VENDOR QUALIFICATION

Frequently Asked Questions

Developed by the AABB subsection: Cellular Therapies Quality Operations
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How do I ensure compliance with the audits?

Work with your vendor contacts to clarify any concerns or findings following a vendor assessment/audit. If the vendor is not responding to your inquiries, do you have a qualified secondary vendor option?

Monitor deviations or complaints pertaining to the product or services provided by the vendor.

- Define a threshold by supplier criticality that would trigger an investigation or action on your part.
- Use information as part of re-audit for a vendor. Are the numbers acceptable? Has the vendor been responsive to reports? Etc.

Whom should I use as vendor/provider contact?

This question should be considered from two separate perspectives. Your facility should establish a contact on the vendor side that would be most suitable to answer your quality questions. Depending on the nature of the vendor (supplies, equipment or services), the contact may be an account representative or a quality counterpart to your organization. Establishing contact with multiple individuals will ensure that someone on the vendor side is always available to respond to your inquiries.

In the same way, your organization should create a system that includes multiple contacts within your facility to ensure that should someone leave your organization, or be out of the office, a critical vendor notification would be received in a timely manner.

How often do I conduct the audits?

Use a risk assessment approach to determining how critical the vendor’s supply or service is to your process. Determine as part of your process, for each level of criticality, the frequency of the audits. Additionally, it is recommended that the depth, breadth and indicators that may trigger a re-evaluation are established to increase the agility of your organization when responding to variances.

When should I perform an on-site audit?

A risk-based approach is recommended. The more critical the vendor’s supply or service is to your process, the more intense your assessment. Consult your critical supply and equipment list when defining the possible candidates to
receive an on-site audit. Additional consideration has to be paid to the practical aspects of conducting an on-site audit. In cases where the audit is deemed essential and the provider is international or far removed from the immediate vicinity of your facility, you may try to combine a vendor audit with other business-related trips that may accomplish more than one goal.

Still, on-site audits may not be feasible from a time or financial standpoint. In these cases, you may need to:

- Perform a more detailed desk assessment or increase the frequency of the audits.
- Increase your specifications/requirement, i.e.: appropriate accreditation for the service/supply (ISO, AABB, ASHI, etc)

### Do service providers need to meet specific accreditation requirements?

In cases where the specification or requirement is critical to the supply or service that is provided, and service or supply directly affects the safety, purity, potency or quality of your product accreditation requirements should be evaluated by your company. The way of ensuring compliance with accreditation requirements may not be as straight forward as just checking if the vendor has a particular accreditation or membership. In cases where a provider is not accredited by a recognized organization, you may need to evaluate their compliance by means of your own audit.

Some services such as infectious disease testing, may have regulatory or accreditation requirements that require CLIA certifications or US FDA registration. If this is the case, you may request copy of CLIA certification and/or FDA registration. In addition, due to the critical nature of infectious disease testing, it is recommended that one review the service provider (vendor’s) testing procedures to ensure compliance with manufacturer’s instructions and current testing requirements.

### Can I ask about FDA Recalls, Letters or Actions?

Yes, you can. Also, ask about the vendor’s responses and the current status of any actions by regulatory agencies, when applicable. As part of your Vendor Qualification or periodic re-qualification, you may also query the FDA website for recall actions and warning letters pertaining to a vendor.
**How do I respond if a vendor cites “Confidentiality” regarding the audit?**

Your request to the vendor should always indicate that the audits are a regulatory/accreditation requirement of your organization, and that the results will be used to establish your facility’s internal ability to meet standards of practice. The vendor should explain why answering your request is a breach of confidentiality for them. At that point, you will need to assess if you accept “Confidentiality” as an appropriate response for denying your audit’s request, and if such denial constitutes an action that disqualifies the vendor. That said, a change of approach may be beneficial to both parties:

- Can you restate your question? **For example:** You ask to see actual audit reports and a vendor cites “confidentiality” restrictions. Would an audit schedule be enough evidence of an audit program? Usually, the regulatory or accreditation burden is whether audit system is in place, not necessarily the sharing of results of the assessments.
- On the other hand, you need to ask yourself: One might be concerned and view this as an indication of the vendor’s customer service practices, which should be part of your assessment.

The recommendation is to establish a plan before the circumstance presents itself, so that your audit process is not delayed by unexpected responses.

**Does every supply have to have an “expiry date”?**

No. In cases where a vendor does not assign an expiry date, most regulatory or accreditation requirements call for your organization to make a determination of how you will use the product on an individual basis.

**Do I have to qualify every supply, vendor and service provider?**

No. Use a risk based approach to determine which vendors and service providers to qualify, how frequently and how in-depth an assessment to perform. A critical vendor performing a manufacturing step may need to be assessed with an on-site audit annually, while others may be performed using a desk (documentation) assessment with less frequency. Vendors of a non-critical supply may never be formally assessed, other than the establishment of a product specification sheet to be used by inventory staff when receiving product into your facility.
Once initially qualified, how do I maintain vendor qualification?

After initial qualification, your organization should establish an audit schedule that will ensure the periodic assessment of your vendor in order to determine if any changes in provision or service have occurred, that may affect your products. The frequency of the re-audits should be established based on several aspects:

- The critical nature of the supply or service in relationship to your products.
- The frequency of vendor service or manufacturing SOP changes.
- Any changes in vendor ownership.
- Monitoring of deviations and complaints by setting an internal threshold that would trigger an investigation or action on your part.

