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The 10 Best – And 10 Worst – Things You Can Do When FDA Inspects Your Firm

A Compliance Corner collection

by Shawn M. Schmitt

From our archives: Despite the COVID-19 pandemic severely curtailing the US FDA's ability to conduct on-site facility inspections, it's still vitally important for manufacturers to remain audit-ready. In this collection of a 10-part *Compliance Corner* series, four longtime industry experts share evergreen advice on the best and worst things firms could do during an inspection.

Despite the COVID-19 pandemic *severely curtailing the US Food and Drug Administration's ability to conduct on-site facility inspections*, it's still vitally important for manufacturers to remain audit-ready.

Earlier this year *Medtech Insight* brought you a 10-part *Compliance Corner* series on the best and worst things firms could do during an inspection. In this story we've collected all 10 parts, with evergreen advice from some of industry's top experts.

Offering tips is David Elder, executive VP for consulting firm Greenleaf Health, and a former director of the FDA's Office of Regional Operations within the Office of Regulatory Affairs (ORA); John McKay, CEO and chief compliance officer for consulting firm Q1 Associates; Susan Schniepp, a fellow at Regulatory Compliance Associates; and Steve Niedelman, lead quality systems and compliance consultant at the law firm King & Spalding, who worked at the FDA for 34 years in both the ORA and the Center for Devices and Radiological Health.

Here is their 10-point list of inspection do's and don'ts:

No. 1

BEST PRACTICE: Establish and follow a robust procedure for hosting FDA inspections.

WORST PRACTICE: "Wing it" by not using an inspection SOP – standard operating procedure – when investigators visit your site.

Elder: "Here's my advice: Having an inspection procedure, training on it and following it in the heat of battle – aka, during an inspection – is certainly one of the things that we all believe is appropriate. And the converse, thinking you don't need a procedure, is inappropriate."

McKay: "Many firms have an SOP called 'Hosting Audits and Inspections.' The SOP will include things such as a list of inspection participants – the scribe, the runners, and those people working in *the front room and the back room*.

"When you do that, you can show the SOP to the investigators and explain to them: 'This is how we host our regulatory inspections. This is the procedure we're following, and this is the list of things that our scribe is capturing. And we're doing this to better serve your request, to put our best foot forward by explaining our management systems – and our records – to you so this inspection is most efficient.'

> ***"Remember that when you write SOPs, when you're dealing in an inspection, it's all about perception and putting your best foot forward." – Susan Schniepp***

"Now, keep in mind that these investigators all have different personalities. Nowadays they're trained better, and they're trained on how to ask questions. But they are going to have some skepticism. They're going to have a trust-but-verify attitude. So, the more open you can be about your process and explain it to them, the better."

Schniepp: "I'm going to tell one of my most embarrassing moments. It was my second day on the job as VP for a company – it was a small company – and the FDA came to inspect. And I thought, 'Well, I haven't been trained. I don't know anything. So I'll observe my director of quality while he handles this audit.'

"And he was very proud of his SOP, which was about how the firm handled inspections. He gave it to the FDA investigator, who read it and saw the line: 'Don't lie to the FDA.'

"Well, to say the least, I sat there thinking, 'Oh my gosh, why is that line in the SOP?' After all, if you put that line in an SOP that explains how the company handles regulatory inspections, the investigator is going to wonder exactly what we're doing the rest of the time that we need to remind our employees not to lie to the FDA.

"So, remember that when you write SOPs, when you're dealing in an inspection, it's all about perception and putting your best foot forward. Don't write SOPs like *you're* reading them. Instead, write them like *someone else* is going to read them – because they are. And especially don't include the line 'Don't lie to the FDA' – because you shouldn't be lying, period."

No. 2

BEST PRACTICE: Prepare and maintain a site overview slide deck for use during the inspection's opening meeting that can be accessed immediately and covers key products, operations and people.

WORST PRACTICE: Resurrect an outdated slide deck for the opening meeting or use a deck that was made for other purposes, such as marketing or internal reviews.

Elder: "The slide deck should include information on key products, operations and people. A lot of companies have these, but the word 'maintain' is used for a reason. Things change, people change, products change, processes change.

