Among its many federal mandates, the U.S. Food and Drug Administration (FDA) is responsible for helping to ensure that unsafe foods, medications, and other products do not make their way into consumers’ hands. One of the ways it fulfills this responsibility is by conducting inspections and audits of manufacturers’ facilities.

For manufacturers, an FDA inspection audit is a key step in the approval process—and failing an inspection or audit can set a company’s go-to-market strategy back by months, if not years. If a company isn’t prepared to meet the FDA’s requirements, learning this during an inspection or audit could lead to shuttering the company’s operations altogether.

When conducting inspections and audits, FDA agents go by the agency’s Investigations Operations Manual. This is a 541-page tome (as of 2021) filled with voluminous and highly-technical specifications and requirements. The chapter on Establishment Inspections is 137 pages on its own and covers walk-through inspections, federal labeling laws, and everything in between.

As a result, passing an FDA audit inspection is not an easy process. Rather than
simply letting FDA agents roam their facilities and inspect their files, companies need to prepare thoroughly, and they need to play an active role in the inspection or audit process. This is true for all types of FDA audits and inspections, including those for:

- Biotechnology
- Computerized Systems for Food Processing and Drug Establishments
- Medical Devices
- Pharmaceuticals and Other Drug Products
- Foods and Cosmetics
- Foreign Medical Devices and Pharmaceuticals

In addition to the Investigations Operations Manual, the FDA has also published Inspection Guides for each of these categories. Companies must take the contents of the pertinent Inspection Guide into consideration as well when undertaking their preparation efforts. While passing an inspection or audit is not easy, it can be done, and knowing what to expect is critical for avoiding an unwanted result.

Preparing for a Successful FDA Inspection Audit

With all of this in mind, what do companies need to do in order to prepare? Here are five keys to passing an FDA inspection or audit:

1. Make Sure You Know What the FDA Will Be Looking For

In “What should I expect during an inspection?”, the FDA emphasizes the importance of learning as much as possible about the inspection process. As it states, rather bluntly, “It is in your best interest to fully understand FDA's inspection procedures.”

So, what are FDA agents going to be looking for? Equally important, how are they going to look for it? In order to answer these questions, it is necessary to take a deep dive into the FDA's Investigations Operations Manual and the relevant Inspection Guide.

As a baseline, the goal during an FDA inspection or audit is to demonstrate compliance. The FDA doesn't expect more, and going above and beyond in one area is not going to make up for compliance deficiencies in another. Passing an inspection or audit requires compliance across the board—and, crucially, the ability to demonstrate compliance with appropriate documentation.

While establishing (and documenting) compliance with regard to certain obligations is fairly straightforward, there are lots of issues that require careful attention to detail and an approach that specifically takes the company's compliance obligations into account. This includes various general obligations and obligations that apply to specific types of products, drugs, and devices.
2. Make Sure You Know What the FDA Will Find

Once you know what FDA agents will be looking for, then you can turn your focus to what they are going to find. This means conducting an internal inspection or audit prior to the FDA’s arrival.

As with any type of internal inspection or audit, the purpose of this inquiry is not to substantiate the company’s desired result, but rather to provide unbiased insight into the strength of the company’s FDA compliance program. If there are issues that need to be addressed, identifying them and addressing them before the FDA’s inquiry begins will be critical for avoiding difficult questions and undesirable results.

When conducting an internal inspection or audit in anticipation of an onsite visit from FDA agents, it is necessary to evaluate not only the facilities and records to which the agents will have access but also any issues to which these facilities or records may lead.

At this point, the company cannot have too much information (although the company will want to be careful to ensure that any potentially damaging information is protected by the attorney-client privilege to the extent possible). The FDA agents conducting your company’s inspection or audit will dutifully fulfill their role, and they will not leave any relevant stone unturned.

3. Prepare, Prepare, Prepare

Next, it is time to prepare, prepare, prepare. Companies facing FDA inspection audits should ensure that their facilities are ready, and they should ensure that they have all relevant documentation on hand and ready to be discussed with the FDA’s agents onsite.

Any person who will come into contact with the FDA’s agents should be briefed on what to expect, what to say, and what not to say—and there should be clear chains of command for when issues arise above an employee’s level of authorization, knowledge, or expertise.

An FDA inspection is a process, and it is a process that can take time. While company leaders may be anxious to complete the process and get a positive result, attempting to rush the process can raise red flags. As the FDA says, it is best to understand the agency’s procedures; and, rather than attempting to intervene, companies should instead seek to facilitate a streamlined investigation.

4. Engage Counsel to Play an Active Role in the Inspection or Audit

While our discussion so far has focused on what companies should do when facing an FDA inspection or audit, the reality is that many, if not most, of the steps discussed above, should be undertaken by (or at least with the oversight of) the company’s legal counsel.
Due to the complexity of the issues and procedures involved—as well as the risks of failure—it is advisable for companies to engage legal counsel to manage the FDA audit or inspection process.

Ideally, a company will engage FDA compliance counsel early in the process of building out its facilities and developing its products that are subject to FDA approval. This will allow the company’s counsel to provide advice during the development phase, which can lead to substantial cost savings in the long run.

It will also allow the company’s counsel time to prepare for an eventual inspection or audit—putting the necessary procedures, protocols, and documentation in place in advance rather than in a last-minute push for FDA inspection success.

In addition to guiding the company’s preparation efforts, the company’s counsel can manage the inspection process as well. This will involve communicating with the FDA’s agents, making sure the inquiry stays on course, challenging any investigative efforts that overstep the agency’s bounds and answering any questions regarding the company’s FDA compliance program.

5. Work with the FDA to Resolve Any Issues as Efficiently as Possible

Even with thorough preparation, it is not uncommon for issues to arise during an FDA inquiry. As the agency explains in “What should I expect during an inspection?”:

“At the conclusion of the inspection, the investigator will . . . leave with your management a written report of any conditions or practices, which, in the investigator’s judgment, indicate objectionable conditions, or practices. This list of ‘Inspectional Observations,’ also called an FDA Form 483, can be used by your firm's management as a guide for corrective action, since the FDA representative will not usually recommend specific corrective measures. Your firm can and should respond to the FDA-483 during the discussion with the investigator. In fact, corrective actions or procedural changes that were accomplished immediately in the presence of the investigator are regarded as positive indications of your concern and desire to voluntarily correct discrepancies.”

While companies should challenge any misguided allegations of noncompliance, they should also keep an open mind to remedying any valid issues the FDA’s agents identify. Doing so promptly—and in collaboration with the FDA when warranted—can prevent inspectional observations from going from bad to worse.

It is imperative to work with the company’s FDA compliance counsel at this stage as well, as the FDA expects companies to develop their own corrective measures in the majority of circumstances. Ultimately, the goal is to receive the FDA’s seal of approval, and company leaders need to keep this in mind before, during, and after the inspection process.

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