

SURVIVING THE LIFE SCIENCES AUDIT

Kim Vitray, Vice President of Operations at McElroy Translation, a member of the non-profit Globalization and Localization Association, reveals how to survive an audit.



Our favourite vendor just called in a bit of a panic. Despite working for your department for many years, they are concerned because the auditor of your life sciences company just got in touch. But, have no fear. The auditing process is generally routine and does not need to cause your vendor any strife or sleepless nights. Life sciences companies that are ISO-certified and/or FDA-registered are required to conduct audits of all and any vendors providing products and services to the company.

The fact is that increased competition and more rigorous internal and external regulatory pressures have led to greater scrutiny of all outside suppliers, including packaging, drug manufacturing and storage companies. The company for which I work, McElroy Translation, a language service provider and GALA (Globalization and Localization Association) member, has provided services in translation and localization to life sciences clients for almost three decades. In the last 2 years, however, we have been audited twice — the first two times ever! The challenge for pharmaceutical companies lies in ensuring that best practices and standardized processes across a wide range of industries are in place and well-documented.

Although an audit may be a routine practice that vendors now need to endure, it must be taken seriously. Yet, it need not be just a burden: strategic vendors should consider it to be an opportunity to excel and receive a valuable endorsement of their work. Client managers can help vendors to prepare for the audit proactively and, in the end, will be rewarded by knowing that the vendor they have chosen has also received the seal of approval from the auditor. 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, re-engineer processes and services that benefit all



our clients, not just the one conducting the audit. So how can your vendor convert the audit into an opportunity? Work with them on a few simple steps, and they are ensured success. In short: Prepare, Reveal and Refine.

Prepare

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 very little information on how to prepare. What's difficult about these audits is that there is not an agenda, making it difficult to anticipate what to expect. For our first audit at McElroy 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, McElroy has 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. The second time we knew what to expect. In anticipation, we prepared a host of documents, including the following:

- 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 chart
- Employee handbook
- 2005–2007 on-time delivery reports
- 2005–2007 customer issue logs
- 2005–2007 customer surveys
- Certification templates.

In addition, we set up 30-minute sessions for the auditor to visit the management personnel, and tidied up our offices 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. When selected for an audit, being prepared with adequate documentation is critical, 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.

Reveal All

Generally, the auditor will come to the vendor's offices for a day or two of questioning, interviewing and reviewing of processes and documents. At this time, the best approach is to reveal all warts rather than trying to conceal them. There is a good chance that the audit will uncover those problems anyway, because the auditor evaluates data thoroughly and deeply. Furthermore, if the



THE AUDIT PROCESS MAY BE DIFFICULT AND TIME CONSUMING, BUT THE END RESULT IS A MORE EFFICIENT VENDOR THAT HAS CONTINUOUS QUALITY IMPROVEMENT MECHANISMS AND ACCOUNTABILITY IN PLACE.

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, our audit this year 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 are approved, conditional 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 (called ELJOTS) 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/task from that log at random, and I had to show her the job description for that position that documented what was required to do that task, 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 that they evaluate, because vocabulary from industry to industry is different (which is interesting for us as a language provider!). 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, likewise, it reassured us that we are, indeed, the right choice for our clients. We felt rewarded by the audit process.

Refine

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 that is 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 McElroy’s case, the initial result of our most recent audit was “conditional approval.” We were commended for our co-operation with the process, but the auditor noted three non-conformances that we must address to receive final approval. We were

required to respond with a Finding/Response Tracking Record that explained corrective actions taken to resolve the non-conformances within 30 days, and we are currently working on a Corrective Action Plan that is due within 90 days. Importantly, the refinements we make for the final approval will make us a stronger vendor. For example, we were asked to formalize our documentation process. Doing so will not only give us final approval on the audit, but also improve our overall processes. Furthermore, the report gives us a chance to reinforce policies internally. As the Vice President of Operations, I oversee time and activity logging — not always a favourite 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 record-keeping really do matter.

Although 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 we have complied fully. We can also re-evaluate 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 and time consuming, but the end result is a more efficient vendor that has continuous quality improvement mechanisms and accountability in place and provides reliable top-tier products and services to its life sciences clients. So, share this guide with your vendors and help them to prepare, reveal and refine. The outcome is a winning situation for everyone — vendor, auditor and client. **Pharma**

For more information

Kim Vitray
Vice President of Operations
McElroy Translation
910 West Avenue
Austin, Texas 78701, USA.
T. +1 512 472 6753
E. customerservice@mcelroytranslation.com
www.mcelroytranslation.com