Compliance Corner: Device Maker Irrimax Shares 11 Tips For Acing Your Next Virtual Audit

By Shawn M. Schmitt

24 Dec 2020

If anyone understands the ins and outs of remote audits, it's Christy Coleman. She's VP of regulatory for Irrimax Corp., which has been through four virtual audits under the Medical Device Single Audit Program since the COVID-19 pandemic began. Coleman shares 11 best practices in this *Compliance Corner* feature.

Read the full article here

"There is a limited number of opportunities during the course of an FDA inspection where you get to present something to the investigator. Otherwise, you're responding to questions. And when you're responding to questions, you're not in control of the situation.

"Therefore, when you have this opportunity, typically at the very beginning of the FDA inspection, it's your time to present information without that information being given in response to an investigator's questions. So the content of the slide deck is actually quite important.

"When it comes to the slide deck, I've seen some companies stick to just the facts: 'This is our company, this is our address, we have a 40,000 square-foot facility, we make these three

products, and these are the approval authorization numbers for our products.' OK, that's great. It's informative. It tells FDA something. However, when you do that, I believe you're missing an opportunity to tell more about your company.

"For example, maybe you make a product that treats a rare disease that's helping people live a longer life. Or maybe you were just inspected by a European health authority and received a perfect score. Or maybe you've been inspected by FDA 10 times and were never issued an FDA-483 [inspectional observation form]. Or maybe you have a clean recall history.

"So, all of those other facts – which are pertinent – could serve you well, were you to present them to an investigator at an opening meeting. It would create a positive first impression and would certainly be in your favor to do so."

Niedelman: "With all that said, I do know there are FDA investigators out there who don't want to hear any opening presentations – don't want to know, don't care. They just want to start the inspection and hit the ground running. They think an opening presentation is a waste of time.

"Sure, you can say, 'We think it's important for you to understand this or that, so you have a good overview of the firm,' *et cetera*, but at the end of the day some investigators just want to keep moving forward."

No. 3

BEST PRACTICE: Promptly respond to investigator requests for information and records.

WORST PRACTICE: Take an inordinate amount of time to retrieve information and records, requiring the investigator to ask more than once.

Niedelman: "Have ready for investigators any SOPs that you know they're going to ask for. Why should they have to wait? You know they're going to ask for them. Investigators are going to want to review your procedures and see if you follow them, so I would have certainly all of your quality system SOPs ready to go."

Elder: "Your ability to properly respond to investigator requests may be contingent on having documents already printed in a back room and ready to go into the front room, where the investigator is doing their work.

"But sometimes it's not as simple as a document; instead, it's an information request. One typical FDA information request that's going to cause a manufacturer to pull some data out of their system would be a training record. So, you could be asked for a training record, or you could be asked for all training records, or you could be asked for, say, the training records of two individuals the investigator saw operating a piece of equipment when the investigator was

physically inspecting the plant.

"For some of those information requests, you may not be able to have them automatically staged, because some FDA investigators want specific fields in that data.

> *"Don't make the investigator ask a second time. That would really frustrate the heck out of me when I was an FDA investigator." – David Elder*

"So, for procedures, a batch record, things that are readily available – you should be able to provide those things very quickly. But for data requests, it's reasonable that it's going to take a little bit longer to fulfill.

"It's also important that you don't make the investigator ask a second time. That is something that really frustrated the heck out of me when I was an FDA investigator. Sometimes I would ask for something and it wasn't readily available, and then six hours later I would say, 'Well, where is this document?' and they'd say, 'Oh, we have it right here.' The fact that I had to ask again for the same information used to drive me crazy.

"Just so you know, when investigators ask for something, they're going to write a note to themselves that they asked for it. And when they finally get the info, they're going to check that note. So, don't think you as the manufacturer can game the system and say, 'Well, I'm only going to give it to them if they ask a second time, because they might forget.' Guess what? They're not going to forget."

Schniepp: "Also remember: When you talk to an investigator about procedures, don't overuse acronyms. Companies like to talk in acronyms – 'PR 517 SOP 62795.' No – don't do that. Call it what it is. Is it a CAPA or a deviation? Then call it a CAPA or deviation. If it's 'SOP 12345' and it covers your change-control system, then say, 'This is our SOP on our change-control system, and the number is…" But don't make the investigator learn your lingo. You may talk to each other in lingo at your firms, but when you're dealing with the FDA or any inspecting body, they don't know your specific culture around those types of things. So talk to them and translate the information."

