Supplier Audits – Keeping it Simple

An important part of a successful Quality Management System (QMS) is having a compliant Supplier Management Program. Purchasing Controls, including Supplier Management, are required within the Medical Device Industry, but are also relevant to many industries. Supplier Audits can be a large part of the Supplier Management Program; however, they become overwhelming. This White Paper focuses on requirements per 21 CFR 820.50, ISO 9001:2008 § 7.4, ISO 9001:2015 § 8.4, ISO 13485:2003 § 7.4, ISO 13485:2012 § 7.4 and ISO 13485:2016 § 7.4 and provides ideas for keeping Supplier Audits simple.

Why Are Supplier Audits Important?

Purchasing Controls regulations / standards include Supplier Evaluation and selection requirements. Manufacturers are required to establish and maintain the requirements that must be met by suppliers / external providers. 21CFR 820.50(a) states that each manufacturer shall:

(1) Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented.
(2) Define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results.
(3) Establish and maintain records of acceptable suppliers contractors, and consultants.

ISO 13485:2016 § 7.4.1 provides the following criteria for the evaluation and selection of suppliers:

a) Based on the supplier's ability to provide product that meets the organization's requirements;
b) Based on the performance of the supplier;
c) Based on the effect of the purchased product on the quality of the medical device;
d) Proportionate to the risk associated with the medical device.

It goes on to state the organization shall plan the monitoring and re-evaluation of suppliers. Records of the results shall be maintained.

Similar requirements are also included in ISO 13485: 2012, ISO 13485: 2003, ISO 9001:2015 and ISO 9001:2008.

Supplier Audits, whether On-site or Desktop, can be a key element in Supplier Management Programs. They can also be a useful tool in conducting required supplier evaluations and re-evaluations. They can also be managed in a way that is simple as well as compliant.

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On-site vs. Desktop Supplier Audits

Supplier Audits can be conducted On-site at the supplier's facility or Desktop (remote), depending on the situation. It is up to the Manufacturer to determine which is most appropriate for initial evaluations, as well as for re-evaluations.

On-site audits may provide the opportunity to view the supplier facility, equipment, processes as well as meet with key personnel at the supplier site. This may be desirable for initial evaluations or for critical suppliers. One thing to consider; however, is that audit content can be very similar for On-site audits as well as Desktop audits. This makes Desktop audits a good option when considering time and cost associated with travel, as well as keeping it simple.

Supplier Audit Content

Supplier Audit Content should be appropriate to the requirements, including quality requirements, of the products / services to be purchased. Consider the following:

1. Supplier's ability to meet specified requirements;
2. Supplier performance;
3. Effect of the purchased product on the quality of the medical device (end product);
4. Risk associated with the medical device (end product); and
5. Nonfulfillment of purchasing requirements.

Audit Forms can be created based upon product / service or supplier specific requirements. One approach for simplicity is to generate a single Audit Form which may include the use of check boxes and dictates the sections to be completed. Sections within this form can be based upon the products / services provided. This form can review key, applicable Quality Management System (QMS) elements, while covering product / service / supplier specific requirements. Example categories may include:

1. External Manufacturer (Subcontractor for Finished Goods, subassemblies, etc.)
2. Raw Material Supplier
3. Distributor
4. Service Provider (Consulting, Design, Calibration, Preventive Maintenance, Repair, Pest Control, etc.)
5. Tooling, Custom Equipment, Software, Facilities
6. Sterilization (Ethylene Oxide Sterilization, Gamma Radiation, etc.)
7. Laboratory Testing
8. Records Management / Storage

Whether a single Audit Form is created, or if applicable Audit Forms are created per category, applicable requirements based upon the above considerations should be addressed. This may also include content specific to applicable regulations / standards.

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Objective Evidence

Upon execution of the Supplier Audit, it is important to review Objective Evidence. During On-site audits, Objective Evidence may be reviewed and evidence of the review noted on the Audit Form. This may include reference to procedures (numbers, titles, revisions, etc.), validation reports (numbers, titles, revisions), training records (per employee, training type, etc.), production records (products, work order numbers, lot numbers, etc.), etc.

It is important to note, that this level of review can also take place for Desktop Audits. There may be occasions where suppliers are hesitant to provide proprietary documents for Desktop Audit purposes; however, these concerns can often be addressed through the completion of Non-Disclosure Agreements (NDA). With an NDA in place, a Desktop Audit can be completed with a thorough review of Objective Evidence in support of the audit results.

Documentation

Upon completion of the Supplier Audit, document the results. Documentation within the relevant Audit Form, making reference to relevant Objective Evidence is appropriate. An On-site Audit Report may be finalized with the Auditor's signature and date. For Desktop Audits; however, it is beneficial to also obtain a signature and date from a Supplier Representative. This confirms that the Supplier participated in the Desktop Audit, and is aware of the Audit Report contents. The requirement for this; however, may be determined by the manufacturer.

Maintain the completed Audit Report with Objective Evidence according to Supplier Management Program requirements and in accordance with record retention requirements.

Summary

Supplier Audits are an important part of a successful QMS and can be utilized to fulfill criteria within a Manufacturer's Supplier Management Program. Supplier Audits can be conducted as On-site audits or Desktop Audits, depending on the needs of the Manufacturer. Whether conducted On-site or Desktop, Supplier Audits are a useful tool in conducting required supplier evaluations and re-evaluations. The use of simple Audit Forms (checkboxes, single form, etc.) as well as selection of Desktop Audits, where appropriate, may simplify the Supplier Management Program, while maintaining compliance.

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