TRACEGAINS

FDA AUDIT CHECKLIST

Pre-Inspection Day

Be Prepared for an Audit 365 Days a Year

After the Food Safety Modernization Act (FSMA) final implementation, the U.S. Food and Drug Administration (FDA) has been enforcing more stringent rules during routine inspections. Investigators conduct lengthy facility inspections, review records, and collect microbiological samples for off-site testing. Over the next few years, FDA inspectors must conduct an onsite review of every registered food facility within the United States. TraceGains has assembled the following checklist to help companies prepare for the arrival of FDA investigators.

- ☐ **Appoint designated individuals:** Assemble an inspection team responsible for managing the inspection while the FDA is on site. The inspection team should consist of:
  - Responsible person.
  - Inspection escort.
  - Subject matter experts.
  - Recordkeepers.

  Additionally, make sure the primary representative is up-to-date on FDA's Preventative Control Qualified Individual training.
- ☐ **Establish a meeting place:** Set up a separate place in your facility where the team will meet with FDA investigators. The space should big enough to accommodate records review. If records are kept electronically, have computer monitor(s) to display the information requested. Records should never be left unattended.
- ☐ **Complete written food safety plan:** Ensure your company's written food safety plans are drafted and endorsed by management.
- ☐ **Makes records readily available:** Confirm all relevant records are organized and easily accessible. Your team should be able to quickly retrieve anything from within the last few months. Technically, the FDA requires most records be available for two years, but most investigators don't request anything older than three months.
- ☐ **Document corrective actions:** All corrective actions should be documented and made available to inspectors. These should identify the cause of any issues, actions taken in response, and a written conclusion.
- ☐ **Institute and enforce "No" policies:** FDA investigators normally want to take photos or have company representatives sign a statement or affidavit. If your company has a blanket no photography policy in place, it can prevent any photography from taking place. But it's critical that policy is in place before any inspection. Additionally, employees should be instructed not to sign anything. The law doesn't require anyone to do so.
- ☐ **Have an FDA attorney on call:** If your company doesn't already employ an FDA attorney, it's a good idea to engage one before any inspection takes place. This outside counsel should be included on an emergency contact list who can be reached at any time during the inspection.
- ☐ **Perform a mock inspection:** There's no better way to fully prepare your staff and facility for an FDA visit than an internal mock inspection. Your attorney or another consultant can perform the role of investigator. Not only does this help your team get ready to work with real inspectors, but the mock inspectors can offer feedback on any potential problems they identify.

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Once FDA inspectors arrive at a facility for an onsite examination, manufacturers still have a lot of work to do. We've put together this checklist to help companies work with inspectors.

☐ Arrival

- Typically, FDA inspectors announce their arrival. They're required to present credentials and Form 482: Notice of Inspection-Request for Records as soon as they arrive. Company personnel should notify counsel as soon as possible once the investigators are on site.
- Collect business cards from everyone, if possible. Otherwise, make sure to document everyone's name, title, and operational unit. Most inspection teams will only include one to two members. At times inspections teams may include a third member who is often observing for training purposes.
- Have all FDA personnel sign in as you would any other plant visitor. They might object because they have been trained to do so because they believe it limits their ability to document their visits (e.g. photography).
- If anyone is unable to provide identification, a reason for the visit, or a Form 482, you may refuse admittance. Also, confirm that the visit is a routine rather than a "for cause" inspection.
- Ask the inspectors to wait in the reception area until the "most responsible" person is available to greet them.
- Do not allow anyone to enter with any photographic or audio recording equipment, including cell phones. They might object because they have been trained to do so and might even suggest it could constitute a refusal to permit inspection.

☐ Accommodations

It's imperative that companies undergoing an FDA inspection provide a dedicated work space to investigators. It should have a door, preferably one that locks, and is not adjacent to any employee workspace.

☐ Walkthrough

Nearly every FDA inspection begins with an initial walkthrough so that investigators can familiarize themselves with the overall layout of the plant, the process flow, and to allow them to identify any obvious areas of concerns. There are some things to keep in mind during the walkthrough:

- FDA inspectors should always be with an escort, and never left alone outside of their designated work space.
- FDA personnel must adhere to the same sanitary protocols as any other plant visitor (e.g. masks and hairnets). It might not get mentioned, but they're looking at this, too.
- Investigators might have – or create – a rough sketch of the plant layout. This is permissible as long as no confidential commercial info is included.
- Again, do not allow video, photographic, or audio recording.
- Plant personnel do not have to speak with FDA inspectors – who also aren't otherwise allowed to "interfere" with employees. All questions should be taken up with the escort during the walkthrough. In fact, make it clear to all employees that they are not to answer inspectors' questions during the walkthrough.
- All questions and answers – provided only by designated personnel – should be documented in a daily activity report.

