Supplier Qualification:
"How To" Lessons from an Auditor

This paper is a compilation of five (5) subject matter blogs from industry consultant Rob Packard. Rob shares tips, best practices, pitfalls to avoid and his own supplier qualification experiences. Christine Park, quality expert, and guest author, also contributes one article. They include:

1. How to Qualify a Supplier
2. 3 Tools for Qualifying Suppliers
3. How do you qualify a supplier that doesn't have a Quality Management System?
4. Why did you Qualify that Supplier?
5. Contract Manufacturers Need Strong Risk Management Processes
6. "Are You Ensuring Supplier Quality" Guest Blog, by Christine Park

How to Qualify a Supplier

Section 7.4 of the ISO Standard states that companies shall *"evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements."* This requirement is vague, but the medical device industry has developed a surprisingly limited number of approaches to address the requirement of this clause. The most common approach is to ask for some combination of the following: 1) ISO certification, 2) a copy of the supplier's Quality System Manual, 3) completion of a supplier questionnaire, and 4) performing a supplier audit. Unfortunately, all four selection criteria are flawed.

ISO Certification

The best way for me to explain why these criteria are flawed is to use an analogy. Let's compare qualifying a new supplier with recruiting a new employee. ISO certification is sort of like a college degree. You can make some general assumptions about a potential job candidate based upon which school they got their engineering degree from, but the degree is still just a piece of paper on the wall. As the old joke goes: What do you call the person that graduated last in their class at medical school? *Doctor.*

Some registrars have a better reputation than others, but the name of the registrar is only as good as its worst client—who had four major nonconformities during their last audit and is about to lose that certificate. To improve this approach to supplier qualification, a potential customer could ask for a copy of the most recent audit report. This information is dependent upon the quality of the audit, but this would be a big improvement over requesting a copy of the certificate.

> CAUTION: Audits are still just samples—very small samples.

The Quality System Manual

The second selection criteria I mentioned is: the Quality Manual. The Quality Manual is analogous to a resume. The purpose of a resume is two-fold: 1) to provide an interviewer with information, so they can ask the interviewee questions without looking like an idiot, and 2) to provide objective evidence that a company did not illegally discriminate against a candidate that the hiring manager did not like.

I suppose you could argue that the purpose is to help candidates get a job, but in my own experience less than 10% of resumes submitted result in a job interview—let alone a job offer. The purpose of a Quality Manual is *NOT* to help a company get new customers. If I am wrong about this, I need to do a much better job of marketing my Quality Manuals in the future.

Some suppliers have the nerve to say that their Quality Manual is proprietary. *Humbug!* Proprietary information should not be in the Quality Manual. You can copy a manual from another company and edit a few of the details. I will gladly write you a Quality Manual in less than a week that will pass any auditor's review. You can even buy a Quality Manual online. This almighty document just explains the intent of the quality system—which is to conform to the requirements of the ISO Standard. Several auditors will tell you that this can be done in just four pages. When you request a Quality Manual from a supplier, your primary intent should be to use this document for the purposes of planning an onsite supplier audit. Any other purpose is just a waste of your time—unless you need to write a Quality Manual of your own.

Supplier Questionnaires

The third selection criteria I mentioned was: a supplier questionnaire or supplier survey. Questionnaires are analogous to employment applications. Coincidently, supplier questionnaires are often required by companies when a Quality Manual or ISO certificate is not available. Do you find the similarities eerie?

Questionnaires are typically 15-20 page documents that someone has plagiarized from a previous employer. I have seen various versions of this questionnaire, but several of them appear suspiciously similar. Hmmm?

I am not sure what the original intent of this type of document was, but I think it was intended to capture detailed information about potential suppliers for a company in the Fortune 500®. For most companies, 80% of the information on the questionnaire is meaningless. Customer requirements for a supplier are typically few in number and specific to the product or service being purchased. Therefore, please use your MRP system as a template and ensure that the questionnaire answers all the information you need to add the supplier to your system as an approved supplier.

