

FDA Inspection Readiness

A Guide to Preparing
Subject Matter Experts

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Introduction

FDA inspectors are knocking at your door—are you ready? Your first thoughts may be of logistics—meeting space, document availability, condition of your facility—but what about personnel? Are your employees prepared to face FDA inspectors who are trained to dig out the kind of information you may not want them to have?

The employees that know the most about your front-line operations are usually the ones that have the least experience with inspections and therefore are more likely to slip up. That's why training of subject matter experts (SME) deserves at least as much attention in your inspection readiness plan as more tangible aspects like documentation and equipment function.

It's as important to understand how FDA inspectors operate as it is to understand what systems they'll be reviewing: the techniques they use, the cues they look for in interviews, how they prepare for the inspection, their mindset and motivation.

The first day on the job, FDA inspectors take an oath of allegiance to the U.S. government and swear to uphold the Federal Food, Drug and Cosmetics Act. Right from the beginning, they are officers of the government, just like an FBI agent or a U.S. marshal, and they take their job just as seriously.

An inspector's goal is to find violations, and they are good at it. They are highly educated and trained not only in the tenets of good manufacturing practice but also in techniques for eliciting information from individuals. And their advancement within the agency is tied to their results.

Putting an unprepared SME in the same room with these professional interrogators is a clear invitation to disaster. No matter how intelligent, well-educated and capable your people are, they can slip up and lead inspectors through doors you might prefer to keep closed. FDA inspectors can draw conclusions from what your SMEs say, what they don't say, even the way they do or don't say it. The best way to guarantee those conclusions reflect well on your business is to prepare your staff for their moment in the spotlight and make sure they practice, practice, practice.

This report offers guidance on developing an SME training plan, including selecting the right kind of people to participate, assessing vulnerabilities and strengths, understanding common FDA interrogation techniques and testing readiness with simulated inspection interviews.

Preparation—Selecting and Training SMEs

Surviving an FDA inspection is all about managing risk—understanding your weaknesses, anticipating how inspectors will perceive them and preparing your staff to respond. The human factor may present the biggest risk of all. You can't completely control what your employees will say, but careful consideration and preparation will help prevent problems on that front.

The first step is evaluating your SMEs to decide which will fare best in an inspection and which present too much of a risk to put in front of inspectors. Several factors should be considered in this analysis.

1. Competency in answering an inspector's questions. Your SMEs must be ready to answer questions related to the areas of risks you have identified. They also need to be ready to provide clear explanations of your system, your procedures and your associated records.
2. Performance under stress. Consider how individual SMEs react to stress. Will they keep calm or will they panic? Are they likely to respond to inspectors' challenges by passing the buck or pointing the finger at management? Needless to say, such loose cannons should never be allowed to face inspectors.
3. Demeanor and attitude. Think about the kind of impression an individual may make on inspectors. Does he or she appear professional, appropriately dressed and confident? Is his or her attitude one of openness and cooperation or hostility and fear? Can the SME make eye contact and speak clearly and with authority?
4. Adaptability. Can the SME handle unexpected requests and changes in tone or direction?
5. New personnel. If any of your key SMEs are new to their positions or to the company itself, they may need some extra coaching. They may need extra time to practice inspection interface skills and learn how to work with an inspector.

Next comes the process of training the SMEs you have chosen to represent the company. It's important to note that this training shouldn't be conducted only in response to an impending inspection. It should be planned and carried out well in advance of any potential inspections. Making SME training part of the company's standard operating procedures (SOP) allows you to develop a thorough program, rather than rushing to meet a deadline.

Training for SMEs—in fact, any personnel involved in inspections—should go beyond the obvious topics of company policies, protocols and SOPs, and federal regulations and requirements. Trainees should learn about inspection etiquette and presentation, techniques inspectors will use to elicit information, the types of questions they may ask and how to respond effectively.

