The Supplier Auditing paper is a compilation of seven (7) subject matter blogs from industry consultant Rob Packard. Rob shares tips, best practices, pitfalls to avoid and his own auditing experiences. Christine Park, quality expert, and guest author, also contributes one blog. And includes:

- Who Does Supplier Audits in Your Company?
- Which Suppliers Should You Audit?
- The Supplier Audit Agenda
- How to Finish Your Audit Schedule by December 31st
- Supplier Survey with a Twist
- Supplier Evaluation – Less is More
- Supplier Evaluation – Take 5
- When are Supplier Quality Agreements Most Beneficial?

Who Does Supplier Audits in Your Company?

I believe that there are three primary purposes for conducting supplier audits:

1. "For cause" audit, where the auditor is investigating the root cause of a nonconformity
2. Qualification audit, where the auditor is assessing if the supplier should be added to the Approved Supplier List (ASL)
3. Re-evaluation audit, where the auditor is verifying that the supplier is maintaining proper production controls

The problem with these three audits is that most companies send the same people—regardless of the purpose. Usually companies send a purchasing manager or a supplier qualify engineer to conduct supplier audits. Occasionally, the two will do a team audit. Resources for auditing suppliers are tight in most companies. Therefore, I do not recommend this "one size fits all" approach. Instead, I believe that each purpose should be matched up with a specific type of auditor.

"For cause" audits need a supplier quality engineer who has strong investigational skills and will be able to identify the root cause(s) of a nonconformity. The auditor should also be capable of training the supplier on how to respond effectively to a Supplier Corrective Action Request (SCAR).

Qualification audits are ideal opportunities for a team approach. There are quality issues to consider, but there are also financial, scheduling and capacity issues. A cross-functional team approach works best in this case. A team also reduces the potential for biased individuals making inappropriate recommendations.

Re-evaluation audits should not be conducted by purchasing or supplier quality engineers. The reason is that neither position is typically responsible for performing incoming inspection. If you don't perform inspections regularly, you may not be aware of all the problems to search for. Therefore, I recommend using QC inspectors for this activity. QC inspectors know exactly which quality issues have been found recently, because the QC inspectors identify defects during incoming inspection, in-process inspections and during final inspections.

I don't think that my approach to "For Cause" or Qualification audits is unusual. However, using QC inspectors to perform supplier audits is uncommon. There are two other reasons why I believe companies should consider this approach. First, inspectors would get a rare opportunity to go on a business trip and be reimbursed for the travel. For those employees that rarely travel, this can be an opportunity for recognition by management and a perk (i.e., – free meal, lodging and travel). Second, supplier quality engineers could easily fill in for a QC inspector to become more familiar with parts and components, as well.

Which Suppliers Should You Audit?

There are two criteria that are the most popular for evaluation of suppliers: 1) percentage of lots accepted, and 2) percentage of on-time delivery. Both of these metrics have potential limitations. For example, what if a good supplier ships only two shipments this year and there is a problem with one shipment? The reverse is also possible. What if a bad supplier ships lots every week? Ten bad lots per year will result in an 80% quality rating.

On-time delivery has other issues, such as, does purchasing update the due date in the MRP system when they ask suppliers to push out the delivery date due to soft sales volume? If a supplier expedites an order in half the normal time in their "best effort" to meet your requested due date, should they receive a negative result for percentage on-time delivery if they are one week late?

The points above help identify limitations of supplier metrics. In the end, if you have a critical supplier—there is no substitute for auditing them. Unfortunately, auditing costs money. So which suppliers should you visit?

The "critical suppliers" is often the answer, but how do you decide who is critical? Well…benchmarking is a good idea. For example, a Notified Body (NB) must audit "critical suppliers" that do not have ISO 13485 certification. They define "critical" as subcontractors that perform high-risk processes, such as contract sterilization, subcontractors that perform contract packaging, and suppliers that manufacture finished devices. Health Canada even provides some

guidance on the definition of critical subcontractors and how the NB shall determine which "subies" need to be audited.

