

OUTSOURCING EFFICIENCIES

Eight Simple Strategies for Exceptional Customer Audits

Picture this. You saunter into the office Monday morning and are told that auditors from “Big Wig OEM” will be conducting an on-site evaluation in six weeks.

Do you:

a) Suddenly envision six weeks of stress-filled, sleepless nights, lying wide awake in bed, thinking of all the internal audits that never got done, all the open complaints that have yet to be addressed, the non-conformance issues from last year’s audit that haven’t been complied with.

Or ...

b) Muse that it will be nice to hear how Carol’s (Big Wig’s auditor) Alaskan cruise went as she was really looking forward to that during last year’s audit, and that you’ll be able to highlight how you fixed that packaging issue she noted last time.

Ideally your reaction resonates with the latter. In any event, following these tips and guidelines will help ensure that audits of any kind—customer, U.S. Food and Drug Administration (FDA), International Organization for Standardization—will be stress-free opportunities to demonstrate your efficient, effective manufacturing capabilities.



Joe Rotino, Angel Domingo

Take a Walk Down Memory Lane

Thoroughly review the prior year’s audit. Were you cited for any non-conformances? Were recommendations made or observations written down by the auditor?

If there were, have those concerns or suggestions been completely addressed, closed out and taken off the table?

All medical device audits generally orbit around the same core elements.

These are:

- a) Management review processes;
- b) Internal audit processes;
- c) Corrective and Preventative Action (CAPA) and complaint processes;
- d) Process controls; and
- e) Non-conforming material controls.

If your review of last year’s audit with the OEM customer reveals that you have not addressed certain problems or there are core elements that are not up-to-date, deal with those matters first. You want to avoid repeating the same corrective actions twice.

Don’t Freak, Don’t Fret

OEM customers typically will send you an agenda for the audit in advance. However, if they don’t, take it upon yourself to proactively request one. Agendas can shed light on what to prepare for and how much time the audit will take.

Additionally, it can serve you well to ask the auditors prior to their visit if there are specific areas they plan to focus on during their evaluation. For example, if you learn that they plan to concentrate on design controls, you can allocate more prep time to scrutinize that area as well.

If you have less than a month to make corrections, there is no need to panic. Take a deep breath. While you cannot fix everything in a few weeks, you can identify pressing inefficiencies or errors in your processes and start putting corrections in place.

Gather your team and prepare to get busy. In addition to your past audit review, examine recent or open complaints from the auditing customer. Scrutinize any device repair history. Then, open a CAPA on yourself.

CAPA is part of the FDA's model for Quality Systems Inspectional Technique. The purpose of CAPA is to collect and analyze information; identify and investigate product and quality concerns; and take appropriate corrective and/or preventive action to prevent their recurrence.

For example, let's say your ad hoc internal review spotlights four label complaints that were identified during the last evaluation and have not been remedied. Opening up a CAPA before the upcoming audit helps you recognize where you should center your attention.

So, when the auditor arrives and sees that there's still a labeling issue, you can confidently explain that you've:

- Opened up a CAPA;
- Identified that it will take 30 days to upgrade the software necessary to correct the problem;
- Closed out steps one and two in the meantime by re-writing the procedure and re-training associates; and
- Implemented a double-checking process where a supervisor now signs every label to ensure that errors are not repeated.

Is the entire issue fixed before the audit? No. But these proactive measures demonstrate that you are finding your own deficiencies and addressing them. This boosts an auditor's trust and confidence in your company and your systems.

Get Your House in Order

A customer audit usually takes a day—maybe a day and a half. Therefore, it's impossible for an auditor to evaluate every area of your company's quality system.

This is why a review of your CAPAs and complaints often are an auditor's starting point. It quickly tells the story of your main challenges with quality and the elements necessary to meet regulatory requirements.

After the review of CAPAs it is determined that the causes of systems issues are linked to deficiencies in one of the following three areas:

- 1) Management Controls;
- 2) Process Controls; or
- 3) Design Controls.

For example, if a medical device you have developed experiences field failures, it either: a) wasn't designed properly, b) wasn't manufactured properly, or c) your management controls and document system is inadequate.

Therefore, in addition to an internal CAPA process, it is vital to comprehensively assess your entire quality system—management, process, and design—every year with an internal audit.

Different companies have different approaches to how they handle internal audits. An efficient strategy is to segment your system and tackle small parts throughout the year. For instance, if you have 16 key processes, break them up into smaller elements and look at four per quarter. This makes internal audits more manageable and assures that you get them done.

