTF SG3 to provide AHWP input and perspective in development of GHTF guidance documents:

✓ Actively participated in reviewing .developing, and finalizing GHTF N17 Quality management system – Medical Devices – Guidance on the control of product and services obtained from suppliers.

✓ Actively participated in development of GHTF N18 Management System – Medical Devices – Guidance on corrective action, preventive action and related QMS processes .

✓ Currently working on development of N19 - Quality Management System - Medical devices - Criteria for characterizing the significance of QMS deficiencies.

AHWP WG3

- developed QMS survey and disseminated to member economies.

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.

- Survey out come

➢ 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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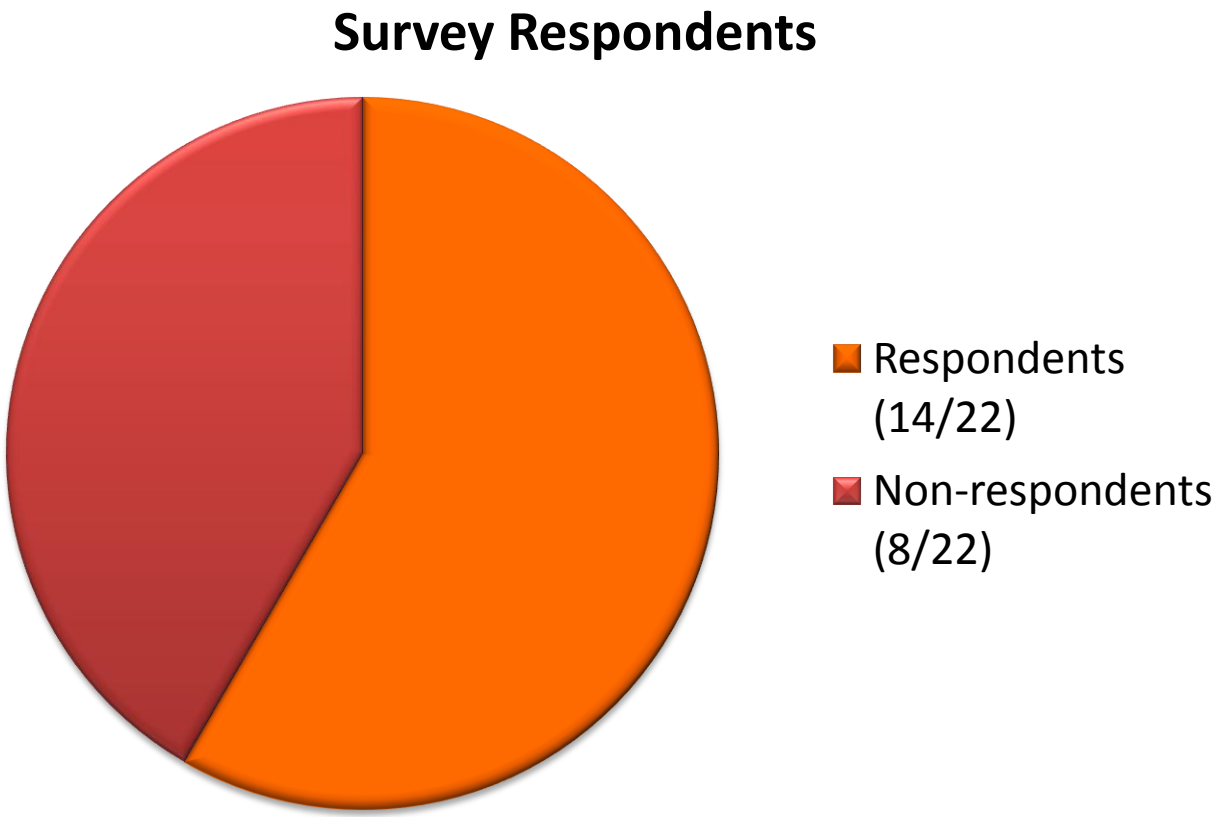
QMS Survey