Internally, your supply chain and quality assurance team have to develop a list of suppliers that will be audited. In general, I recommend that all "critical" suppliers be audited at least once every three years (equal to the certification cycle). However, your auditing schedule is a plan that should have "wiggle room." You may want to add a supplier with new quality issues that appeared after the initial audit schedule is developed, or within close proximity to another supplier you were going to audit anyway in order to reduce travel costs. You may also want to postpone your visit when other priorities take precedence.

Practically speaking, you might just decide to audit your 10 worst suppliers each year. This might be determined by qualitative, cross-functional rankings, rankings for nonconforming materials, or by the number of supplier corrective action requests. There is no "right" or "wrong" way to determine which suppliers should be audited, however, the best companies have strong supplier quality programs to reduce scrap.

The Supplier Audit Agenda

When you attend a lead auditor course, the focus is on Quality System auditing. However, when you perform a supplier audit—the Quality System is not the focus. The focus of a supplier audit can fall into two primary categories: 1) qualifying the supplier, or 2) re-evaluating the supplier.

Suppliers are not required to have a registered Quality System. Therefore, many of the things that an auditor might learn about audit agendas in a lead auditor course just don't apply. However, one thing always applies: reviewing previous quality issues. When I audit internal auditing and supplier auditing programs, I find that one of the most common mistakes is failure to close-out previous nonconformities. Therefore, the second section of my audit report template is a review of previous audit findings. If you have no previous findings, ensure your audit report states that. If you are qualifying a new supplier, ensure that the new supplier doesn't have the same problems you are having with current suppliers.

When you close the previous issues, there are two approaches. The first approach is close previous issues at the beginning of the audit—immediately after the opening meeting. This is the most common strategy. The second approach is to close previous issues as you audit the applicable area. For example, if you have previous issues in the area of incoming inspection and maintenance records, it might make sense to close these findings when you audit these areas. The advantage of

this second approach is that it ensures that the process owner is closing the previous finding and facilitates the sampling of additional records.

What has little value in the supplier audit agenda? Auditing the Management Review process has the least value, because the supplier is not required to have a Quality Management System. In fact, subcontractor audits for BSI never include management reviews, CAPAs or internal audits—the three required areas for every quality system audit.

What are the most valuable areas to audit? Incoming inspection, control of nonconforming materials, preservation of product, production controls, training and process validation are the areas I typically audit. I like to start in the nonconforming material area and see which materials are on hold. Then I like to sample the incoming inspection records for those raw materials. Next, I like to see how the company is storing those raw materials—if they are accepted. I typically cover these three areas as one process audit. This also happens to be the process audit I like to use for training new auditors, because the audit of incoming inspection results in numerous audit trails in the support process areas of document control, training, calibration, etc.

The next area I will go to is the production area. For this portion of the audit, I am doing a process audit of the production process. I usually request that we schedule the audit for a time when the production area is actually running the product(s) of interest. A process flow chart is helpful in planning this portion of the audit, and I will often write some notes directly on a copy of the process flow chart.

I conclude the audit with follow-up trails in the areas of: 1) document control (to ensure the supplier has the most current versions of all documentation "we" provided), 2) calibration (to ensure that all measurement devices used for inspection are calibrated), and 3) training (to ensure that all personnel working on "our" product are properly trained).

Since I do not have to spend time on Quality System issues during a supplier audit, I spend more time sampling records in the other areas. Therefore, I might sample 5-10 records in each of the above areas instead of 3-4 records. In fact, if the number of samples available to sample is small, I may even sample 100% of the records.

How to Finish Your Audit Schedule by December 31st

Let's say that there are 34 days until the end of 2013. You have four supplier audits and three internal audits to complete. Of course, all but two of these audits are overdue. What should you do?