You should also have a product or service specification that gives you some more questions to ask. Ideally, your questionnaire will be organized in the same order that you enter the information into the MRP system. Then, this questionnaire will make the data entry easier for the purchasing agent adding the supplier to the database. Questionnaires and surveys are great, but brevity is next to Godliness.

Supplier Auditing

Finally, we come to the auditor's favorite—supplier audits. Audits are similar to job interviews. Ideally, you want a cross-functional audit team and you might need to visit more than once. Unfortunately, most companies cannot afford to audit all their suppliers. Some companies try to perform desktop audits, but these are seldom effective as a method for qualifying suppliers. I guess I think of a desktop audit as a "phone interview." I use phone interviews to prescreen candidates before I pay more money and waste other peoples' time with on-site interviews. Desktop audits of suppliers should only be a precursor to an on-site audit, so your supplier quality engineers do not have to spend so many nights at the Hampton Inn.

Desktop vs. Remote

"Desktop" audits used during the qualification process for a new supplier are not the same as a "Remote" audit used to re-evaluate an existing supplier. Desktop audits historically would only review Quality System documentation, while a remote audit reviews records, metrics, data analysis, nonconformities, etc.

If a supplier has a great performance record, and you have already performed an on-site visit, a remote audit may be appropriate. If you have not performed an on-site visit at a supplier, you probably should not give the supplier any work that you can't verify 100% during incoming inspection.

To build upon the analogy that I began with for the interviewing of a potential employee…A desktop audit is analogous to a phone interview of a potential employee, while a remote audit is analogous to performing an annual review remotely for a subordinate that works at another location. If the news is all good, it's ok to give an employee an annual review over the phone, Skype or GoToMeeting. If the news is not good, you need to show up in person and answer the person's questions. You might also want to suggest ways they can improve.

Picking Your Targets

If audits are your best selection criteria, how can you make the most of your auditing resources? Also, how can you qualify all your suppliers if you only have enough auditors to audit five (5) percent of the approved supplier list? I suggest to "Start at the end."

What I mean by this cryptic, four-word phrase is that auditors should start at the end of the ISO Standard with sections 8.5.2 & 8.5.3 (Corrective and Preventive Action (CAPA Process). This is the heart of a Quality System. If you disagree, remember that FDA inspectors are required to review the CAPA system during every Level 1 inspection. Registrars also review the CAPA process during every assessment—not just the certification audits. The purpose of the CAPA process is to fix problems, so they don't come back—ever.

If you think that a new supplier is never going to make a mistake, you might as well quit looking. You want suppliers with strong CAPA systems. If a supplier has a strong CAPA system, problems will be fixed quickly and permanently. To sample the CAPA process, an auditor only needs the following: 1) CAPA procedure(s), 2) CAPA log(s), and 3) handful of completed CAPA records—selected not so randomly from the log(s). These records can also be reviewed during a desktop audit to improve the effectiveness of your pre-screening process. If suppliers are resistant to giving you the log or actual records, ask them to redact any sensitive information. If you have executed a nondisclosure agreement, the supplier should agree with this approach.

Working from the back of the Standard, the next process to sample is clause 8.4 (Analysis of Data). If the company has a requirement for customer satisfaction to be measured (ISO 9001:2008 section 8.4a), this is a great place to focus. There are four types of information that must be included in data analysis:

1. Customer Feedback,
2. Product Conformity,
3. Process / Product Trends, and
4. Supplier Data.

The quality of the analysis will tell an auditor as much about the company as the data itself. Data analysis records can also be reviewed during your pre-screening process.

Clause 8.3, Control of Nonconforming Materials, is the third area to look at. To sample this area, you will need the "Holy Trinity" again: 1) procedure, 2) log, and 3) records. When you review these records, you want to look very closely at any nonconforming materials that are reworked or accepted "as is". Either of these two dispositions should be ULTRA-RARE. Everything else should be processed efficiently as scrap or Return To Vendor (RTV).