- Survey initiated in early 2010 with survey form distributed to AHWP member economies in Q2



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QMS Survey

QMS Requirement	China	Hong Kong	Chinese Taipei	South Korea	Chile	Saudi Arabia	Jordan
Importer	Yes	No	No	Yes	No	Yes	No
Seller / Distributor / Authorized Rep	Yes	No	No	No	No	Yes	No
Finished Device Manufacturer	Yes	Yes	Yes	Yes	No	Yes	Yes
OEM	Yes	Yes	Yes	Yes	No	Yes	No
Applicable Standards	ISO 13485 ISO 9001 GMP for medical devices	ISO 13485 Local Stds	ISO 13485	ISO 13485 Local Stds		ISO 13485 ISO 9001 US FDA QSR	ISO 13485 Local Stds US FDA QSR

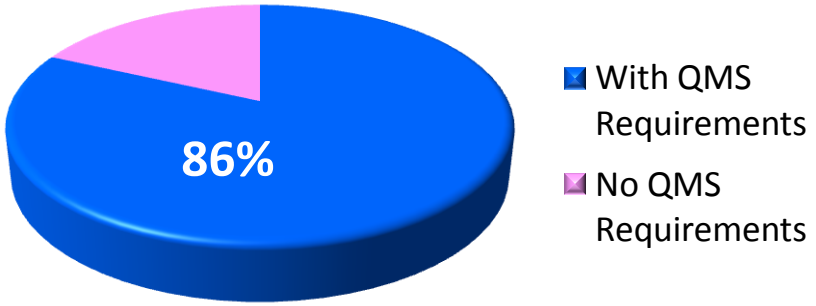
QMS Survey

QMS Requirement	Thailand	Singapore	Malaysia	Laos	Philippines	Indonesia	Vietnam
Importer	No	Yes	No	Yes	No	Yes	No
Seller / Distributor / Authorized Rep	No	Yes	No	Yes	No	Yes	No
Finished Device Manufacturer	Yes	Yes	No	Yes	Yes	Yes	Yes
OEM	Yes	Yes	No	No	Yes	Yes	Yes
Applicable Standards	ISO 13485 Thai GMP 2005	ISO 13485 Good Distribution Practice for MD		Local Stds	ISO 13485 Local Stds	ISO 13485	ISO 13485 Local Stds

