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4 Indispensable Pre-Inspection Actions

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An FDA inspector is coming to your facility right now. They may not come tomorrow, but every pharmaceutical, biologic, and medical device manufacturer will have to face and manage an FDA inspection. There are some vital pre-inspection activities, given by Bill Hall at IVT's 18th Annual Validation Week, that will guarantee not only confidence when confronting an FDA inspection—but also compliance.

1. Internal/Mock Audits

The value of internal audits have been discussed here before. Internal audits should be performed using the same groups that will host the actual FDA inspection (i.e., QA/QC, Regulatory Affairs, Production, Engineering). Mock audits give you the chance to identify and fix problems. They also allow your facility continuous improvement in terms of handling the audit process. An internal audit will also help you identify where there are gaps in documentation.

2. Review of Critical Documentation

Comprehensive documentation for validation and manufacturing procedures is cornerstone of audit readiness. The analysis of the documentation can be divided into different document types.

Validation Master Plan

Make sure your validation plan is current and referencing a "lifecycle approach" to validation. Make sure it references statistics being utilized when collecting, evaluating, and monitoring data.

Change Control Documentation

For any changes have been indicated to have impact on the validation status of processes, equipment, or critical utilities have the appropriate follow-up activities (such as revalidation) been completed and signed off. Review "as built" drawings to ensure they accurately reflect any changes made to equipment.

Critical SOPs

Know what are your critical standard operating procedures (SOPs) in relation to your SOPs.

Training Program & Records

Keep your training programs and any record up to date. This should include laboratory personnel.

Equipment Qualification Documentation

Confirm you have appropriate documentation for design qualification, installation qualification, operational qualification, and performance qualification.

Process Validation Documents

If there have been any failures or deviations during the execution of validation, review the findings, follow-ups, and corrective and preventive actions.

Also guarantee summary reports and protocols are readily available.

3. Write an Inspection Procedure

Write a procedure that details the steps of the inspection and where resources will be allocated during the inspection. Namely, who does what where and why.

4. Review Critical Quality Systems that interface with Validation

Procedures and corrective actions are the two biggest reasons for regulatory actions. Review the change control, recall, annual product review, deviations/exceptions, and preventative maintenance procedure.

Tags:
GMP - Auditing Investigations & Inspections, GMP