If a potential supplier passes all three "tests" described above, you are ready to address clause 8.2.4—Monitoring & Measurement of Product. In this section, there is a requirement to maintain records of product release and verify that product requirements are met. If the raw materials supplied can be 100% verified, and the supplier is cooperative in supplying all of the detailed data, then you can effectively audit these requirements by paperwork alone. However, if the manufacturing process requires validation or the lot release paperwork, batch record, or Device History Record (DHR) is a 50-page tome—then you had better make flight plans.

The good news is that very few suppliers will pass the first three tests and implode during the on-site audit. Also, with three process audits complete during your desktop audit, you should be able to reduce the duration of an on-site audit. Finally, for low-risk suppliers, you have a strong basis for provisional approval of suppliers to proceed with prototype runs before you schedule an on-site audit.

3 Tools for Qualifying Suppliers

If you could afford to audition suppliers for a few months against hundreds of other competitors, then only the qualified suppliers would be approved. Unfortunately, you don't have the same budget that American Idol has. So what should you do instead?

Most companies use the same three, tired tools to qualify suppliers: ISO Certification, Quality Manuals and questionnaires. ISO certification is a weak tool, because certification is only as good as the registrar's worst client. Quality Manuals are intended o define the intent of your supplier's Quality Management System, while most of the details are located in procedures. You only need a copy of your supplier's Quality Manual to help you plan audits. Supplier questionnaires seem to be the most popular tool, but most of the questions require a "Yes/No" response that suppliers rarely answer negatively. To assess the qualifications of potential suppliers more effectively, try using the following tools instead:

Tool # 1: Statistical Process Control
Most companies require a Certificate of Compliance (CoC) with every shipment. A CoC is useless. Just like the "Yes/No" responses to questionnaires, you will never see a CoC that indicates something is wrong. A Certificate of Analysis (CoA) is much more useful, because the CoA has actual data, and the tolerance range is typically indicated for each test or measurement that was performed by the supplier. The best report you can get from a supplier is a statistical analysis of each specification during the prototype production lot. When you have a Statistical Process Control (SPC) run chart, you know quantitatively if the supplier is capable of making acceptable product. The run chart can also be used to develop an appropriate sampling plan for incoming inspection.

Tool # 2: Process Validation
Process validation is much more than determining if a process is capable of producing a consistent product. An SPC run chart can do that. Process validation tells you what range of operating parameters will produce a consistent product. Therefore, when you have process deviations or measurement devices are slightly out-of-calibration, you will know if your supplier's process will still make acceptable product. The validation of a process should also identify which variables are critical indicators of the process. This information can be used to reduce the number of variables and specifications that are monitored for a production process, and focus both your supplier's resources and your own.

Tool # 3: Supplier Auditing
A multi-disciplinary team audit of a potential supplier is an effective tool for assessing a supplier's qualifications, and will help build a stronger relationship between your team and the supplier's team.

Before you conduct an audit, it is important to plan the audit to ensure you get the greatest possible value. The following recommendations are important to supplier auditing:

1. Use a risk-based approach to auditing suppliers (this goes beyond just critical and non-critical)
2. Strategically select auditors and train them well
3. Plan the auditing goals and objectives for the team in advance
4. Create a formal audit agenda that defines which processes each auditor will be focusing on

Auditing 100% of your critical suppliers may seem impossible, due to limited resources, but have you ever seen a cost/benefit analysis?

What's the cost of rejects, rework and product redesign?

How do you Qualify a Supplier That Doesn't Have a Quality Management System?

Ignoring the obvious question of why doesn't a medical device supplier have a quality management system, if you are a contract manufacturer, you should ensure that you have a clause in your supplier qualification procedure that says you don't need to qualify suppliers that are mandated by your customers.

