The Expert's Guide

Avoiding Audit Nightmares

Proactive Nightmare Prevention

A typical baseline FDA inspection will last at least 5-7 days if no significant issues are uncovered. The audit team should clear their schedules and be prepared to support the inspection until your response is made. The audit is priority number one.

Management should walk the entire facility well in advance of the inspection to identify any areas not in a state of control, unsanitary, cluttered, or in disrepair. From the lobby to the bottom of the pest trap, first impressions will make or break an audit.

Prepare a comprehensive opening presentation for the inspector. Include company overview, history, products, management, organization structure, facility overview, significant processes, and inspection history.

Make certain everyone is familiar with the Quality Policy and where to find it and that updated procedures are on the shop floor.

Training your key subject matter experts, management and employees during "drill" mock audits will let you sleep better at night.

Perform Terrific, Not Horrific

Proper behavior and etiquette during an audit is key to avoiding damning results.

Never

-Lie, forge signatures, fabricate documents
-Volunteer information or answer questions that weren't asked
-Attempt to answer "what if?"
-Philosophize, ramble or editorialize
-Express your personal opinions
-Guess answers or auditor questions
-Be sarcastic
-Become defensive or evasive
-Argue with an investigator or your peers
-Point out deficiencies or errors
-Comment on quality or admit non-compliance
-Feel the need to talk when it is quiet
-Assume a discussion is "off the record"

Eliminate Scary Documentation

Inadequate documentation remains the leading cause of 483 warnings which can lead to additional costs, diverted management resources, spoiled reputations and shaken stakeholder confidence. On the other hand, good documentation practices save money, time and headaches.

Documentation must be clear, correct, concise, coherent, and consistent. Also known as the 5 C's. Decisions, disposition rationales, actions, reasons for inaction, results and methods of investigations and your risk analysis efforts must be well documented or they didn't happen. Upgrading your documentation practices is a wise investment.

The FDA Response

A written response to 483 Observations are expected within 15 days

Use your CAPA system to address corrections

Perform and document a retrospective review of systems and products

In reviewing your response, the FDA considers:

The overall adequacy of your corrective action and whether it addresses the specific violation, related violations, related products or facilities, and contains provisions for monitoring and review to ensure effectiveness and prevent a recurrence.

They look to see whether documentation of the corrective action was provided to enable an informed evaluation; and is the timeframe for the corrective action appropriate and what progress has been made. And is the corrective action taken in compliance with the law or regulations.

Your response to the FDA must be prepared with all diligence and gravity.

Schedule your confidential project discussion today!

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