Supplier Audits – Conducting Desktop Audits

You are participating in a risk based Supplier Management Program. You have multiple Supplier Audits to conduct, a limited budget and a tight schedule to adhere to. What can you do?


When Is a Desktop Audit Appropriate?

As discussed in Supplier Audits – Keeping it Simple, 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.

Within a risk based Supplier Management Program, manufacturers have the ability to provide a risk score to each Supplier, based upon the materials / services they provide and the resulting impact these materials / services have on final product quality. The risk
scores established can help to determine Supplier Criticality and whether a Desktop Audit is appropriate, or if an On-site Audit is required.

What Should a Desktop Audit Consist of?

Supplier Audit Content should be appropriate to the requirements, including quality requirements, of the products / services to be purchased. Supplier Audits – Keeping it Simple provides additional detail on Supplier Audit Content, including Audit Form creation information.

A good way to start the Desktop audit process is to ask the supplier what regulations / standards are applicable to them. Ask the supplier to provide their FDA Establishment Registration Number and any ISO certificate(s) they hold, where applicable. FDA Establishment Registration shows that they are subject to FDA inspection and applicable Good Manufacturing Practices (GMP) regulations. ISO Certification shows that they have completed an ISO Audit(s) and demonstrated compliance to the relevant ISO standard(s). In these situations, it is likely that the Supplier has a strong Quality Management System (QMS). This information can aid in the determination of how in-depth the Desktop audit should be.

Example Desktop Audit Form Questions

If the supplier has confirmed that they are FDA Registered / ISO Certified, the Audit Scope may be reduced to request information specific to the needs of your organization / product. The following areas may be of particular interest for material suppliers:

1. Personnel
a. Are your employees trained to perform their job functions?

2. Purchasing Controls:
   a. How do you qualify and maintain your suppliers?
   b. Do you maintain an Approved Supplier List?

3. Production and Process Control:
   a. If you perform testing on product, is your testing equipment calibrated?

4. Acceptance Activities:
   a. Do you inspect / test any product upon receipt?

5. Nonconforming Product:
   a. Do you have a specific area to store non-conforming product?
   b. How is Nonconforming product handled (Scrapped, Reworked, Used As Is, Returned to Vendor)?

6. Corrective and Preventive Action (CAPA):
   a. Do you have a CAPA system?

7. Complaint Files
   a. Do you have a system for receiving and investigating customer complaints?

8. Change Control:
   a. Do you have an established procedure for change control, which includes customer notification of changes?
These questions can be modified to suit the products / processes provided by the supplier. Additional explanations and support information can also be requested as Objective Evidence. This may include document references (numbers, titles, revisions, etc.) as well as the provision of actual support documents (calibration certificates, Certificates of Analysis / Conformance, production records, training records, etc.).

For suppliers that are not FDA Registered and/or ISO Certified, these same questions may apply, but can also be expanded upon. At times, it may be worthwhile to provide an audit form requesting information on all QMS elements.

**Documentation**

As discussed in Supplier Audits – Keeping it Simple, documentation of the Supplier Audit results is necessary. Documentation within the relevant Audit Form, making reference to relevant Objective Evidence is appropriate. Request the Supplier’s signature and date on the Audit Report (completed Audit Form) as evidence that the Supplier participated in the Desktop Audit, and is aware of the Audit Report contents.

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

**Summary**

Desktop Supplier Audits can be a useful tool in conducting required supplier evaluations and re-evaluations. A risk based Supplier Management Program can aid in the determination of when a Desktop Audit is appropriate.
Performing the audits with a focus on relevant standards / regulations for the products / services provided by the supplier can provide the same information that would be viewed during an On-site audit. Requested information and Objective Evidence, along with the signed Audit Report can be retained according to Supplier Management Program Requirements. Overall, a Desktop Audit process can save time and reduce cost, while maintaining compliance.

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Nola Benstog is a diversified professional with a thorough knowledge of Quality Management Systems. She has over sixteen years of experience in the areas of Quality Assurance, Quality Control, Regulatory Affairs, Validation and Sterilization in both industry and consulting roles. She has worked in the medical device, pharmaceutical, combination product and nutritional supplement industries with experience ranging from start-ups to Fortune 100 and 500 companies. She began her career as a Technician in a Microbiology Lab and has held various positions up to the Executive Management level throughout her career. Nola received a Bachelor of Science in Microbiology from Weber State University and a Master of Business Administration from Utah State University. She has been an American Society for Quality (ASQ) Certified Quality Auditor (CQA) since 2007.

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