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Hope is Not a Strategy: Be Ready For FDA Inspections

Life science companies understand the FDA inspection process is a cornerstone towards ensuring safety and efficacy in products. When companies are prepared for inspections, it is easier for the FDA personnel to do their jobs of accessing information and assessing compliance. Being prepared for inspections is not about cutting corners or feigning compliance, rather it is about everyone doing their part to ensure safety and efficacy. Patient safety is the top priority.

> True inspection preparedness supplements internal audits with a practiced inspection process and behavioral training for key personnel.

Despite this knowledge, many organizations get bogged down in the day-to-day or get consumed by special projects. This results in inspection preparedness taking a back seat. For many medical device, biotech and pharmaceutical companies, inspection readiness becomes simply the internal audit program.

While internal audits are a key component of inspection preparedness, they tend to be informal, less intense and focused more on auditing than inspecting. True inspection preparedness supplements internal audits with a practiced inspection process and behavioral training for key personnel.

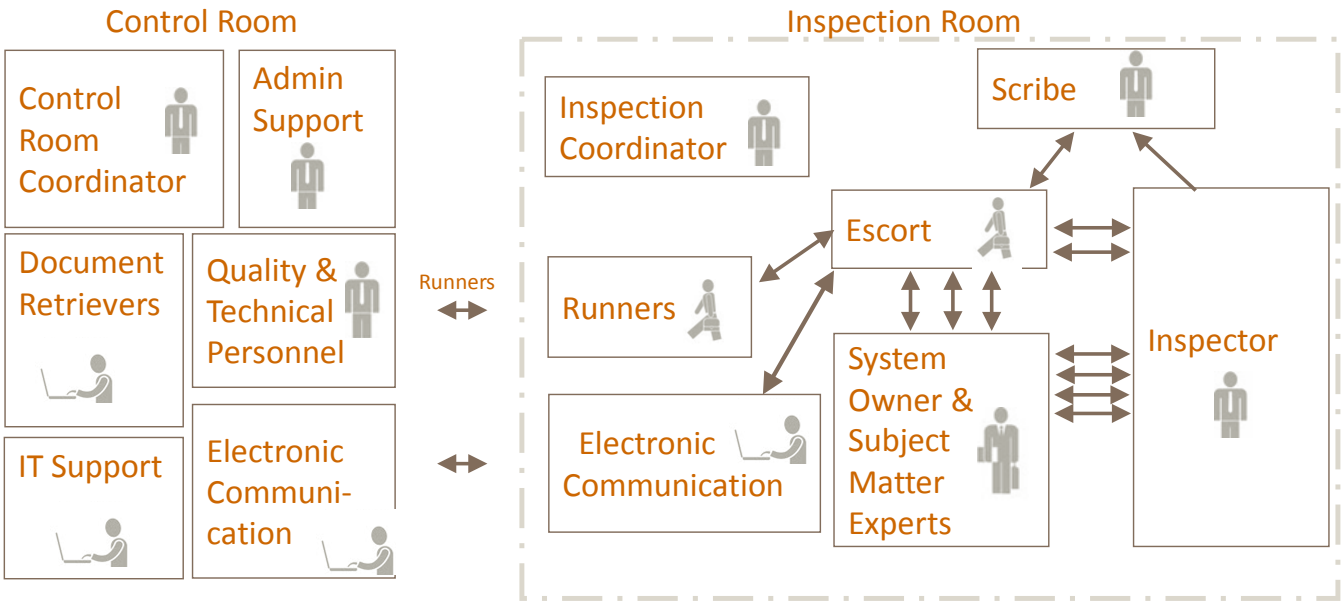
Inspection Process

Before an inspection occurs, organizations should have an inspection process and practice through mock inspections. Like any process, inspection readiness needs a plan that is executed, assessed and continuously improved upon.

Ideally, the inspection process will encompass the activities of the Inspection Support Team, the Control Room Team and the System Owners including the functional subject matter experts (SMEs).

Inspection Support Team

The Inspection Support Team is the primary interface with the FDA inspector. Key roles on the team include: the Inspection Coordinator, the System Owners or SMEs, the Escort and the Scribe. An overview of the roles and responsibilities for organizations is on page 2.



The Inspection Room (Front Room) Team

The Inspection Coordinator manages the overall process in the Inspection Room. While inspectors often walk the facility, the Inspection Room provides a focal point to access documentation and answer questions from the inspectors. This room is sometimes referred to as the Front Room.

The Escort is the primary point of contact for the FDA inspector; the Escort is responsible for managing the conversation and completing data requests. These requests are given to a runner who, in turn, delivers the requests to the Control Room, which is sometimes referred to as the Back Room. After receiving the request, the Control Room responds by either accessing documentation or setting up interviews with appropriate personnel. Runners take the data back and forth between the Control Room and the Inspection Room.

The System Owners or SMEs review and present materials to the FDA inspector. This role also provides continuity and context for answers. After System Owners or SMEs are dismissed from the Inspection Room they report back to the Control Room for debriefing.

The Scribe is present to take general notes relative to conversations that are ongoing in the Front Room. These notes aid the team during and after the inspection and may be useful in developing responses to any FDA observations that may arise.

Instant messaging is also an asset between the Front and Back Rooms providing instant communication for critical issues being discussed. For example, if documents are not being delivered in a timely manner to the inspector and the inspector is becoming anxious, it is helpful for the Inspection Room to query the Control Room on the expected delivery time-frame.