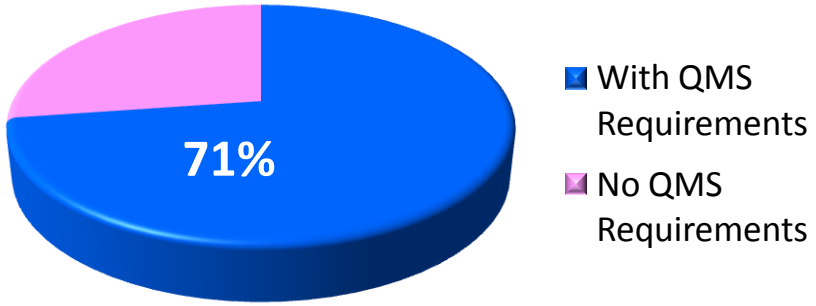
QMS Survey

Member Economies with QMS Requirements

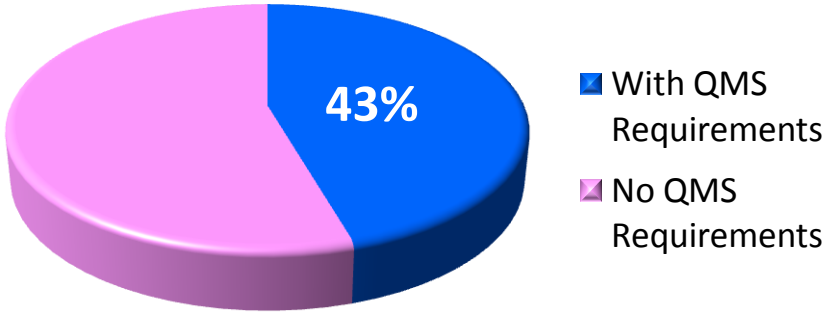
Finished Device Manufacturers



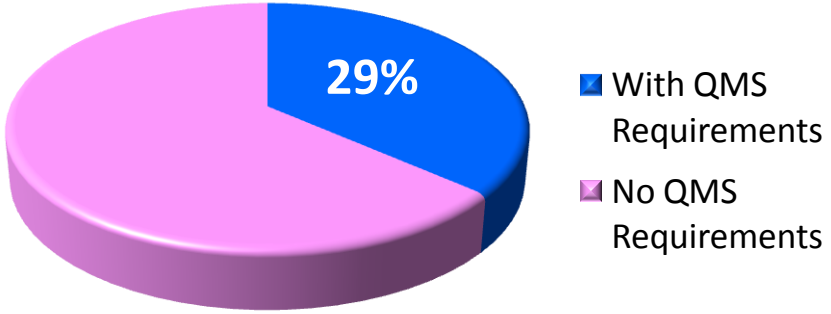
Original Equipment Manufacturers



Importers

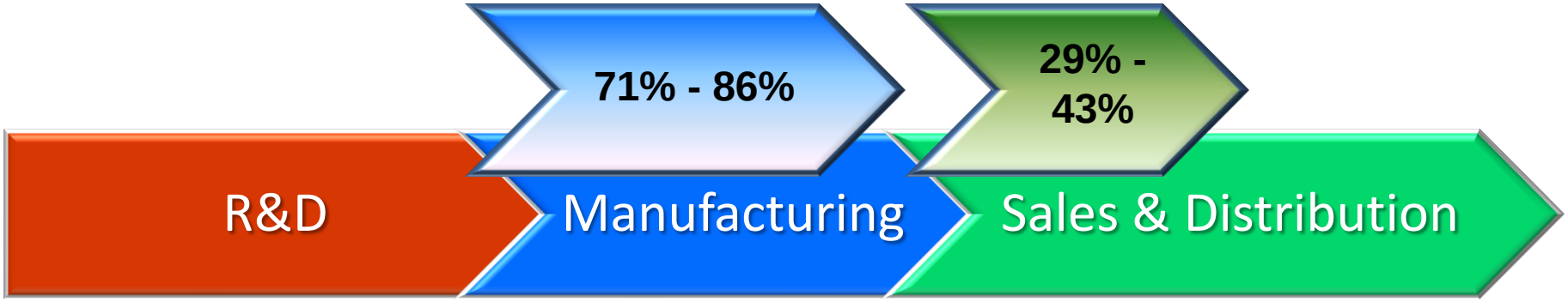


Sellers/Distributors



QMS Survey

- ISO 13485 is the most common standard adopted
  - 83% (10/12) for finished device manufacturing
  - 100% (10/10) for original equipment manufacturers



- Issues for further evaluation
  - Certification and surveillance audit frequencies
  - Assessment resources and methods
  - QMS change control requirements

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QMS Survey Conclusions

- 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.

Brief description for Quality management system Developed by GHTFSG3 &AWHP3

N17- Quality management system– Medical Devices – Guidance on the control of product and services obtained from suppliers:

Scope:

- provides guidance for medical device manufacturers on the control of products and services obtained from suppliers.
- For the purposes of this document:

✓ 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 .
- Final document approved by GHTF Steering Committee on 11 December 2008.
- Document posted on GHTF website on 5 February 2009.
- 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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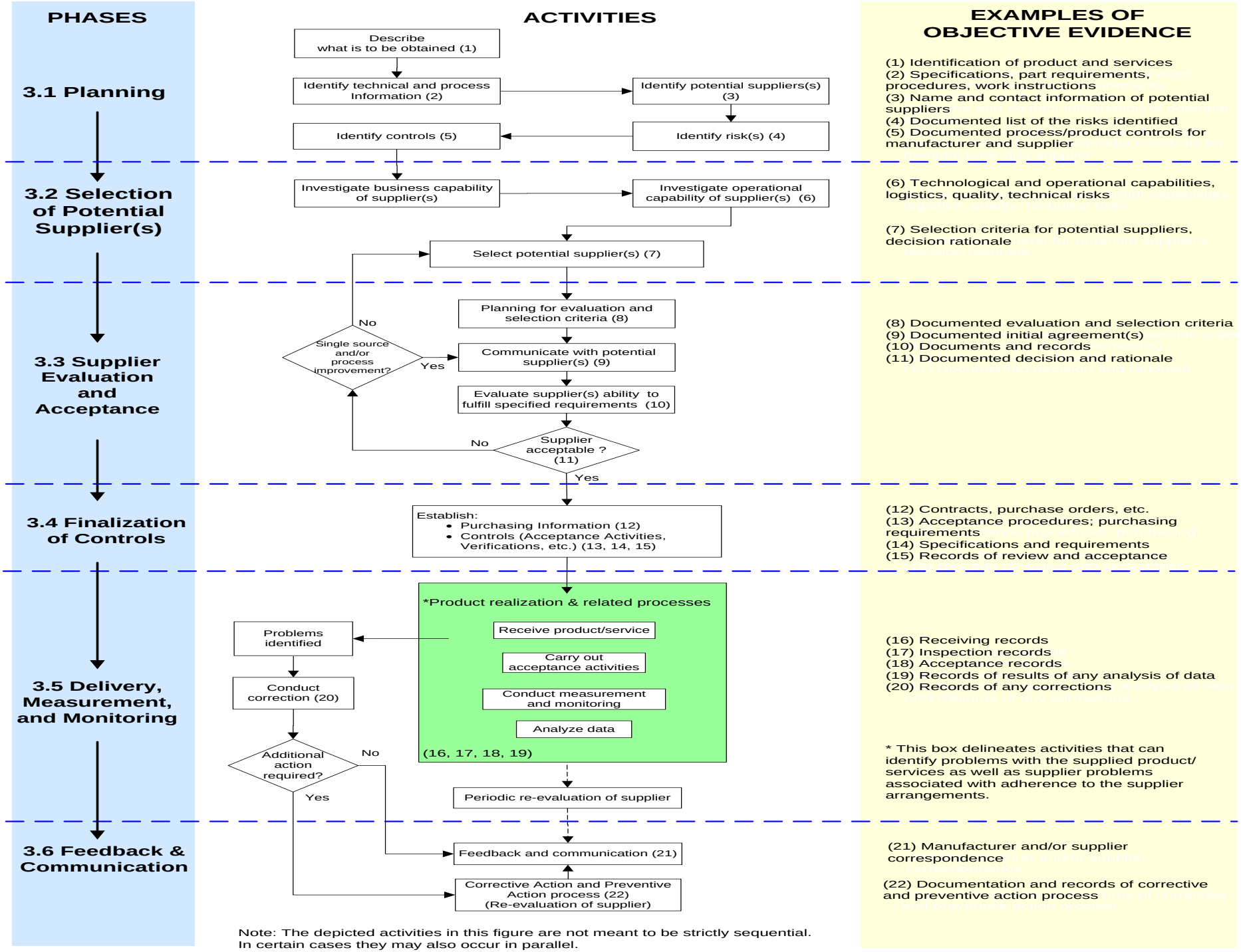
Brief description for Quality management system (QMS) cont

General Principles for N17:

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

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

❑ The diagram below illustrates key activities that a manufacturer would perform, along with examples of the type of objective evidence that could be generated to help demonstrate the manufacturer‘s control:



Note: The depicted activities in this figure are not meant to be strictly sequential. In certain cases they may also occur in parallel.