Options that might be readily available to you include:

1. Get some help
2. Perform remote audits
3. Reschedule some of the audits for next year

There are some great cartoons and jokes about doing more with less, but if you intend to complete seven audits before the end of the year you might need some help. There really isn't any time left to train someone, so that they are capable of conducting an effective audit by themselves. In fact, I expect training a new auditor to take at least six months before I believe they are ready to work solo. Even if you are less demanding than I am, you still would need time for classroom training and shadowing a couple of audits. Therefore, the best I believe you could hope for is one or two solo audits of the seven you need to complete.

Realistically, your only source of help would be auditors that are already trained and consultants. The last month of the year is historically very busy for everyone–especially quality assurance auditors. Therefore, consultants will not be cheap, and you should commit to any qualified consultants that are available without too much delay (then again, maybe they are available because they are not very good). If you have any in-house auditors that are already trained, do everything you can to get some of their time in the next few weeks.

Option two is to perform remote audits. This is a viable option for you to justify for a supplier with an impressive quality track record, or suppliers in other countries. However, a remote audit is not the same as asking a supplier to complete a survey. ISO 19011:2011 provides some guidance specific to remote auditing in table B.1 of Annex B.

For a remote audit, you should still sample just as many records—if not more. You should conduct interviews by phone, Skype or some similar technology. You should analyze any available data to help identify which processes appear to be effective and which processes need to improve. If you are performing a remote audit for your first time, I recommend focusing on the same processes that you would normally audit in a conference room, rather than processes that you would typically audit where they occur—such as production controls. Regardless of which process you check, you should always request data.

Option three is to reschedule some audits for January 2013. I have suggested this so many times to clients, but very few follow this advice. If your company is late in conducting some audits, the important thing to do is to document this, reschedule the audits, and take corrective action(s) to prevent it from recurrence. If you wait until January, you will have additional time to train an auditor, as well. Finally, consultants historically have more time available in January than December.

In parallel with your efforts to catch-up on your schedule, I also recommend the following:

Create a quality objective that measures "on-time delivery" of audits and audit reports. This is an effective metric for managing an audit program.

Investigate the reasons for audits being overdue. If the occurrence was preventable, then I recommend initiating a CAPA. This will have two effects. First, your third-party auditors will see that you have identified the problem yourself and taken appropriate corrective action(s). If you also discuss this during a Management Review, this information can be used effectively to change the grading of an audit finding to a "minor," or to potentially eliminate the finding altogether. Second, it will ensure that this doesn't occur again.

Supplier Survey with a Twist

I must admit, the first supplier survey I ever used was copied from another company and we just changed the header. You might think this is quite unethical, but get real. I have seen that exact same survey form during at least a dozen audits I have done over the past decade. I have also had to fill out that document.

You know the one…it's 29 pages long and asks you a bunch of inane questions that nobody will care about.

To fix the mess we have all created, I have a few simple suggestions:

1. Don't copy another supplier survey forms and make your own form instead.
2. Cut your survey down to **ONE** page.
3. Focus on collecting supplier information first.
4. Require suppliers to update this form at least annually, or when they change something.
5. Ask open ended questions.

29 pages is insane. Who thought that was a great idea? Personally, I think the theory behind this approach is that we will screen out the really poor suppliers that don't want our business in the first place. In reality, management delegates the completion of this form to a subordinate that they want to punish. I don't think I need to explain the theory behind a one-page document.

You need supplier contact information, size of the facility, number of employees, shifts, website, software capability, etc. This is obvious information that you need to know about your supplier.

Ensure you give the supplier this form in MS Word format, so they can fill it in with minimal effort. Next year, when you want them to fill it out again, give them the original in MS Word format, so they can redline changes. This makes it easy to see what changed and reduces the effort required to update this annually. Why do you need a signature and date on this stupid form? I do not know. If you can think of a good reason, go ahead and make your supplier sign and date the form. If you can't, don't require a signature and date just because everyone else does.

You should have a supplier agreement that requires notification of changes. This should include significant changes to the QMS. Updating the supplier survey is a great way to do this—especially if the supplier can redline the previous version.

