

## 12 Essential Ingredients for Successful Clinical Research Supplier Audits

By Chuck Crumpton

A supplier audit is an effective way to identify and eliminate supply-chain risks and other issues that could detrimentally affect your own organization's performance. With robust audits, study sponsors and other organizations involved in clinical research can continually improve their quality by ensuring that performance standards are high and problems in need of corrective or preventive actions are dealt with promptly.

There are two types of supplier audits:

- **Qualification audits.** Organizations conduct a qualification audit (also known as a selection audit) before placing orders for products or services with a supplier. This audit gives essential insights into the supplier's product and service capabilities and internal quality controls. Qualification audits create a baseline for subsequent surveillance audits. They may go into less detail than surveillance audits, but can still be extensive.
- **Surveillance audits.** Organizations periodically conduct surveillance audits to ensure ongoing compliance with applicable requirements and change management. These audits examine the supplier's key processes, such as production and material controls, training and qualification, change control, preventive maintenance and calibration, cleaning, hygiene and contamination control, management of sub-suppliers, management of deviations, corrective actions, internal audit and management review. During surveillance audits, the auditor can review prior audits to see how performance has changed. A surveillance audit offers an opportunity to assess progress and results in the following areas:
  - Process quality and effectiveness
  - Continual improvement programs
  - Compliance with standards and requirements
  - Previously identified areas of concern

Both types of audits are important in establishing a supplier's credibility and compliance.

### Tips for Auditing Suppliers

Apply the following tips to ensure effective supplier audits:

#### 1. Build Trust

The purpose of an audit is to identify risks so they can be cooperatively addressed over the term of the relationship. Communicate that the audit is not a hunt for defects to be used to the supplier's disadvantage. Rather, the objective is to help ensure that both parties will be satisfied with a harmonious relationship. Audit results can also help strengthen the relationships the supplier has with other customers.

An audit and the process that follows should be a mutually beneficial exercise that builds trust between parties. Ideally, the supplier will come to trust the customer as a resource with which it can openly share its challenges and as a partner in developing solutions for them. On the flip side, the customer will come to trust the supplier for its transparency, high quality, reliability and low risk.

In contrast, emphasizing the watchdog role may cause the auditee and its personnel to hide risks. You may still be able to find them, but it will take longer.

Audits must be independent of bias and influence by the auditee. Nevertheless, you can still cultivate open and trusting working relationships with your auditee with the following strategies:

- **Start early.** Start building a relationship with the auditee long before an audit is scheduled. Meet with the auditee to gain an understanding of their concerns and perspectives. Encourage transparent and open communications that build mutual trust and respect.
- **Learn their business.** You will quickly lose credibility if you ask the auditee to educate you from scratch about their industry, their organization and their department. With a baseline of knowledge, you can ask intelligent questions, understand the answers and focus on the unusual.
- **Set expectations.** Assure the auditee that audits are a standard practice, that being audited does not mean they are in trouble and that timely bad news will not get them in trouble. Explain that you are talking to them because of their expertise and importance. Describe the audit objectives, scope, process and timeline.
- **Maintain open communications.** Keep the auditee informed on the audit's progress and any important changes or developments.

## **2. Do Your Homework**

If you are not familiar with the auditee organization, research their products, management structure, locations, financial statements, analyst reports, press releases, news articles, etc. Check FDA's website for warning letters, import alerts, etc.

Check social media to learn about current responsibilities, professional experience, education, certifications and other relevant information about pertinent personnel.

Gather, organize and review contracts, delivery specifications, customer complaints, work instructions and other information and documents from previous audits.

## **3. Arrange a Good Point of Contact**

It is best to have a single primary point of contact before, during and after an audit. Before the audit, the contact can help with preparation. During the audit, they can expeditiously find answers, documents and people for you and interpret your findings. After the audit, they can arrange any necessary follow-up.

## **4. Remember Why You Are Performing the Audit**

In certification audit, the focus is on compliance with standards promulgated by organizations like the International Organization for Standardization (ISO). In supplier audits, such compliance is important to the extent it affects the customer; but product specifications, quality agreements, complaint handling and other factors that directly affect the customer are more important.

As mentioned above, qualification and surveillance audits have different purposes and, therefore, different scopes.

### **5. Focus on Important Risks and Deviations**

Do not waste time on process, documentation or other deviations that do not have a material effect on the customer. However, a pattern of deviations may be revealing.

Effective key performance indicators (KPIs), key quality indicators (KQIs) and key risk indicators (KRIs) can help you focus on the nonconformities that matter. You may have to help your suppliers develop these indicators.

### **6. Develop Your Audit Plan with the Auditee's Input**

Share your audit plan with the auditee. Get their input on scope, timelines and context. For example, is the quality manager new on the job or is a production line just starting up? Ask them to ready people for interviews and prepare documents for review. In some circumstances, catching auditees by surprise may be a good tactic, but do not expect them to like it or to be prepared. As a bonus, involving the auditee with the audit plan communicates that you trust them to steer you in the right direction.

### **7. Use Checklists Intelligently**

An audit checklist gives structure to an audit, helps it stay on track and avoids omissions. A good checklist is flexible. However, one that is vague or too narrow can waste time and ignore important issues.

Allow off-checklist time for open-ended questions, follow-up questions and unplanned investigations.

### **8. Interview Top Management First**

Interviews are one of the best ways to gather unexpected information during an audit. After the opening meeting, interview the highest-level executives first to understand context; strategic direction; organizational dynamics; and leadership understanding, attitudes, engagement and level of commitment.

### **9. Deal with Confidentiality Restrictions**

As an auditor, you will likely see the auditee's confidential information, perhaps including information that might help the auditee's competitors, and information about your own competitors. The confidentiality agreement you will likely sign and the auditor's code of ethics requires you to keep all such information confidential, even from others in your own organization.

Auditees are more likely to hold back important information in qualification audits, given that there is no business relationship yet and there may never be one. It may be possible to obtain the information you need in ways that do not create confidentiality problems (e.g., by viewing redacted documents or a manufacturing process, but not the actual product).

Third-party auditors do not have the same confidentiality conflicts of interest that your own auditors have and their livelihood depends on their reputation for probity.

## **10. Beware of “Forgetful” Auditees**

When auditees do not want to share embarrassing information, they may say they forgot the information, the documents are not available, they’ll get back to you on that, etc. Consider statements like this to indicate distrust, a defective quality management system or both. Auditees are often reluctant to share customer complaints. Take note of such cases for later follow-up with the dissatisfied customer.

## **11. Do Not Assume There Is Only One Way to Do Something**

In previous audits, you may have seen a particular process performed the same way by different suppliers. That does not mean there is no other proper way to perform that process. Circumstances can differ. Your auditee may have even found a better way. Your role as auditor is only to determine whether the auditee’s process meets the customer’s needs and risks are well-managed.

## **12. Be Helpful**

When you see opportunities that do not violate your confidentiality obligations for the supplier to improve their processes, especially in risk and quality management, ask them if they want your advice. If they do, offer it in a constructive manner to the right person.

## **Conclusion**

Qualification audits can help customer/supplier relationships start off on the right foot. Surveillance audits can help strengthen the relationships and keep them going strong. Few suppliers eagerly look forward to a customer audit, but a good auditor can make it so.

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