As mentioned previously, FDA inspectors are adept at digging out information, so SMEs should learn to recognize their methods and how to react to them. Inspectors typically ask several different kinds of questions that present varying levels of risk.

- *Closed questions* are narrowly focused and require only very brief answers, often simply “yes” or “no.” They usually are employed to verify statements and address uncomplicated issues.

- *Open-ended questions* are designed to encourage the SME to talk and provide whatever information he or she wishes. They are very broad, such as “What can you tell me about ...?” or “What do you think about ...?” Inspectors often use open-ended questions to dig into complicated or sensitive areas.
- *Leading questions* are phrased to suggest what kind of answer the inspector is seeking, such as “You don’t believe that process is effective, do you?” These questions usually crop up in the final stages of an inspection, sometimes after an SME has let some potentially damaging information slip.
- *Nondirective or neutral questions*, such as “How do you like your job?” appear in the early stages of an inspection. Inspectors often use them to establish basic facts and identify potential issues.
- *Assumptive questions*—possibly the trickiest kind—are designed to put the interviewee at ease and imply that the inspector already knows and accepts the answer, so the SME feels free to provide information he or she might otherwise not have shared.

It’s just as important to pay attention to how the inspector is listening as it is to what questioning techniques he or she is using. The inspector may be using either the active listening or passive listening approach.

Active listening involves effort to make sure the questioner understands the response. Inspectors may paraphrase an SME’s answer to make sure what they heard is what the SME meant. Or they may ask an SME to clarify a response. Another active listening technique is to summarize the conversation at the end of each topic, again to verify that the questioner has understood the response.

When an inspector is in active listening mode, the SME has the opportunity to expand on his or her responses, which may or may not be beneficial. SMEs should be careful not to stray from the specific topic and open other lines of inquiry.

The passive listening technique can be more difficult to handle. When an inspector asks an open-ended or leading question and then just sits back in silence, an SME may be tempted to fill the void with more information than is strictly necessary. SMEs must be trained to just answer the specific question and then stop talking regardless of what the inspector does.

Knowing when to stop is probably the most important thing SMEs should learn. Other rules of response trainers should stress include “Tell the truth.” Lying to an inspector never pays off, and the damage to your company’s credibility will be long-lasting. This is why it is so important to identify your areas of weakness in advance so you can, first of all, correct them. And if you can’t eliminate a problem entirely, SMEs should know how to discuss it in a way that casts the best possible light on the company.

SMEs also must allow the inspector to complete the question before responding. They should not guess or assume they know where the question is heading. Just as important, once the inspector has finished asking the question, the SME should repeat the question to verify that he or she has understood it or ask for clarification if not.

Interview Dos and Don'ts

Do:

- Answer all questions honestly;
- Say “I don’t know” or “I’ll get the answer for you;”
- Avoid such phrases as “I think,” “Sometimes/often/usually,” “never,” and “next time;”
- Avoid qualifiers, such as “typically,” “normally,” “generally,” and “usually;”
- Stop speaking once the question is answered;
- Repeat every question that is asked;
- Ask for explanations or interpretations of what you do not understand;
- Control your temper; remain courteous and professional; and
- Maintain eye contact.

Don't:

- Volunteer information;
- Be sarcastic;
- Guess answers;
- Attempt to answer “what if?” or hypothetical questions;
- Argue or disagree with any inspector statement;
- Philosophize, ramble or editorialize;
- Point out deficiencies or errors;
- Apologize for problems or comments made by an inspector;
- Feel the need to respond to every comment made;
- Become defensive or evasive;
- Look away, fidget or look nervous; or
- Enter into casual conversation during the audit.

Practice—Simulating Inspector Interviews

The culmination of all this training should be “mock” interviews. SMEs need to practice all of their new skills before facing the real thing. Ideally, they should participate in two or more simulations before participating in a real FDA inspection.

