

## **Five ways to prepare for an FDA Inspection**

As a regulatory body, the U.S. Food and Drug Administration (FDA) inspects organizations involved in the manufacturing of drugs, biologics, and medical devices. Many of these regulations enforced by the FDA affect clinical and laboratory sites by applying best practices such as good laboratory practices, good clinical practices, human subjects' protection, and requirements for institutional review boards. FDA investigations are carried out in the same process whether they are inspecting a large manufacturing site or a small laboratory. For a small facility, an FDA inspection is often challenging if the quality team lacks experience and resources, however, a clear understanding of the inspection process and structured approach to inspection preparation can reduce the uncertainty of success of the final inspection.

The preparation for an FDA inspection must start long before the actual scheduled inspection day in order to demonstrate that your organization invests in both high quality and process improvement – essential to impress regulatory authorities. Here are a few ways in which your organization can prepare for your next FDA inspection:

### **1. Conduct internal mock audits**

Although a mock inspection cannot fully prepare you for the actual inspection, it will help you identify the weak spots in the procedures and put you in a better position to revise them in accordance with the FDA regulations. The mock audit also provides an opportunity to learn from the mistakes, anticipate questions that might be asked, and train the key personnel who are directly involved in the actual inspection.

### **2. Analyze risks and take required actions on non-conformances**

Since the FDA investigators thoroughly inspect every process, conducting an internal audit will help you identify potential risks in your processes and provide an opportunity to take the required corrective, preventive, or improvement actions to resolve non-conformances raised during an internal audit. Focusing on key problem areas and how they link with each process will help improve the processes that might draw negative attention from FDA investigators.

### **3. Easy access to the current quality manual**

Efficient documentation is the basis of a successful FDA investigation. Inspectors will always ask for procedure manuals to review for each department, therefore, it is essential to have the most up-to-date and comprehensive quality manual for the entire facility. Procedure manuals must be easily accessible and distributed to all key personnel so that any questions raised during the audit may be answered by your team.

### **4. Train appointed personnel to accompany the investigator and conduct employee training prior to a live audit**

Electing at least two or more representatives to accompany the FDA investigator will ease the pressure of this responsibility on a single person. The selection criteria of the representatives who will accompany the investigator must be based on their knowledge, ability, expertise relative to the processes and must be trained to interact with the investigators as well as be familiar with the inspection policies. Once the representatives have been chosen based on these important qualifications, they

should then train the employees who will be impacted by the inspection in general inspection policies and expected conduct during the inspection. Training others can be a great way of assimilating important messages and clarifying common doubts prior to the live inspection conducted by the FDA investigator.

## **5. Prepare Standard Operating Procedures (SOP'S) for the inspection day**

Before the inspection day, you must create an operating manual detailing the following:

- Conduct and behavior
- Roles and responsibilities
- Document retrieval processes
- Actions permitted during inspection
- Documentation of inspection findings
- Inspection follow-up and response procedures

This manual must be distributed to all those involved in the inspection well in advance so that they may clarify any inconsistencies and appropriate revisions can be made prior to the live audit.

## **Conclusion**

Going through an FDA inspection is not something many companies look forward to as it requires a great deal of commitment and an allocation of resources prior to the actual inspection day, however, being prepared for an FDA inspection will not only help you pass the inspection with low negative outcomes but will also boost the confidence of your quality team. Regular review and improvement of processes helps organizations in improving their preparedness for an inspection.

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