

## 6 Considerations During an FDA Inspection

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As the FDA inspector scours the halls of your facility, panic begins to set in. Regardless of preparation, how your group handles an FDA inspection can be the difference between a regulatory citation and a big sigh of relief. The following are six things, taken from a presentation from Bill Hall at IVT's 18th Annual **Validation Week**, you need to consider during an FDA inspection.

### 1. Follow the SOP

As discussed before, have a procedure that outlines the steps of the FDA inspections and assigns personnel during the inspection. Following this procedure will reduce the stress of everyone involved.

### 2. Document Danger

Make lists of documents and document numbers requested by the FDA inspector. Provide document reviewers prior to handing original documents to inspector. Two copies of each document should be made and one of them retained. You must provide documents in a timely fashion. For the validation group, it is especially important to have validation-related information readily available, such documentation for critical utilities (e.g. Purified Water system) and the preventative maintenance program.

### 4. Take Notes!

It is critical to take comprehensive and copious notes during the inspection. Throughout each day of the inspection, involve upper management in the findings and directions of the ongoing inspection.

### 5. QA&A: Question Asking and Answering

Notify all employees that FDA is on-site and they should follow protocol when asked questions. Remember, "I don't know the answer to your question, but I will locate someone who can answer it" is a valid response. Make sure the proper person answers the inspectors' questions (i.e., the person that has the most intimate knowledge of the issue).

When interacting with the inspector, create good listening habits. Read in between the lines when the inspector is asking questions. Try to figure out the reason for the questions and how your answers will lead to further questions.

At the end of each day of the inspection, request a daily debriefing of the day's findings. During this debriefing, it is reasonable to inquire about the next day's inspection activities.

## **6. Let it Flow**

Create flow diagrams of the various manufacturing processes. Numbered steps and diagrams will facilitate the inspection and help inform the inspector as to how the overall process is carried out. During the inspection, identify critical processes and provide a rationale for determining critical steps.

## **Also See:**

Special Edition: Conducting Audits, Gap Assessments & Corrective Actions

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