Who should conduct this simulated inspection? Best practice is to use personnel who are independent. They may actually be people from your own company if you have different corporate groups or multiple sites. You may be able to bring in somebody who is independent from within your company. You can also use external, experienced consultants that have both experience with FDA inspections—they may be former inspectors—but also have industry experience to really understand the business side of things. The person should also be very experienced with quality systems.

So what methods are used? During a simulated inspection, the mock inspector will ask questions that would be anticipated during an FDA inspection. Your SMEs answer as they would during a real inspection. This provides your SMEs an opportunity to experience what it’s going to feel like to sit in that hot seat across from someone they don’t know.

The process also gives you a chance to assess your SMEs’ performance. You can see how someone is going to react to pressure when they are pushed a little bit by an inspector. Sometimes you may need to make adjustments. Either you can provide an SME with additional coaching and practice, or sometimes you may need to bring in a different person to work with the FDA inspectors.

From this exercise, SMEs will learn the importance of what they say. They’ll be able to see different paths an inspector can take based on the answers they give.

Setting the Stage

Let’s look at a typical scenario for a mock inspection. A leader on the management team—it might be the director of quality—gets the ball rolling. She’s responsible for working with the management team and site staff to ensure that everyone is ready for the inspection, just as she would for an actual FDA inspection.

As she begins to organize, she contacts the manager of the compliance department and asks him for current information on FDA enforcement trends and also for the results of internal audits. He may tell her, for instance, that there have been a lot of warning letters issued by the FDA related to complaint procedures and that the company’s own internal audits found some similar observations.

Armed with that information, the director of quality gets her team of operations and quality personnel together and asks them to identify some of the compliance risks that might surface during an inspection. In this instance, the team looked at:

- Warning letters for the past and current years;
- Internal audit results;
- CAPA, nonconformance and complaint trending;
- Field actions; and
- Process monitoring.

The team finds a few issues, including an elevated complaint rate for a particular product and an internal audit observation for their complaint handling procedure not requiring the evaluation for further investigation and not being documented. That ties to one of the top issues in recent warning letters from the FDA.

The quality director takes the information from the readiness team and meets with the senior leadership team at the site to undergo the mock inspection. Members of the management team at that site add their perspectives. The management team is aware the action plan to address the complaint handling issue is in process, but it's overdue. They share the fact that there is a new operations manager in the manufacturing area and that corrective actions are still in process.

After meeting with management, the quality director finalizes her plans, identifying key risk topics. They include:

- The complaint-handling CAPA, which has a missing element and is late; and
- The documentation and associated investigation and CAPAs.

The quality director also identifies key areas for SME preparation. Two SMEs who are essential are the manager of complaint handling, because of the key issue with the complaint CAPA, and the new operations manager.

So let's take a look at an example of a simulated inspection between an inspector and an SME. The interview should focus on the multiple topics that need preparation. In this case the focus is on complaint procedures.

Scene One: Just the Facts

***Inspector:** Do you have a procedure for complaint handling?*

***SME:** Yes, we have a procedure for complaint handling. It's been recently updated because of an internal audit observation.*

***Inspector:** I see. Could I see a copy of the updated procedure, the associated change record, the internal audit report and the CAPA associated with this observation?*

***SME:** Sure, we'll get you that information.*

***Inspector:** While we are waiting for the documents I requested, can you tell me what the observation was.*

***SME:** Sure. The observation was that the procedure didn't require that we document the evaluation we perform to determine whether or not a further investigation is required.*

***Inspector:** What are the actions that you have taken?*

***SME:** One of the actions is overdue. We updated the procedure to require that the evaluation is now documented, a rationale for why we're not going to perform further investigation, if that's the case, and the signature of the individual who performed the evaluation. We're making a change to the software to accommodate this.*

Feedback—As part of these simulated inspections, the person acting as the inspector can provide coaching and feedback. In this scenario, he notes that the SME made some mistakes that should be avoided in a real inspection:

