

Surviving a life sciences audit: a guide for vendors

Kim Vitray

Despite working for her department for many years, the girl down the hall is in a panic. Why, you ask? Because she just got called by the auditor of the life sciences company. However, the auditing process is generally routine and does not need to cause vendors fear or panic. US Food and Drug Administration-registered and/or ISO-certified life sciences companies are required to conduct audits of all vendors providing products and services to the company.

The fact is that increased competition and more rigorous internal and external regulatory pressure have led to greater scrutiny of all outside suppliers, including packaging, drug manufacturing and storage. The language service provider (LSP) for which I work has provided services in translation and localization to life sciences clients for almost three decades. Just in the last two years we have been audited twice – the first two times ever. The challenge for pharmaceutical companies lies in ensuring that best practices and documented processes across a wide range of industries are in place and well documented.

While an audit may be a routine that vendors now need to endure, it must be taken seriously, but it need not be just a burden. Strategic vendors will consider it an opportunity to excel and receive a valuable endorsement of their work. Client managers can help vendors prepare for the audit proactively, and in the end the clients will also be rewarded, knowing the vendor they have chosen has also received the seal of approval from the auditor.

I know this to be true because we just completed our second audit in two years. While getting the notice that an audit is pending can be unsettling, I can vouch that it also provides

an opportunity to evaluate and, if necessary, reengineer processes and services that benefit all our clients, not just the one conducting the audit.

So, how can your vendor turn the audit into an opportunity? Work with them on a few simple steps, and they are assured success. In short, prepare, reveal and refine.

Preparing

Do not begin the day before the auditor shows up, but rather when the audit notice is given. The more vigorously the vendor prepares, the more likely the provider will be pleased with the outcome. Unfortunately, there is little information on how to prepare. What's difficult about these audits is that there is no agenda, thus making it difficult to anticipate what to expect.

For our first audit in 2006, we were completely unaware of the questions that would be asked or the data that would need to be provided. We actually used an article published by another vendor to prepare ourselves. But as a company, we have long pursued meticulous and systematic documentation of our processes and policies, aiming for continuous improvement and regular review, so we were able to pull together the necessary information.

This time we knew what to expect. In anticipation, we prepared a host of documents, including:

- 2005-2007 on-time delivery reports
- leadership/management résumés
- procedures notebooks (IT, editing, production, operations/administration, project management)
- disaster recovery plan
- quality manual, including the *ASTM Standard Guide for Quality Assurance in Translation*
- job descriptions and organizational charts
- employee handbook
- 2005-2007 customer issue logs
- 2005-2007 customer surveys
- certification templates

In addition, we set up 30-minute sessions for the auditor to visit with each management staff person, and we tidied up our offices



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in preparation for a possible tour. Moreover, I made myself available throughout the audit, making sure the auditor had a go-to person for follow-up questions.

Being prepared with adequate documentation is critical in an audit, but it is also crucial to communicate with the auditor prior to the meeting to understand the agenda, such as what items need to be discussed, key personnel they would like to interview, what the expected duration of the audit would be and so on.

Revealing

Generally the auditor will come to the vendor's office for a day or two of questioning, interviewing and reviewing of processes and documents. At this time, the best approach is to reveal your warts rather than trying to conceal them. There is a good chance the audit will uncover those problems anyway because the auditor evaluates data thoroughly and deeply. Furthermore, if the vendor is upfront about potential issues, trust can be established, making the entire process smoother. Finally, the auditor will be more likely to give the vendor ample opportunity to fix problems if the vendor is clear about what those issues might be.

As expected, the most recent audit we completed was extremely rigorous. I spent most of the morning answering questions about our workflow, proprietary project management software, training, disaster recovery, customer issue tracking, on-time delivery and more. We needed to produce as much documentation as possible to support each area of the operation. The auditor had a long list of checkpoints, and she explained that we would be scored on a scale of 0 (not compliant) to 5 (fully compliant) for each checkpoint, resulting in a total score that would indicate whether we were approved, conditionally approved or unapproved as a vendor.

An example best illustrates the intensity of the audit. The auditor selected a random job for the pharmaceutical company conducting the audit. The company is one of the major medical device manufacturers, and we have completed many translation projects for them, so I had no idea what job would be selected. With the job chosen, I had to walk the auditor through the activity log in our project management system and show that we followed the documented process, had kept all the document iterations, and could

prove who did what and when. Then she selected one employee and task from that log at random, and I had to show the job description for that position that documented what was required to do that tasks and then show the résumé, performance evaluations and training records of that employee to prove that person met the qualifications of the job description, received regular and appropriate training, and was evaluated regularly.

One of the most difficult tasks for the auditor is determining how quality assessment and management differs in each industry she evaluates because vocabulary from industry to industry is different – which is interesting for us as an LSP. So, for example, the auditor would ask about something called X in quality audit language, and we would know it as Y in a more practical environment. It took some back and forth for both of us to figure out we were talking about the same thing.

The evaluation was strenuous, but afterwards it reassured us that we are, indeed, the right choice for our clients. We felt rewarded by the audit process.

Refining

After the audit, the vendor receives a draft report indicating whether the vendor is fully compliant, conditionally compliant or not compliant. Full compliance is rare. Most often, the vendor receives compliance conditional on a few issues that must be addressed. The vendor then has a period of 90 days to comply before the final report is filed.

In our case, the initial result of the most recent audit was “conditional approval.” We were commended for our cooperation with the process, but the auditor noted

three nonconformances that we had to address to receive final approval. We were required to respond with a finding/response tracking record, explaining corrective actions taken to resolve the nonconformances, due within 30 days, and then submit a corrective action plan due within 90 days.

Importantly, final approval is not the only goal. Our internal goal was to make us a stronger vendor. For example, we were asked to formalize our documentation, and doing so would improve our overall processes.

Furthermore, the report gave us a chance to reinforce policies internally. As the vice president of operations, I oversee time and activity logging – not always a favorite area for employees. But now I can use the audit process to show our staff that filling out training forms, logging activity in the project management system, tracking customer issues and other types of recordkeeping really do matter.

While the entire audit process was time consuming, we can now go back to our advocates within the pharmaceutical company as well as other life sciences clients and let them know what changes we have made. We can also reevaluate our marketing listings in supplier directories, such as the GALA Language Technology and Services Directory, to ensure that we are highlighting the positive points unveiled by the audit. The audit process may be difficult, but the end result is a more efficient LSP that has continuous quality improvement mechanisms and accountability in place and provides reliable top-tier products and services to its life sciences clients. The outcome is a winning situation for everyone – vendor, auditor and client. **M**

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