



**GHTF SG3 Training (Quality Systems)
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on
Harmonization of Medical
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**SG3/N17R9/2009 “Quality
Management System – Medical
Devices – Guidance on the Control
of Products and Services Obtained
from Suppliers”**

- A Status Update and Introduction -



Study Group 3

- GHTF Final Guidance
- **Title:** Quality management system – Medical devices - Guidance on the control of products and services obtained from suppliers.
- Document available at:
<http://www.gh tf.org/documents/sg3/sg3final-N17.pdf>



Control of Suppliers

- When a medical device manufacturer chooses to utilize suppliers, the manufacturer should ***ensure control over any product or service obtained*** from such suppliers as defined within the quality management system (QMS).
- This ***extends further if the supplier sub-contracts work.***



Scope

- A product or service is one which is purchased **or otherwise received** by the manufacturer.
- A supplier is anyone that is independent from the manufacturer's quality management system.



Scope of Quality Audit/Internal Audit

- This includes a supplier that may be part of the manufacturer's organization but operates under a separate quality management system.
- In other words, if the supplier is not a part of the manufacturer's internal audit (quality audit) scope, then the supplier is under a separate quality management system and is considered an internal supplier. *(Note: These quality management systems may be identical!)*



Scope of Quality Audit/Internal Audit

- Corporations or companies that have corporate quality policies and procedures do not necessarily place all divisions or groups under the same quality management system.
- One division or group can be an internal supplier to another division or group within the same corporation/company.

Internal suppliers are to be controlled in a similar way as external suppliers are controlled.



Internal Suppliers

- The controls for internal suppliers are not necessarily handled through Purchase Orders, Contracts, or the like, but instead other types of control mechanisms such as
 - internal agreements
 - procedures or
 - quality plans.



Manufacturer's Responsibility

- The “manufacturer” or entity, that has the ultimate responsibility for its quality management system, cannot relinquish (contractually or otherwise) its obligation and responsibility over any or all functions within the quality management system. This means **the responsibility for complying with the quality management system requirements cannot be delegated to any supplier** (internal or external) of products and services.



Regulatory Audits

- Regulatory authorities and third parties will inspect/audit a manufacturer to confirm that **objective evidence of control over products and services from suppliers is present, or readily available, at the manufacturer's site.**
- **Failure to have any evidence on-site, or provide access to any objective evidence of the controls associated with products and services from suppliers could result in the manufacturer's quality management system being non-compliant.**



Six Phases of Supplier Controls

- 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 and responsibilities
 - Delivery, measurement and monitoring
 - Feedback and communication, including Corrective Action and Preventive Action processes



Planning

In establishing the controls for product and services obtained from suppliers, it is expected that planning initiates the process.

The output of this activity may be in the form of design and development plans, quality plans, purchasing plans, etc., as defined in the manufacturer's QMS.



Planning

Objective evidence may include:

- Identification of the product and services to be obtained. This can be a general description or a specification, if already available.
- Product and service requirements/specifications for parts, materials, process, software, environment, testing, etc.
- QMS process requirements, such as procedures/work instructions for adverse event reporting, QMS auditing, clinical monitoring, design, manufacturing, calibration, maintenance, verification activities, record keeping, etc.



Planning

Objective Evidence may include (continued):

- Name(s) and contact information of potential supplier(s).
- Documented list of the risks identified.
- Although not a regulatory requirement, it is advisable to document business risks.
- List of potential controls as a result of identified risk(s)



Selection of potential supplier(s)

When selecting potential suppliers the manufacturer should investigate their business and operational capability, which may include technological capability, to ensure that the supplier can provide the necessary quality, safety, performance and reliability of the products and services.



Selection of potential supplier(s)

Objective evidence may include:

- The manufacturer's assessment of the supplier's resources (e.g. facilities, personnel, infrastructure), current product/service portfolio
- Documentation and records provided by the supplier, such as environmental control records, equipment maintenance programs, calibration records, qualification records of appropriate personnel, process validation records, capacity planning, certificates, etc.



Selection of potential supplier(s)

Objective evidence may include (continued):

- Documentation of potential suppliers
- Selection criteria (ideally defined up front), and
- Decision rationale



Supplier evaluation and acceptance

Generally the processes in this section are constructed in the following steps:

- Planning for evaluation and selection criteria
- Communication with potential supplier and refinement of the requirements
- Evaluation of the potential supplier's ability
- Acceptance of the supplier



Supplier evaluation and acceptance

Objective evidence for the evaluation and acceptance phase can be provided through:

- Documented evaluation and selection criteria
- Documented initial agreement(s)
- Documents and records
- Documented decision and rationale



Finalization of controls and responsibilities

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

- Complaint handling
- Root cause analysis (based on e.g. customer complaints)
- Corrective action and preventive action
- Product risk management
- Design



Finalization of controls and responsibilities

Other typical areas (continued)

- Labeling/traceability requirements
- Technical documentation (of the supply)
- Change control requirements
- Creation and retention of documents and records
- Supplier audits (including sub-tier suppliers, if appropriate)



Finalization of controls and responsibilities

Objective evidence may include:

- Contracts, purchase orders, interface agreements etc.
- Acceptance procedures; purchasing requirements
- Specifications and requirements
- Records of review and acceptance



Delivery, measurement and monitoring

In this phase the accepted supplier will deliver products/service according to the agreed arrangements and these products will be used by the manufacturer in the product realization process.

Within this process the manufacturer will establish checkpoints to monitor the supplier's performance to ensure that specifications as well as customer and regulatory requirements continue to be met.



Delivery, measurement and monitoring

Typically these activities consist of:

- Receiving product/service
- Carrying out acceptance activities
- Conducting measurement and monitoring
- Analyzing data

Objective Evidence is the records from these activities.



Feedback and communication, including Corrective Action and Preventive Action process

Provisions should be in place for the manufacturer to inform the supplier of whether the manufacturer's expectations are being met. Feedback should be both positive and negative. The manufacturer should ensure that there are effective lines of communication open to both parties to discuss problems/complaints or other matters. It is important that a relationship be developed between parties so that any problems can be resolved quickly in a cooperative way.



Feedback and communication, including Corrective Action and Preventive Action process

- When problems are identified and corrected there should be a determination as to whether feedback for a successful correction is necessary or whether feedback is given on an ongoing basis.
- If a Corrective Action or Preventive Action (CAPA) is initiated, additional feedback and communication may be necessary. As part of this action the manufacturer may need to re-evaluate the continued suitability of the supplier.



Feedback and communication, including Corrective Action and Preventive Action process

While some of the corrective action (CA) and preventive actions (PA) may be delegated to a supplier, the overall responsibility for these activities resides with the manufacturer.

CA and PA related decisions and effectiveness checks cannot be delegated!

If CA/PA activities are delegated to suppliers, the manufacturer needs to ensure that:



Feedback and communication, including Corrective Action and Preventive Action process

- Provisions for CA/PA related activities performed by suppliers are defined in the manufacturer's QMS.
- Based on the products provided by a supplier, all CA/PA 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).



Feedback and communication, including Corrective Action and Preventive Action process

- The supplier's obligations related to his CA/PA responsibilities 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 CA/PA activities (e.g. timely processing of corrections).
- Documentation and records related to a supplier's CA/PA activities are controlled and readily available.



Feedback and communication, including Corrective Action and Preventive Action process

Objective evidence may include:

- Manufacturer and/or supplier correspondence
- Documentation and records of corrective action and preventive action process