For the remaining suppliers you are considering to add to your Approved Supplier List (ASL), you need a SIMPLE set of criteria for how you qualified the supplier. Guess what that magical document should be? (Answer to be provided shortly…)

Many companies use a supplier self-evaluation survey and I don't consider them a useful document. A one-page supplier information form seems more appropriate. No signature required! And please make it a Word document. The supplier qualification procedure needs to be generic for all raw materials and services you purchase. The problem is that everything you purchase has different requirements. So instead of wasting your time with writing one procedure that has wiggle room for every single product or service you will ever purchase, don't even try. Instead, write a SIMPLE procedure. This procedure needs only be one page long. It needs four requirements:

1. New suppliers must **complete** a supplier information form and submit it to the company. This should be updated at least once annually, and whenever there is a change to the information provided (i.e., – notification of change).
2. You need at least two people to approve the addition to the Quality Management System. This can be done on your Engineering Change Order (ECO) or Document Change Order

(DCO) form for changing the ASL. If the supplier is customer-mandated, you need the customer's approval and the purchasing manager's. If the supplier is internally selected, you need at least purchasing and QA to approve it.

3. You should have objective criterion (probably more than one requirement) that are product/service related for acceptance of the supplier. This criterion **SHALL** be under document control and the revision shall be communicated to the supplier when orders are placed. See ISO 13485:2003, section 7.4.2 (Purchasing Information).
4. Finally, you need a reference to your purchasing procedure (one of the required 19 documents) and your supplier re-evaluation procedure.

If you have not already guessed, the "magical" document is called a purchasing specification. For capital equipment, you may require that a capital expenditure justification be completed in lieu of the purchasing specification. For a calibrated instrument, tool, or fixture the requirements should be documented in the applicable procedure or work instruction. For example, for measurement of this cannula, a calibrated optical comparator is required with 20x magnification. Reference the inspection procedure or drawing and you are done.

For those of you that would like to keep your ASL shorter, which I recommend, if you don't think you will be using the supplier more than once, you might want to give the buyer the option of documenting the purchasing specification on the purchasing requisition instead. This might be very helpful for those engineers that are doing R&D or validation work.

For example, I need a bag of resin that meets the following raw material specifications—but we don't currently use this material, and I'm not ready to submit one for approval. That's why the engineer is ordering the bag of resin. She needs to test the material in the application and gather some preliminary data as justification for the new raw material specification.

There are hundreds of other ways to qualify your suppliers, and many of them work well if you follow your procedure. If your procedure is SIMPLE, your Monday's will be better.

Why did you Qualify that Supplier?

I suppose there are a lot of possible answers to this question. I would avoid moronic answers like, "because that's who we've always bought 'widgets' from." "Grandfathering" suppliers is a VERY BAD IDEA! Would you keep an employee that was totally unqualified for their current position just because they were qualified for the job they were hired for initially?

Please don't answer that question. I'm afraid that some criminally stupid manager might say yes.

I am a strong proponent for fairness and training people, so they can be promoted from within. Unfortunately, sometimes people just can't keep up with the growth of the company. This happened to Charlie's Dad in the movie Willie Wonka, and it can happen to the genius founder and CEO of a growing company.

If I have an employee that is not qualified for their job, I start by retraining them. I love to teach, so I can spend too much time trying to train someone that might not have the aptitude. I like to use the approach of training people until they get it right or they quit. "Quitting" doesn't necessarily mean leaving the company. It could mean applying for a different job. It could also mean some out-placement coaching from a consultant. No matter what, I try to make it work first—then I terminate. When I terminate, I do so with kindness, compassion, legally and with ample notice.

Suppliers should be handled no differently. You should re-evaluate your suppliers on a regular basis and terminate your contracts with unqualified suppliers. This will probably require the same level of diplomacy (i.e., – retrain them, identify an alternate, and negotiate a transition plan that is reasonable for all parties).

