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## Building an internal audit checklist

By Kelly Huckabone

This month I am going to tackle a tough topic. The actual task of creating an internal audit checklist is not tough. It is deciding on the scope, format, and approach that makes it daunting for some auditors. My approach has always been, “keep it simple.”

The first thing I do is make the connection to the ISO clause the process falls under and review the regulation to ensure the procedure meets the minimum requirements of the standard. I personally like the approach of examining the process that is being audited and then identifying the following: inputs, outputs, risk, key steps and measurements, and key performance indicators (KPIs). As I evaluate the process, I draft questions that will provide evidence that supporting documentation is following the SOP.

Let's walk through an example. If the procedure indicates the receiver needs to review and sign the incoming receipt form, you could request to check some of the forms to ensure completeness and accuracy.

It is best to use open-ended questions during audit discussions because this approach facilitates two-way information sharing. If there are gaps within a process, the auditee will typically openly discuss whether the environment is considered “safe.” This means that our process of questioning and interviewing is collaborative and not meant to be punitive. Here is a list of some of our favorite questions that can be applied to any process audit:

- Describe the high-level process.
- What are the gaps that you see with the process?
- If you could change one thing about the process, what would it be?
- What key records are generated from this process (request to see a random sample)?
- Are there any open correction and preventative actions (CAPAs) for this process?
- Have you had feedback from other departments about issues related to the process?
- Have all key employees been trained on the procedure (request evidence)?
- What is the impact to the customer if there are gaps or issues with the process?

The ideal internal audit checklist will facilitate an open and transparent dialogue that will quickly identify any gaps or opportunities within the process being audited.

Best of luck with your internal audits. Thank you.

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### About the author

Kelly Huckabone is the North American Audit Program Manager who oversees the Unity™ Lab Services internal and external customer and supplier audit programs. Kelly is a certified risk manager, lead auditor with the American Society for Quality (ASQ) and has been conducting audits for over 25 years for different quality systems, including ISO 9001, 13485, and 17025, as well as Health Canada and the FDA.

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