- **Providing extra information.** In this case, the SME provided extra information that was not required to answer the question. When asked about the procedure, she said, “We changed it because of an internal audit observation.” The inspector didn’t ask if the procedure had been updated, only if there was a procedure. The SME also stated that corrective actions were overdue. And then the SME included the details of that internal audit finding, which the FDA is not entitled to see.
- **Offering documents the inspector is not entitled to receive.** The SME agreed to provide an internal audit report. The FDA is not entitled to see internal audit reports, although inspectors can request the resulting CAPA report. This mistake opened up issues for the inspector to probe even further. In fact, this led the inspector to ask what the observation was, when really none of this information should have been entered into the inspection. The SME again offered up extra information when she stated that the actions were overdue. The inspector had asked only what the actions were, not whether or not they had been completed on time.

Recommended follow-up—The external expert recommends the site develop a procedure that outlines the company policy for providing documentation to regulatory agencies. The procedure would specify items that the company would not normally provide in an inspection, such as internal audits, pictures, video recordings and personnel or financial information. By outlining this information in a policy, it’s easier to prepare your SMEs on how to answer if an inspector asks for these items. This also gives SMEs some backup if they have to deny an inspector’s request.

So it’s helpful to have such a policy and be sure everyone is trained on it. When issues arise, you can manage that risk and maintain a good, positive relationship with the inspector, which is very important to success.

Scene Two: Hold Your Temper

Inspector: *When will the actions be complete?*

SME: *I think they may be done in about a month.*

Inspector: *How late are they?*

SME: *I believe a month or so.*

Inspector: *A month or so? Why is this OK? (Inspector leans forward and takes an aggressive tone.) Do you think it’s OK to continue to not appropriately evaluate complaints?*

SME: *Well, no. (SME folds arms.) But management didn’t assign somebody to the validation right away.*

Inspector: *How long did it take management to assign someone? Don’t they think this is important?*

SME: *I don’t know. (SME sounds irritated.) You’ll have to ask them.*

Inspector: *All right. Let’s bring in the manager who was responsible to assign the resources and ask them.*

SME: *OK. (SME sighs.)*

Feedback—After this exchange, the inspector points out several problem areas.

- **Avoid the phrase “I think” and other qualifiers.** Advise your SMEs to stay away from qualifiers like “I think,” “I believe,” “I suppose,” or “To be honest.” They may be common phrases in our everyday speech, but they give an indication the SME is not clear on his or her answer or that something else may be wrong.
- **Don’t answer a question if you don’t have the necessary information.** The proper response is, “I don’t know, but I’ll get you the answer.” People often are afraid to do that, but it’s really the best case if you don’t know the answer.
- **Make sure your SMEs know important facts about your operation.** From their research, the inspection readiness team deduced that CAPA would be an area of risk. The SME should have been briefed on the details of the CAPA and what is happening with it.
- **Stay cool under stress.** When the inspector took an aggressive tone, the SME’s composure was shaken. In fact, she implicated the management team when she responded that managers hadn’t assigned someone to perform the validation work on time.
Don’t get into any type of commentary with inspectors. Sometimes these comments can end up in the establishment inspection report (EIR), where the inspector documents the events of the inspection, including key statements from personnel who are interviewed. The comment could also lead the inspector to conclude that management isn’t appropriately engaged or performing their duties. So stay away from such comments.
- **Keep your attitude positive.** The SME also used an inappropriate tone of voice when pressed by the inspector. She became argumentative and defensive, folding her arms, which is classic negative body language. Inspectors will watch people’s body language and listen to the tone of voice for clues that there is a problem. In fact, all FDA inspectors receive interview and body language training.
- **Don’t open the door to new issues.** When the SME said, “You’ll have to talk to management,” she opened the door for the inspector to bring management in, which is exactly what happened. There may be appropriate times to bring management in, but you want to be thoughtful and purposeful about how and when that is done.