Can I ask about Customer References?

Yes. Most reputable vendors use customer references as a selling tool and are happy to share the contact information, in some cases even boasting about their client lists. Another way to get references is from your colleagues in the field whom are usually very candid about their experiences with vendor/suppliers. Networking within the industry can give you valuable insight into how the particular vendor is perceived by other customers, their competitors, and critics. Some questions to ask are:

- Do they have experience with a vendor?
- Do they know someone who has experience with a vendor?
- Any “Horror Stories” to share?

When conducting re-audits, assess the customer service you have received in the past and the willingness of the vendor to help you solve your problems.

Are all vendor audits the same?

Although on the surface all vendor audits can seem similar, there are some definite differences between supplies, equipment and service audits. By using a risk-based approach to determine by the criticality of the supply or service, your organization can define what kind and how detailed to be in your audit. Customize you audits for the supply or service. Use the same checklist for supplies and services that are similar in nature.
**Is there a specific format for a vendor audit?**

No. Each organization/facility should define its own standard format, including any required elements that may be specific to individual accrediting or regulatory organizations. In general, an audit should be concise (short), pertinent (direct) and focused (targeted).

Concise is key because long questionnaires are usually poorly received by the vendors and compliance with the audit is severely impacted. Best results are obtained when desk audit questionnaires are perceived by the auditee to be non-intrusive and polite.

Pertinence is related to how directly the questions in the audit relate to the purpose of the assessment. For example, it is useless to ask the vendor of a supply that is non-specific to the cell therapy or transfusion medicine industry whether they are AABB accredited, since they do not have to be accredited. On the other hand, you can ask additional questions that would document compliance with general quality system rules.

A focused audit is usually direct and to the point, which gives the auditee a sense that their time has not been wasted with useless requests. When explaining the need for the audit to the vendor, try to engage them as a partner in your efforts to assess the quality of your products, not just as a means to evaluate them. The assessment of the company should have been carried out before a decision was made to do business with them.

**Should I check my institution’s existing contracts when negotiating with a vendor?**

Yes. This is particularly true in cases where your institution is part of a large hospital or healthcare system. In some cases, your organization is already in business with a vendor, which may turn out to be an added benefit to you. The vendor already has “roots” in your institution and that could translate into a financial windfall and a more attentive supplier. Additionally, as in the case of testing services, an institutional contract will likely already cover confidentiality aspects of the scope of work and some regulatory requirements.

A caveat to also keep in mind is the situation where the selection of an institutional vendor is done using a bidding process. If your department was not involved in the initial selection process, make sure that the conditions and specifications used to grant the bid also fit the needs of the cell therapy laboratory.
- **Do I need to consider Local and Regional regulations?**

  Yes. A vendor qualification should always ensure that a vendor can meet all local, regional and/or national regulatory requirements. This is particularly important in states with additional regulatory burden beyond federally mandated requirements. When evaluating a supplier of HPC products that may be international, also consider any rules related to importation of biohazardous materials.

- **Should I qualify more than one (1) vendor for critical supplies?**

  As part of your facility Business Continuity Plan you may wish to pre-qualify a secondary vendor of a critical supply or service. This obviously only applies to a selected number of items, and does not mean one has to qualify a complete catalog of products from alternative suppliers. Process validation would still be required if/when you switch vendors unless previously validated. You may also want to qualify multiple vendors if your facility is accepting RFP for a new critical supply or service.

- **What type of documents can I accept as proof of compliance?**

  Use a risk-based approach. If you are outsourcing a critical manufacturing step or a test related to the release of a final product, you may want to see all applicable SOPs related to the process. On the other hand, if you are assessing that a quality program exists, a Table of Contents for the Quality Program may be enough.

  Additionally, due to the large demand for quality system information by their customers, some large manufacturers will have a Quality Systems document that may encompass the majority if not all of the data you may require in a vendor qualification audit. This document could then be attached to your own audit form with the contact information details.

- **What happens if a vendor fails a re-qualification audit?**

  When possible, and as part of your Business Continuity Plan, your organization should have an alternative way (“Plan B”) to obtain the supply or service need. A frank discussion with the vendor should then take place to evaluate their ability to correct the problems that led to the failure and to determine if your organization will continue doing business with the vendor.
- **Is a vendor obligated to respond to a vendor qualification audit?**

  The short answer is yes, but like all things, there are some conditions. From a customer service standpoint, a vendor should always be willing to participate in a well-organized, non-intrusive audit of their operations, particularly during the initial evaluation of their products or services. The request for an audit should always be a formal document that states the need for the audit, its scope, and a reasonable lapse of time for its completion.

  When dealing with a established vendor, audit requirements should have been documented in the initial agreement as an obligatory part of the contract. Under these conditions, a refusal to accept an audit could constitute a breach of contract.

- **Can I use a Third Party Service provider for my vendor qualification?**

  Yes. In cases where QA departments are small and may not have the staff to perform a vendor qualification for all supply and service providers, organizations may choose to outsource the assessments to a third party. But just as if the audits were performed by your staff, the final determination or report would need to be reviewed and approved by a responsible party at your facility.

  In an effort to contain costs, some industry organizations have pooled resources and performed on-site vendor audits of their larger suppliers for all their small affiliated facilities. You may wish to use information supplied by a Third Party Assessor in your vendor qualification assessment. Ensure that your documentation reflects the fact that the data was collected by an external provider.