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☐ Samples

It's typical for FDA investigators to request product samples – either during the walkthrough or after – and companies must comply. Make sure a receipt is issued with each sample that includes an identification of the item, the date it was secured, and the recipient. Finally, companies should also pull two identical samples for themselves at the same time. So, for every sample submitted to inspectors, the company should retain two for its own use.

If the FDA samples finished product for pathogens, consider holding product from the lines that the FDA samples were taken until the results come back. In the event that there are positive findings, you can avoid a recall by disposing the held product.

Aggressively clean and sanitize all areas sampled by the FDA. In the event there is a positive test result, you can argue that any contamination that existed during the inspection was already eliminated and could not have affected subsequent production.

☐ Document Review

Aside from obvious sanitary or other physical issues on the plant floor, FDA inspections are document-driven activities. Since agency enforcement depends so much on food, beverage, and supplements companies policing themselves, accurate, accessible, and updated documentation is critical for a successful, expedient inspection.

- It is important to know what documents the FDA is entitled to review. They have broad authority to review food safety plans and related documents, including shipment records. They do not have authority to review or copy formulations, research, pricing, sales, customer complaints about quality, financial data or employee records other than those related to training.
- FDA personnel should not be allowed to go looking for documents on their own. After the walkthrough, they should be kept in the designated workspace and any requested documentation should be brought to them.
- While FDA inspectors are generally allowed to request copies of documents, those copies should also be made by a designated employee. If any records that are copied are deemed to be confidential, mark the document as such to put the FDA on notice that they are handling trade secret, confidential, and proprietary commercial information that cannot be disclosed or disseminated.

Similar to the treatment of sample requests, companies should make an additional copy of whatever documents the FDA requests so counsel can review them at a later date.

- Electronic records systems, which stores all necessary documentation in a single location, can make the inspection process go more smoothly and quickly.
- If any observations are mentioned during the walkthrough, act immediately to correct them to the investigator's satisfaction. By doing so, you will signal to the investigator that you have a culture of food safety and are committed to quickly resolving any concerns. The investigator may not choose to record those findings on the final Form 483.

☐ Interviews

Personal interviews with employees allow inspectors to include any additional information or clear up any confusion about the data they've collected. These do not have to be adversarial interactions since both parties want the same thing: to get back to work. However, it's worth remembering that:

- FDA investigators do not necessarily have a right to interview any employee aside from management tasked with responsibility for the plant and/or its operations. Anyone the company submits for an interview should have a comprehensive grasp of the specific issue in question and company operations in general.
- Employees do not have to be made immediately available, either, especially if submitting to an interview could interfere with normal company operations.
- No company employee – regardless of whether they've been interviewed – should ever sign any statement.
- If the FDA does present any written statements, companies should try to get copies made. Inspections might not always comply, but it's worth the attempt.
- Additionally, any employee being interviewed should not attempt to answer if they're not absolutely certain about the question. It's always better to simply say, "I don't know."

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Post-Inspection Day

After FDA personnel complete their inspection, they typically conduct exit interviews, where they review their findings. The results can include a Form 483, which details any violations they've discovered. We've compiled the following checklist to help companies navigate the next steps after the investigators leave.

- ☐ **Draft Formal Responses for Any Form 483 or Warning Letter You Receive**
  Typically, any regulatory and/or food safety violations that investigators come across during an inspection will be detailed in an FDA Form 483. While the law doesn't necessarily require a formal response, the general expectation is that companies offer one within 15 business days.

  If those responses satisfy the FDA, the agency usually won't insist on any further action and the matter will end there.

  An inadequate response, though, could compel investigators to issue a "Warning Letter" that can threaten your company's registration and halt production.

  Needless to say, this formal response is critical and should not only be drafted with the help of a qualified attorney.

- ☐ **Support Your Response with Documentation**
  Along with a narrative explaining the steps taken to remedy any violations, provide supporting documentation as evidence. For example, training logs, sanitation records, repair invoices etc. bolster your claim that the violation has been corrected.

- ☐ **Other Follow-up Actions**
  Make sure relevant team members thank the FDA investigators for their time, while reinforcing your company's commitment to both quality and safety. Management also should confirm deadlines for any follow-up actions in addition to verifying whether the agency plans to return for further inspection activity. Finally, company personnel should ensure that agency personnel take all of their materials with them.

- ☐ **Get Legal Help if You're Faced with a Recall**
  If investigators threaten a recall, speak with an FDA attorney as soon as possible. Circumstances can vary wildly, so complying with such a request should be handled carefully and with competent legal advice. Attorneys can also help convince FDA officials that other actions might be sufficient to address any lingering concerns.

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TraceGains developed this checklist in collaboration with our partner, Jason Sapsin who is the Sr. Legal Editor, Food & Drug at Thompson Reuters Publishing. Jason is a former FDA associate chief counsel and has extensive experience working with companies to address their food and drug law and advertising questions and challenges, including domestic and international food, dietary supplements, cosmetics, medical devices, and drug companies.

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