Another nonsensical answer is, *"because they were the lowest bidder."* There's an old government contracting joke about this strategy. I think it sounds something like this, *"a million mission-critical parts,* designed *by engineers that have no clue what the real world is like, built by the lowest bidder, and inspected by a bureaucrat that can be bribed with a bottle of wine and some prime rib."* Personally, I tend to discount the quality of the lowest bidder every time. I always wonder what they forgot to consider when they bid on the job.

If you have read my previous blogs, you already know that ISO certification is not an important criterion for me. I include the thoroughness of a supplier's questions as one of my semi-quantitative criteria for selection. Another factor I like to use is proximity. I believe there is great wisdom in developing a partnership with your supplier. It's much easier to achieve that kind of relationship with another company if they are located close-by. Another thing I look for is a supplier that is better than my company. I would much rather learn best practices from my supplier than spend my resources teaching them to become better. Finally, my favorite criterion is size. I prefer a supplier that is approximately the same size as my company. If we are the same size, then problems should be equally important for both of us. If my company is bigger, we might tend to bully the supplier and the supplier might have difficulty growing with us. If my company is smaller, our problems might not receive the attention they deserve.

There are always other considerations, such as the desire for "one-stop-shopping" to increase your bargaining power. Unfortunately, this approach tends to result in sub-optimal decisions, and makes it more difficult to terminate relationships. Technical considerations are also important, but I rarely find that a good supplier does everything well.

The "fit" of a supplier is another consideration. For example, if your engineers are sloppy when it comes to writing a specification, you don't want to qualify suppliers that will build whatever you ask for—no matter how stupid it sounds.

My SIMPLE advice…Qualify suppliers based upon the intangibles AND the technical details.

Contract Manufacturers Need Strong Risk Management Processes

Have you experienced a discussion similar to this?

Auditor*: "How do you manage risk throughout the production process?"*

Auditee: *"That is the responsibility of our customers. We will prepare a risk analysis if customers pay for it, but usually customers do the risk analysis."*

Most contract manufacturers in the medical device industry exclude design from their Quality Management Systems. Unfortunately, most of the contract manufacturers also associate risk management with only the design process. Risk Management cannot be "not applicable" in an ISO 13485 Quality Management System. The requirement of section 7.1 is: *"The organization shall establish documented requirements for risk management throughout product realization. Records arising from risk management shall be maintained."* The Standard also references ISO 14971 as a source of guidance on Risk Management.

For a contract manufacturer, compliance with ISO 14971 is not my primary concern as an auditor. My primary concern is to verify that contract manufacturers analyze risks associated with the processes that they perform, and do their best to minimize those risks. What I don't understand is why more companies don't want to have strong risk management processes. Risk management is how we prevent bad things from happening. Bad things like scrap, complaints and recalls. Should we expect our suppliers to have a strong risk management process?
Duh.

Contract manufacturers should be doing everything they can to get better at risk management. During pre-production planning they should be asking, *"What happens if…"* The contract manufacturer knows best *HOW* things will fail in production, while the customer knows best

WHAT happens when things fail in production. In order to be safe and effective, both companies need to collaborate on risk analysis.
The reason companies avoid doing risk analysis is because it's time consuming and tedious.

Too bad, so sad.

Balancing my checkbook is time consuming and tedious too, but I balance my checkbook to prevent an overdraft charge. Not doing risk analysis can be much more painful. Scrapping out a part can cost tens or hundreds of dollars. Complaints can cost thousands of dollars. Recalls can cost millions of dollars.

If I owned a contract manufacturing company, I would ensure that everyone in the company is involved in risk management, because we don't want scrap, we can't afford mistakes that lead to complaints, and a recall will put us out of business.

Are You Ensuring Supplier Quality - Guest Blog by Christine Park, *Quality Architech*

"Everyone cares about quality. Just ask them…However, unless someone actively measures quality performance, you must question the commitment to improvement."