The Control Room Team

The Control Room provides the documentation, interviewees and preparation that is needed to support the inspection process. This Back Room team, led by the Control Room Coordinator, processes requests for information, retrieves documents from electronic systems and also triages documents as needed. The control room is staffed with quality and technical personnel who log requests for information and alert department heads within the organization. The control room helps to anticipate and prepare for the next potential questions from the inspectors.

The control room staff accesses and prepares the requested documentation for the SMEs. The SME process involves reviewing the retrieved documentation, preparing for a discussion with the inspector and then presenting in the Inspection Room. SMEs are escorted to and from the Inspection Room for any last minute questions and to ensure debriefing occurs after interviews are completed.

Case Study

The Inspection and Control Room can scale up or down with the nature of the inspection. For example, one organization had FDA inspectors and other auditing bodies on-site for six months. Three Control Rooms were set up which had nearly 100 employees supporting the process and driving efficiencies in providing requested documentation.

Behavioral Training

In years past, organizations were known to train employees to give curt answers to FDA inspectors in hopes that nothing more would be revealed to the agency. This approach created fear and mistrust among employees and set up adversarial relationships with the FDA staff. Practicing the inspection process can be one of the best ways to help employees learn appropriate behaviors and

In order to create the most beneficial inspection process environment, both the agency and the company need to form a partnership. Both the agency and industry want to provide safe and efficacious products, and both understand the role inspections play.

Mock Inspection

Many companies conduct internal audits as part of their inspection readiness. Mock inspections take the next step and allow companies to practice the Inspection Room, the Control Room and the right behaviors in working with inspectors to help them access information needed. A mock inspection can be used to probe further on issues uncovered during internal audits. The mock Inspection Team should bring in SMEs and other personnel as needed for this activity. This helps the organization fully understand areas needing improvement and gives them a platform to take corrective action before the Agency actually arrives.

Too many organizations scramble when an FDA inspection occurs because they fail to be prepared. Since organizations don't perform optimally on the fly, it's important to prepare and practice the inspection strategy in advance, not simply rely on internal audits to ready the organization.

Summary

Best practice organizations understand inspection preparedness is vital in working with the agency to ensure safe and efficacious products. Inspection readiness involves both internal audits and mock inspections. During these mock inspections, organizations set up Inspection Rooms and Control Rooms to help teams learn how to readily access documentation which would be requested during an inspection. Additionally, these practice sessions give employees an opportunity to demonstrate proper behavior and interviewing techniques when working with the agency. Being prepared ensures that the inspection process will run smoother, decreases the likelihood of observations and helps groom the organization and individuals for higher levels of future performance.

Hope is *not* a strategy.

TIPS FROM THE EXPERTS

Behavioral Tips	Control Room Tips
Create an environment that reinforces the positive but recognizes weaknesses, such as “we understand this is an area for improvement” rather than “this has been a problem for a long time.”	Don’t allow the Control Room or the Inspection Room to be referred as the War Room. This encourages adversarial behavioral.
Empower the Inspection and Control Room teams. • Allow them to pull in SMEs as needed. • SMEs must have Control Room clearance to bring in documents to the Inspection Room. Don’t allow a SME to bring in notes or an uncontrolled document.	Bring SMEs into the Control Room to help gather data, review documents, and consult on the answer before they are summoned to the Inspection Room.
Train employees to: • Bring a business card when summoned to the Inspection Room. • Focus on the question asked. Restate the question when unsure of what’s being asked. • Readily admit not knowing the answer. This allows the Escort to follow-up. • Be calm and collected. • Be readily available between 9-5pm on the day they might be needed, or let whereabouts be known. • Walk the fine line between confidence and arrogance.	Carefully read Requests. The language used can provide insights from the Inspector. Anticipate next questions and pro-actively pull documents in this area. For example, if the inspector asked about CAPA, consider bringing up the open CAPAs, high risk CAPAs, the average length of time for CAPAs, the longest amount of open time for a CAPA, etc.
Focus on hand-offs with other team members. Use the Control Room to prep and debrief SMEs between discussions with the inspector.	Help SMEs understand their role in the bigger picture of the Inspection. Prep them on related questions which have already been asked. Fully debrief them after sessions in the Inspection Room.

TIPS FROM THE EXPERTS

Behavioral Tips	Control Room Tips
Recognize the need for training across the organization on inspection readiness. Consider off-site locations as well. • The inspection process starts when the FDA pulls up into the parking lot and interfaces with reception and security personnel. • Don't limit inspection training to just Inspection and SME personnel.	Create a culture of efficiency that pulls documents quickly.
Silence is ok, don't feel compelled to fill the "void" by talking.	Keep track of original documents.
Don't make commitments on how something will be resolved.	Every document that goes to the Inspection Room should go through a minimum of two reviews: 1. Quality Review – make sure it points to valid SOPs and Work Instructions, etc. 2. Technical Review – make sure the SMEs have reviewed and are prepared to speak to the process with the inspector.
Always tell the truth.	Have back-up printers, toner, copiers and paper on hand. Printer drivers load notoriously slowly during duress.
Maintain eye contact and be aware of body language.	Consider back-up SMEs. Inspections occur when key personnel are sick or on leave.