Recommended follow-up—The inspector recommends the company make sure that all SMEs understand how to handle difficult discussions, including how to:

- Maintain a calm tone of voice;
- Maintain positive body posture; and
- Be respectful and listen.

If an inspector is emotional while expressing a concern, that is an important time to listen carefully and remain respectful. In such a case, it’s best to defuse the situation and let the inspector know that you understand what he or she is telling you; or if you don’t, ask additional questions. This doesn’t mean promising corrections. When it comes to any corrective actions, that’s best handled outside the inspection. SMEs should be taught under what circumstances they should defer or say, “At this point, my ability to tell you about how we have addressed this is done.”

Scene Three: Silence is Golden

Inspector: Let's look at the CAPA and the procedure update.

SME: Here they are.

Inspector: What is the change that you made?

SME: We added this section here that requires the evaluation for the need for further investigation now has to be documented, along with a signature of the person who did it.

Inspector: Do you have an effectiveness check?

SME: Yes, the records are checked by another person to ensure that this has occurred.

Inspector: I do not see it here.

SME: Well, we are performing this check. I could show you the records.

Inspector: (pauses.)

SME: Since this will now be a required field in the software, you can't proceed without entering this information. It's a very nice system. Would you like to see it?

Feedback—The pregnant pause is a very effective tool in an interview. Train your SMEs to stop talking when they have finished answering a question. Instead, they should wait until the inspector asks the next question. This is one of the hardest things to handle during an inspection. It feels very awkward. But it's definitely the correct behavior in this situation.

In this simulation, the SME kept talking, providing extra information and offering to show the inspector the computer system.

Inspectors employ a variety of techniques, and it's important for SMEs to be prepared and not fall into any traps. For instance, they may face an inspector who asks questions very quickly. An inspector may phrase a question in a manner that makes it sound like something is wrong, when actually it's just a way to see what kind of information is going to come back. An inspector may want to see if there's going to be a calm, confident answer or if somebody becomes rattled.

Recommended follow-up—The inspector cautions the SME against defending something once an issue becomes evident, such as this example where the effectiveness check wasn't documented. It's better in that situation to simply acknowledge that you understand the inspector's concern.

Scene Four: No Guessing

Inspector: Have you looked at your historical complaint records to ensure an investigation was performed where required?

SME: No.

Inspector: How can you be sure that you have?

SME: Well, we do evaluate all of our complaints. It just wasn't documented before.

Inspector: What about the corrective action to make a software change? This document shows it was due one month ago.

SME: Well, I've looked into this, and we should be done with this within a week.

Inspector: Is management aware of this?

SME: I'll follow up on that question.

Feedback—The CAPA for updating the software was late. However, there was nothing to indicate an awareness of this by management. The SME answered correctly by saying she did not know if management was aware of the situation, that the information wasn't in the record and that she would follow up on the question.

Closing Statements

With the simulated inspection complete, it's time for an assessment. The independent inspector should meet with management, such as the quality director, and go over the results.

Together, they should review what happened in the simulated inspection, going over a list of follow-up actions. That may include specific actions, such as those required for the CAPA, but also the recommendations for individual SMEs and what additional work is needed to get them ready.

In this case, the independent inspector says the SME who was put under the spotlight isn't a lost cause and likely would improve with additional training sessions.

Conclusion

The benefit of this risk-based approach to preparing your SMEs for inspection is that it gives you a chance to look at your areas of weakness, address those vulnerabilities and prepare your key people to represent themselves and the company confidently.

Keep in mind that experiential learning is more effective in training SMEs than classroom instruction. With your simulated inspection, you've provided a realistic environment to prepare them.

The information in this report is based on an FDAnews webinar presented by Julie Larsen, Director of Inspection Readiness Services at BioTeknica, Inc., and Arnold Solomon, who is President of FDA Strategic Compliances, LLC, and a former FDA inspector.