Brief description for Quality management system (QMS) cont.

- **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

- Selection of potential suppliers

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

- 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

Brief description for Quality management system (QMS) cont.

- **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)**

Brief description for Quality management system (QMS) cont.

- **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**

- **Feedback and communication**

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

✓ **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).**

✓ **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).**

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

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

Brief description for Quality management system N18

N18- management system–Medical Devices–Guidance on corrective action and preventive action

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.**
- WG3 Chair and Vice -chair were actively involved in developing guidance document with SG3.
- Document has been distributed to AHWP member economies and awaiting comments/feedback.
- WG3 reviewed comments/feedback and evaluated document for adoption by AHWP in due course.
- Documents will be reviewed by GHTF SG3and AHWP WG3 as part of ISO13485 revision

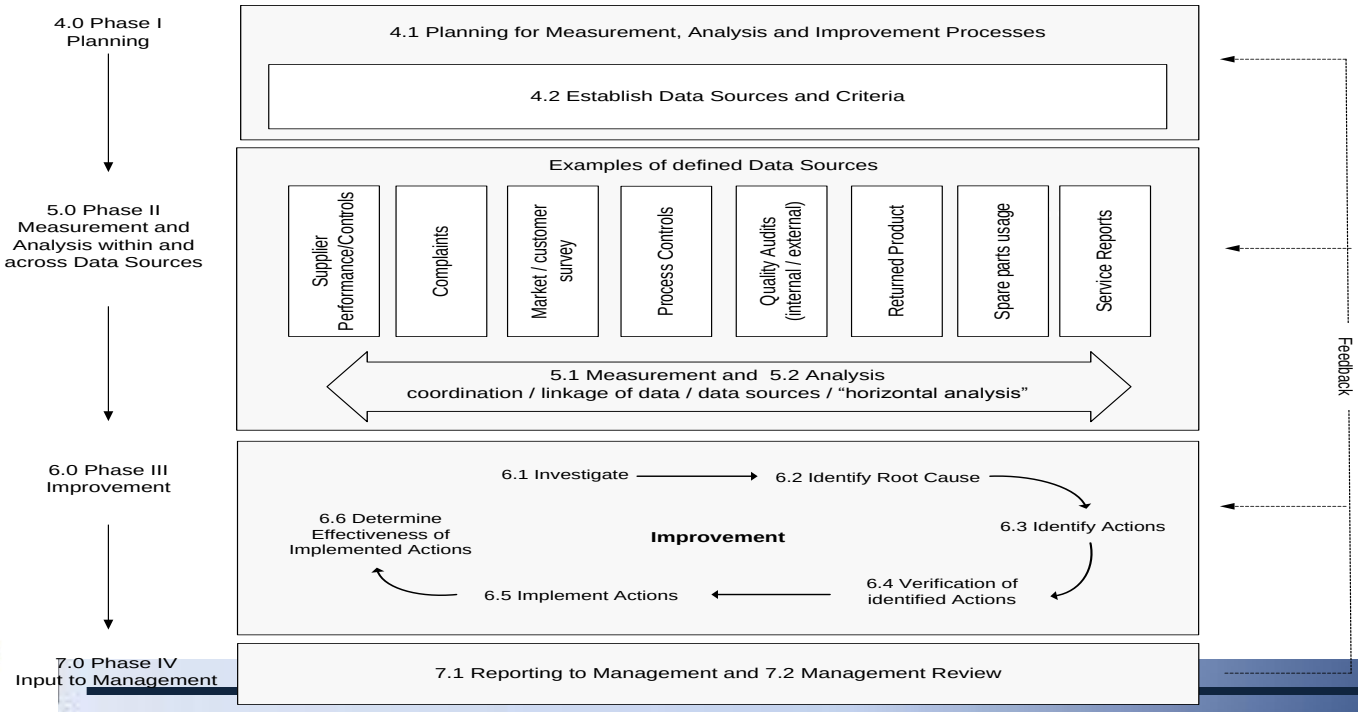
Brief description for Quality management system (QMS) cont.