Supplier management is a process getting much more scrutiny from notified bodies and regulatory agencies these days. The process includes establishing supplier criteria, evaluating capabilities, selection and ongoing monitoring of suppliers. It starts early in the development activity of the product or service where the requirements and/or specifications are outlined, and progresses through the evaluation and selection through ongoing monitoring and support. The application of supplier management depends on the nature and risk associated with the product or services being purchased and/or received.

Ensuring supplier quality requires a baseline understanding and acceptance of **four fundamental concepts:**

1. Supplier assessment is a continuous process

It is too simplistic to this of supplier assessment solely in terms of "sizing up" a supplier prior to purchasing a product. True, that initial sourcing decision is perhaps the most critical in the supplier-customer relationship, but the ongoing fulfillment of the contract also warrants continuous assessment. This is done to ensure high-quality product throughout the life of the contract, to refine our supplier evaluation process, and to keep a "scorecard" for evaluation at the time the contract is due for renewal.

2. Organizations only choose to measure things which are really important to the business.

Everyone cares about quality. Just ask them. However, unless someone actively measures quality performance, you must question the commitment to improvement. You expect suppliers to measure their own performance, but that's not enough. You must define your own metrics and performance measures for the performance of your suppliers. This is the foundation of supplier assessment and management.

3. Informed quality decisions are less costly than those made in ignorance.

While every supplier is not going to be perfect, every sourcing decision can be effective. By going through the supplier assessment process up front, you can ascertain the supplier's strengths and capabilities before the business commitment is made. True, significant cost differences between suppliers might force a re-evaluation of the quality. Sole source suppliers pose different quality evaluation challenges. It is critical there are no surprises after you enter the agreement. There is no substitute for data.

4. Suppliers are assessed in different ways, depending on the potential impact on customer satisfaction and business profitability.

One size does not fit all when it comes to supplier assessment. The breadth and depth of the assessment may differ from product to product. The common thread through the process is the need to make a conscious decision related to the supplier's capabilities early enough to avert financial losses and possibly jeopardize customer satisfaction. The assessment of a non-critical part supplier can begin much later than the assessment of an OEM customer solution provider, because there is far less at stake with more options to recover, if necessary.

One way to manage this assessment is to perform an annual supplier review based on key risk criteria and supplier relationships. Documenting past performance and other quality system activities captures the objective evidence of these decisions and provides a foundation for supporting your decisions.

Many companies develop supply agreements with strategic and/or key suppliers. You should consider adding a master quality agreement to help manage these relationships. Documenting decisions for accountability and responsibility for key quality processes early in the relationship with the supplier can save big headaches.

About the Authors

QA/RA Expert
Robert Packard

Robert Packard is a regulatory consultant with 20 years experience in the medical device, pharmaceutical and biotechnology industries. He is a graduate of UConn in Chemical Engineering. Robert was a senior manager at several medical device companies—including President/CEO of a laparoscopic imaging company. His Quality Management System expertise covers all aspects of developing, training, implementing, and maintaining ISO 13485 and ISO 14971 certification. From 2009-2012, he was a lead auditor and instructor for one of the largest Notified Bodies. Robert's specialty is regulatory submissions for high-risk medical devices, such as implants and drug/device combination products for CE marking applications, Canadian medical device applications and 510(k) submissions. The most favorite part of his job is training others. He can be contacted at rob@13485cert.com if you have specific questions about ISO 13485 certification, or to request help with training or implementation of your Quality Management System or visit his website at www.medicaldeviceacademy.com

Christine (Chris) Park is a proven Quality Assurance professional with a wealth of experience in establishing and remediating quality systems of all sizes. As a consultant, she uses a pragmatic approach to compliance and quality assurance. Ms. Park has successfully focused on results-oriented solutions that integrate quality into the daily business activities of organizations. Her experience in R&D and general manufacturing for medical devices, IVDs, and biotech/pharmaceuticals provides a well-balanced background for her work in compliance. She can be contacted at (678) 480-5411, or visit her website at www.qualityarchitech.com.