

A word from the experts

Importance of audit readiness

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What is audit readiness? Many different quality leaders have their own perspective of what the term “audit readiness” means. I think it means having a strong and mature quality system in place that supports your operations. If you have a mature system, which includes but is not limited to the following, you will have all the key processes to support an audit, whether is it planned or unannounced:

- A good documentation management system that ensures revision control and an annual review of documents to ensure that they reflect the current state and documents that are easily accessible to all employees
- KPI (Key Performance Index) Management – using data to drive business decisions ensures you stay current on trending issues and allows you to be proactive vs. reactive.
- Strong internal audit program which detects gaps and opportunities prior to them being discovered during an external audit
- Training program for all employees that includes quality awareness
- Strong customer complaint and feedback process
- Continual improvement and CAPA (Corrective Action/Preventive Action)
- Employee feedback program

When employees feel connected to the quality system, it becomes part of the culture and part of what they do each day so they should feel confident to be able to discuss what they do with an auditor.

Don't get me wrong, each quality leader will still go through some sort of audit preparation prior to a planned audit and that is a great way to review what should already been in place.

If you have any questions, please feel free to contact me at kelly.huckabone@thermofisher.com