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Being audit ready

By Kelly Huckabone

In one of our past articles we talked about being ready for a scheduled audit. You know the drill: book a room, get your documents ready, notify your stakeholders, and get your house in order. This is important because it ensures the audit goes smoothly. However, being “audit ready” means much more than that. It means using your quality tools every single day to educate, train, assess, support, and influence quality within your organization. Let’s walk through some examples.

You can start by using your internal audit program to take a deep dive into some of those troublesome processes. If you see an issue within a process, document the finding to drive improvement. Use change management techniques to ensure that standard operating procedures (SOPs) are written and updated, training is executed, and that programs and software are validated.

Use your corrective and preventive action (CAPA) program to help teach root cause analysis to other employees within the company. Use internal media to promote and increase your quality campaign. Leverage your document management system and teach a course on how to write procedures and work instructions for the other departments within your company.

Leverage the power of your management review the way it was intended. So many organizations tend to focus on the great things that are happening in quality. Yes, you should celebrate your quality victories but when you have leadership’s full attention, present your concerns and ask for their help.

One of the most powerful areas to support an organization’s audit readiness is through key performance indicators (KPIs). If you are tracking the right metrics, it will be obvious where action should be taken.

An ideal organization is proactive vs. reactive, but at times it can be challenging due to the pace of change we experience. Use your quality tool kit that you already have in place. It might need a little dusting off, but trust me, it is the most powerful device you have to ensure your audit readiness.

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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