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

Brief description for Quality management system (QMS) cont.

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.**



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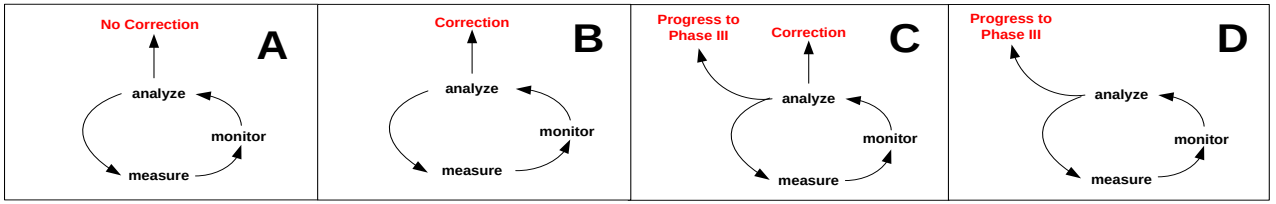
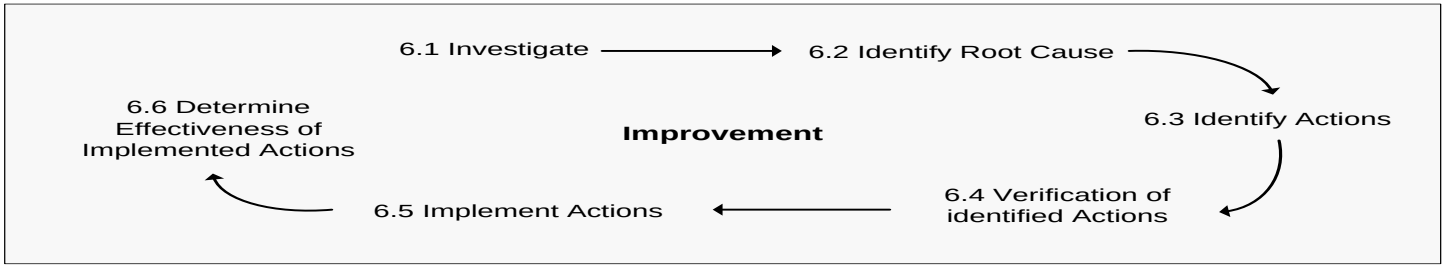
Brief description for Quality management system (QMS) cont.

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.



- **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

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Brief description for Quality management system (QMS) cont.

N19 - Quality Management System – Medical devices - Criteria for characterizing the significance of quality management system deficiencies

- Expected publication date of a proposed draft for public comment: Mid 2011.
- Document currently being developed by SG3 with active involvement/input from WG3.

AHWP WG3Achievements

- Adapted N17 (Guidance on the control of product and services obtained from suppliers) as joint work with GHTF SG3.
- Developed N18 (Guidance on corrective action and preventive action) as joint work with GHTF SG3.

- Circulated N18 to be reviewed by AHWP member economies and industry to be adopted
- Participate in development of N19 with GHTF SG3

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AHWP WG3 Achievements. cont.

N17: Guidance document on control of suppliers

- WG3 Chair and Co-chair were actively involved in developing guidance document with SG3
- WG3 members have reviewed this document and comments/feedback from regulators and industry of AHWP member economies
- No significant issues were raised or identified that required modification of the document for use by AHWP
- This documents adopted by AHWP with no changes

AHWP WG3 Achievements. cont.

N18: Guidance document on corrective action and preventive action

- Document is approved from the GHTF Steering Committee
- WG3 Chair and Co-chair were actively involved in developing guidance document with SG3
- Document has been distributed to AHWP member economies and awaiting comments/feedback
- WG3 reviewed comments/feedback and evaluated document for adoption by AHWP in due course

AHWP WG3Achievements. cont.