My last suggestion is probably the most valuable. For those of you are competent interviewers, you should know the difference between closed-ended and opened-ended questions. For the rest of you, "closed-ended" questions ask for a response of "Yes" or "No." It makes it easier to complete 29 pages in less than a day, but it's also easy to identify the answer that the customer wants to hear. For those of you that have Canadian Medical Devices Conformity Assessment System (CMDCAS) certification, take a look at GD210 sometime. The back of this document has a checklist with clause-by-clause questions. 100% of these questions are "closed-ended." Here's an example: For clause 5.6.2, the GD210 checklist asks, *"Is a review of new or revised MDR part of the input to management review?"* Examples of "open-ended" questions related to clause 5.6.2 would be:

When was your last Management Review?

1. What were the new or revised regulatory requirements discussed in the last Management Review?
2. Who was in attendance at the last Management Review?
3. How many action items resulted from the last Management Review?

You should notice that not only are these four questions open-ended, these are all non-proprietary questions that a supplier should be willing to answer.

Supplier Evaluation – Less is More

Most of the procedures Supplier Quality Engineers write are comprehensive. We all want more data because we think it will help us make better decisions, but I think simple systems are often more successful.

For example, the following system uses just two metrics: 1) the percentage of orders delivered on-time, and 2) the percentage of nonconforming lots. The reason why this works well is that companies can generate automated reports quickly and run the reports frequently. More frequent reviews of suppliers are more effective than annual comprehensive reviews. This is the same argument used for planning internal audits. Most companies favor monthly internal process audits instead of one annual full-quality system audit.

If you want to add more inputs to the supplier evaluation process, think carefully about how difficult it is to collect data and how frequently reports should be generated. Aging of Supplier Corrective Action Requests (SCARs) is a great metric to track, but if a supplier only receives one SCAR per year—how frequently would you run this report?

To be useful, you need metrics that provide almost real-time feedback. Statistical data on process capability for critical dimensions or final testing results is available for every production lot. These metrics are also likely to change from lot-to-lot. Asking suppliers for this type of data involves

weekly or monthly interaction with the supplier. As I stated earlier, higher frequency of data collection and data analysis is more important than more data.

Lot-specific data can be used to justify sampling plans for incoming inspection. You might even ask the supplier to graph the data and provide a brief analysis of the results. These are value-added services that suppliers can provide—and should already be performing in an ISO 13485 Quality System. Regular review of in-process and final inspection data also forces regular interaction with suppliers. The combination of real-time data, applying statistical techniques, and communicating regularly with suppliers is the key to successful supplier management.

Supplier Evaluation – Take 5

None of us has unlimited resources. In fact, the pendulum has swung so far that "do less with more" has now become "do everything with nothing."

Here's a familiar situation…During your most recent annual surveillance audit, the auditor gave you the bad news…"The Canadian MDR requires that you audit critical suppliers that do not have ISO 13485 certification, and these two contract manufacturers should be added to the critical supplier category." Once your blood pressure drops enough, so that you are not in immediate danger of having an aneurism, you might think to ask your auditor how frequently these audits need to be performed. Most auditors will allow a three-year cycle between supplier audits, but this is because of the three-year recertification cycle.

Your company should really adopt a risk-based strategy. For high-risk suppliers, an annual or six-month cycle is appropriate. For moderate-risk suppliers, biannual or three-year cycles might be more appropriate. A supplier I audited recently told me a story that illustrates this.

Their company noted that the FDA was inspecting them every seven years—instead of every two years (FDA's goal for Class 2 devices). The FDA inspector explained that the local office only had enough resources budgeted to perform 50 inspections per year. Each year they take start at the top of their priority list and work their way down the list. Each year that this company fell below the 50-company cut-off, the company moved up the list for the next year. It took them about 7 years to reach the top 50.

In your company, you have a limited number of Supplier Quality Engineers (SQE's) that are available to audit your suppliers. Since SQE's have lots of other job duties, in addition to on-site auditing, I recommend the "Take 5" approach. What I mean is: 1) prioritize your list of suppliers based upon risk (including how long it has been since their last audit), 2) pick the top five highest risk suppliers and schedule those audits throughout the year, and 3) hire another SQE for every fifteen suppliers (5 supplier audits/year/SQE x 3 years/cycle = 15 supplier audits/SQE/cycle) that require on-site auditing. The number "5" is arbitrary, but "5" is in the right order of magnitude.

