TraceGains | Greenberg Traurig

FDA AUDIT CHECKLIST: PRE INSPECTION DAY

Be Prepared for an Audit 365 Days a Year

As a result of the Food and Drug Administration's (FDA) Food Safety Modernization Act (FSMA), food inspections are on the rise. Under FSMA, all high-risk facilities must be inspected by January 2016, repeating every three years; all other facilities must be inspected by January 2018, repeating every five years. With the added pressure for the FDA to come in and perform these inspections, it's even more critical that food manufacturers be prepared before, during, and after an FDA audit inspection.

Pre-FDA Audit Inspection Day Checklist

Put together an Inspection Team that will be responsible for dealing with the inspection when the FDA is on the premises. The inspection team should consist of:

1. Inspection Team

- ☑ **Responsible Person**—Select a high-level officer or manager, someone with ultimate responsibility for the company's compliance. This person could be as high level as the CEO or COO. In some instances, someone like a General Manager might be appropriate.
- ☑ **Inspection Escort**—Select a management level employee (e.g., general manager, operations manager) who is familiar with the everyday operations of the company. He or she needs to be a good tour guide, know where everything is, and be able to answer general questions about the day-to-day operations in the facility.
- ☑ **Subject Matter Experts**—Select team members who are knowledgeable and competent enough to answer very specific questions that the FDA may have. For example, these questions may address intake of products, raw materials; manufacturing/GMPs; hazard analysis and preventative controls; distribution; product traceability/ recalls, and labeling. These SMEs most likely would not be with the inspector throughout the duration of the inspection, but rather would be available when needed for specific questions.
- ☑ **Record-keepers**—It's important to identify important document categories beforehand, particularly those that track closely with topics for the SMEs. Equally important is the development of an organized recordkeeping system, which is where TraceGains can really help. Ordinarily, record-keepers will not have direct contact with the FDA, unless this person is also serving another Inspection Team role.

Particularly in small companies, one person may be serving more than one role so it's important that each of these roles is identified, even if it's only to spread across two or three different people.

2. Additional Preparation

- ☑ Make sure your data is 365 Audit Ready™ with TraceGains, so regardless of when the FDA wants to inspect your facility, you'll be ready.
- ☑ Be sure you have written policies and procedures in place for what to do on inspection day. These will be different depending on your company; there really isn't a "one size fits all" approach, but you do want to have a few broad areas covered, including:
  - ☑ Define duties for leaders of the inspection team
  - ☑ Define acceptable interaction with the FDA during inspections
  - ☑ Define responses to post-inspection issues (e.g., corrective actions)

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