Consistently conducting a complete appraisal of your operation year after year saves a great deal of time, stress and sleepless nights come audit time.

Welcome Fresh Perspectives

Internal audits go a long way in helping you recognize areas of improvement. However, bringing in a third-party auditor sometimes can offer deeper, more expansive insights.

This especially is true when you're pressed for time or preparing for a "big" audit that can have major business repercussions. This might include an audit for a critical qualification, or if the auditor hasn't evaluated your company in a few years.

Whether you tap into the resources and expertise of your local American Society for Quality chapter, or bring in consultants to conduct a thorough, top-to-bottom audit, having a fresh set of eyes can:

- Provide an objective analysis of your company's performance and procedures;
- Offer associates real-life training in what to expect during a formal audit; and
- Improve your quality and control processes before the "real deal."

Address the Elephant in the Room

Third-party "mock" audits can allow you to readily acknowledge potential problems during your actual evaluation—sometimes even before the auditor identifies them—and show what you are doing to amend the situation.

Not only does this further validate you as a scrupulous, aboveboard contract manufacturer, it also saves the auditor a great deal of time—which they appreciate.

Auditors are extremely busy. They have other sites to visit, and reports to write-up and send out. They too want a smooth process and have issues go away as quickly and efficiently as possible. One less corrective action means one less thing they have to write down and follow up on.

Concealing inadequacies or being unaware of them reflects poorly on your company and only leads to a long thread of problems. If you are managing your quality systems sufficiently, there should be no surprises that an audit could uncover.

Seek First to Understand, Then to be Understood

Auditors are just like you and me. They have friends, family, pets and hobbies. You actually may have a lot in common if you take the time to build rapport with them.

Relax and put on a genuine smile when they arrive. Receive them warmly into your “home.” They are simply doing their part to ensure that quality medical products are being created in a quality environment. They aren’t inspecting your organization to find fault or to make your day unpleasant.

Make them comfortable. It’s a long day for them too. If you can, set the auditor or auditors up in a room with a phone and internet access. Give them their own workspace with a place to store their belongings. Bring in lunch for them. If they have been to your company before and shared that they just adopted a dog or are planning a family vacation to Maui, ask them about it.

Establishing sincere rapport is not about schmoozing them so they’ll “go easy” on you. Creating an open, friendly, welcoming environment can help them see you as a human being and not just a piece of paper to audit. But, be sure you remain authentic, since it is not something you can—or should—fake.

Serve and Protect

Many contract manufacturers have multiple clients and have non-disclosure agreements with those clients.

To demonstrate that you have established processes to ensure that none of their intellectual property or technology is shared across customers, they’ll want to see that you have separate documentation procedures in place during your audit. You also may need to take extra precautions to protect their confidentiality, such as:

- Sequestering certain areas;
- Putting up drapes to conceal tables or equipment;
- Masking materials; and/or
- Ensuring that customers’ names aren’t displayed when you pull up a design file or a CAPA.

Customers need to be confident that you’re respecting your non-disclosure agreement and heeding your promise that their business and their competitor’s business are two separate obligations and are handled that way.

Listen, Learn, Apply

After your audit is complete, sit down with the auditor for a close-out meeting and take copious notes.

A few post-audit suggestions:

- Do not add anything that they “missed” or did not follow-up on. Adhere strictly to the facts;
- If you disagree with something that was documented, ask for clarification;
- If their clarification is still something you contend with, incorporate your viewpoints in your response letter; and
- Inquire when their report will be ready and when they need a formal response from you.

When it comes to crafting your formal response, address all the items mentioned in the closeout meeting and include clearly defined internal implementation dates for each item. Submit your formal response and confirm that it’s received by the due date.

Going forward, take the auditor’s insights and ideas for improvement and apply them. It’s not enough just to be aware of issues. You need to actually implement and follow up on each issue so that they are fixed and closed out by next year’s audit.

Embrace the Process

Even if you have all your ducks in a row, critiques of any kind can incite normal jitters. However, if you stick to an internal audit process throughout the year, solicit feedback, and hone your system, OEM audits don’t need to result in restless worry.

With standards growing even higher and regulations becoming more stringent, audits offer an excellent opportunity to enhance communication with your customer, effectively meet their needs and expectations, win and keep good business, and consistently produce high-quality, reliable products.

And who knows? You may even start to enjoy them. ♦

Joe Rotino, is vice president of quality and regulatory affairs, and Angel Domingo specializes in regulatory affairs for Pro-Dex, Inc., an Irvine, Calif.-based company that designs, develops and manufactures surgical devices, components and sub-assemblies for leading global medical device OEMs.