SQE's are responsible for monitoring supplier performance, issuing SCAR's, follow-up on SCAR's, updating drawings, communicating revision changes to suppliers and qualifying new suppliers. If an

SQE is doing more than five on-site supplier audits per year, it will be important for these suppliers to be local. Otherwise, these valuable employees will get burned out fast.

Review your own Approved Supplier List (ASL) and ensure you have properly identified "critical" suppliers. Review your supplier evaluation procedure to ensure that it gives you the flexibility to revise the audit frequency on a risk basis. Finally, review your SQE resources…hiring, recruiting and training a new SQE every two years will cost as much as adding an SQE when the ratio of supplier audits per auditor has exceeded the magical number "5."

When are Supplier Quality Agreements Most Beneficial?

Guest Blog, by Christine Park, *Quality Architech*

There is no one-size fits all approach to developing supplier quality agreements. They are not necessary for all suppliers, and can be used in a variety of business situations, including:

- Original Equipment Manufacturer (OEM) agreement – business arrangement for distribution of product designed and manufactured by another organization, or for another company to distribute your company product. Primary focus for this type of agreement would be regulatory, distribution, traceability, complaint management and CAPA.
- Contract manufacturing – manufacturing is outsourced to another organization. Primary focus for this type of agreement would include design transfer, process controls, including device history, document controls, records management, process validation, risk management, change management, traceability, complaint management, failure investigation and CAPA.
- Contract design – product design is outsourced to another organization. The primary focus for this type of contract would include regulatory, design controls, with emphasis on verification and validation, change management, risk management and document controls, specifically design history file, complaint management.
- High criticality suppliers – These suppliers usually provide major components, or subsystem used in the manufacture of product or finished device. Some examples include suppliers of finished product labeling, custom software, printed circuit boards. FMEA would identify the product or process as a Critical To Quality (CTQ) item. The primary focus for this type of contract would include regulatory, process controls, risk management, change management, document control, record management, traceability, supplier management, traceability and CAPA.
- Services – this may include consulting agreements, calibration, distribution and logistics, or other services critical to the business.

Supplier quality agreements are most beneficial when dealing with OEM and/or high-risk relationships. The challenge is ensuring suppliers are capable of meeting our expectations before

entering into a contractual relationship. This maximizes the potential for success – both financially, and in terms of customer satisfaction.

Once the quality agreement is defined and both organizations understand expectations, it is critical to communicate requirements to other functional groups. The quality agreement should be viewed as procedural in nature and implemented as such. You will need to provide evidence supporting the various agreements in place. Here are some examples for you to consider:

- Both parties agree to implement and maintain a training program. When needed, both parties shall support each other with required training to meet quality system requirements at the affected location. What specific type of training would you show to demonstrate the intent of this clause is being met? If you are relying on your internal training process, ensure you can explain how this program meets the intent of the agreement with the other organization.
- Changes to specifications are made by mutual agreement between the organizations. This would normally fall to the change control process. It is important that the development group and purchasing are aware of this requirement to ensure communications take place.
- Supplier maintains quality system records for five years. Your organization requires records be maintained 20 years. Define the process that will be used to transfer the records back to the owner after five years. Who needs to be involved?

The key to successful supplier quality agreements is to understand the needs of your business, as well as those of the supplier. This is best accomplished early in the process – prior to signing the actual contracts and/or agreements. Have you ever been faced with a situation where you need something to support your business (such as translations, extended records management, who owns the regulatory submissions?, etc.) and the supplier says it is not part of the contract? Wouldn't it be a good idea to work through all of those issues and concerns before you sign the contract?

As you go through your supplier list and prioritization, consider which suppliers would be most appropriate for quality agreements. Where do you have your biggest quality liability? Focus your energies on these key suppliers and establish agreements that are beneficial for both sides.

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