ISO 13485:

- ISO is proposing to establish a common management system standard
- ISO 13485 going to be revised
- SG3 (with active WG3 input and involvement) will be working with ISO TC210 to evaluate the impact and options for dealing this proposal

Recommended revisions to ISO 13485:2003

- **Nature of the revision:**

A) Revision to the scope statement in the standard to clarify its applicability to QMS requirements to essential quality system and not to other essential product related to the requirements.

B) Review the contents of GHTF SG3N18 to identify guidance that should be raised the level of requirements.

C) Extension validation requirements and other quality related requirements to quality system software.

Recommended revisions to ISO 13485:2003 (cont.)

- **Nature of the revision:**

  D) Clarify the different roles and relationships between the organization and other parties in the supply chains defined in various regulatory regimes.

  E) Inclusion of requirement for risk managements beyond the processes related to product realization and extending throughout the life cycle of the medical devices.

  F) Inclusion of requirements related to the post-market information gathering product performance and information gathering during the clinical evaluation of the product for purposes of design validation.

Recommended revisions to ISO 13485:2003 (cont.)

- **Nature of the revision:**

G) The inclusion of requirements related to processes for ensuring the reporting of adverse events during clinical investigations.

H) Allow traceability of design outputs to design inputs to show compliance with product safety and performance requirements, including relevant statutes and regulations.

I) include additional requirements related to “outsourcing” possibly include them among requirements related to purchasing and control of suppliers.

Recommended revisions to ISO 13485:2003 (cont.)

- **Nature of the revision:**

J) Include more specific requirements related to complaint handling that reflect the regulatory requirements related to this subject.

K) include language that clarifies the need for design verification and design validation planning and protocols.

L) Review the Corrigendum “white paper” and incorporate the text changes related to the text formatting changes that were made in the 2008 version of ISO 9001.

Recommended revisions to ISO 13485:2003 (cont.)

- **Nature of the revision:**

M) Include text related to the handling of returned product.

N) Include additional details related to the requirement that the organization clearly define needed environmental controls.

- ISO 13485 Revision User Requirements Survey
- http://www.zoomerang.com/Survey/WEB22CB9ZPRRSP

Future Collaboration With GHTF SG3

- **AHWP WG3 will Continue work with GHTF SG3 and TC 210 and other members of the international committee to review the requesting comments on the need to revise ISO 13485.**
- **AHWP WG3 distributed the ISO 13483 revision survey among AHWP Member Economies as well as industries, and all completed survey sent to ISO TC 210 secretary.**
- **WG3&SG3 encourages all users of ISO 13485:2003 to submit comments via their national standards body**
-

✓ **Wg3&SG3 and TC210/WG1 in discussions on the content and format of next version of ISO 13485.**

✓ **AHWP WG3 will attend ISO 210 meeting that will be hold , March 2012 in UK**

✓ **Great interest from some stakeholders to add more prescriptive requirements**.

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Current Work

Reviewed N18 (Guidance on corrective action and preventive action).

- Initiated survey on the QMS requirements in AHWP member economies and analyzed data from responses received to date.
- Development of N19 (Criteria for characterizing the significance of QMS deficiencies) with GHTF SG3
- Participated with GHTFSG3 ,ISOTC210 for revising ISO 13485

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Current Work .cont.

- Complete AHWP QMS survey by obtaining responses from remaining AHWP member economies and analyzing data
- Complete ISO 13485 Revision user Requirements survey by AHWP Member economies
- Complete development of N19 with GHTF SG3

- Work with GHTF SG3 and ISO TC210 to evaluate need for revision of ISO 13485 and to work on follow-up activities

Adaption Of N18

- AHWP WG3 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

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Title: Quality Management System –Medical Devices– Guidance on the Corrective Action and Preventive Action and Related QMS processes

Authoring Group: AHWP Work Group 3

Ali AlDalaan, MBA-IT
Work Group 3 Chair

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Thank You