No. 4

BEST PRACTICE: Your back room – a separate area where competent individuals fulfill the

requests of the investigator in a timely manner – operates like a well-oiled machine.

WORST PRACTICE: Diminish the vital role that a back room plays in an inspection.

Elder: "We have to treat the back room as an essential function. How well that back room operates is proportional to how well things go in the front room, where an investigator does a majority of their work.

"I often use the analogy of a duck swimming on top of the water: You want the front room to look like the duck above the surface, just gliding along, and the back room is the tail in the water doing much of the work. You don't see it, but it's there.

"Let me give you an example: I once was supporting a client during an FDA inspection and I stayed in the back room. At the company there was a petite young woman who I came to give the nickname 'Sarge.' Sarge ran that back room like nobody's business. She was absolutely in control. She ran it perfectly and she made the people in the front room look good. She gave the information they needed to answer the questions. The communication was great from the back room to the front room, and vice versa. But Sarge ran it. She didn't take excuses from anybody – that's the kind of person you need in charge of your back room."

Schniepp: "It's true – the back room can be very important. I'm also going to give you a real-life example of when the back room saved an audit: A firm I worked at years ago was having an inspection, and on the second day the investigator brought with them a different firm's information and not ours. Because the inspection was held at our facility in San Diego and the investigator came from Los Angeles – hours away – they were going to have to drive all the way back to L.A. and come back with the correct information for our company. That meant our inspection was now going to be extended by another day or two.

Compliance Corner: Being MDSAP-Ready Helpful While FDA Foreign Inspections Paused, Expert Says

By Shawn M. Schmitt

09 Dec 2020
King & Spalding's Eric Henry urges manufacturers – particularly ones with facilities outside the US – to be prepared for a virtual audit under the Medical Device Single Audit Program. He explains how.

Read the full article here

"The back room should check the records before the runner brings them to the front room to make sure they're complete, make sure

they're the right things that were asked for, and make sure it's all the information that's needed." – John McKay

"So I said to the back room: 'Duplicate everything you gave to the investigator yesterday – and I want it in 20 minutes. Because when lunchtime comes, I want the investigator to have that information so he doesn't have to go all of the way back to Los Angeles to get it.'

"That was a case where the back room saved the day, because it, too, had a 'Sarge' who helped retrieve the information at a breakneck pace. The end result was that the investigator was extremely grateful that he didn't have to travel back and forth, and extend the inspection. It set the right rapport with the investigator. And while a situation like that is probably a rarity, it does happen."

McKay: "Also keep in mind that the back room should check the records before the runner brings them to the front room to make sure they're complete, make sure they're the right things that were asked for, and make sure it's all the information that's needed.

"If there's an additional record or document that's been requested that isn't in the back room, give the investigator what you have and let them know that you have to go to a different place to gather the rest of the information."

No. 5

BEST PRACTICE: Staff your front room – a place where investigators do most of their work – with the appropriate key personnel who have the expertise and personality to shine.

WORST PRACTICE: Select your front room personnel based on title alone.

Elder: "When you're picking personnel to take these front room roles, you have to pick people not just based on title. You have to pick the right people to be able to interface with the agency, be it the principal liaison, be it the scribe, or be it the SME [subject matter expert] you have to bring in to answer a particular question. Title alone should not be the sole criteria for putting a person in the front room, because establishing rapport, trust and understanding with investigators is critical.

"And sometimes two people may not mesh. Let's say I'm interacting with the front room liaison as the FDA investigator. They may have said a couple of things that I didn't believe that I questioned, and it turned out that they were erroneous. So now I don't have trust in this person

anymore, but I still have to deal with them for the next several days. That's not the relationship you want to have in the front room."

> *"You might discover that your Plan B or Plan C people turn out to be better in the front room than a book-smart guy." – Steve Niedelman*

Niedelman: "And with regard to the front room folks, make sure you have people who can think on their feet and fully understand the nature of the investigator's questions. Second, don't undervalue or underestimate the usefulness of prepping your SMEs. Put your SMEs through mock questioning. Some people may have all the academic degrees in the world, and they may know this stuff, but they might not be able to deliver.

"And always have a Plan B, because heaven forbid an essential front-room person gets into an accident or something on the day of the inspection. The funny thing is, you might discover that your Plan B or Plan C people turn out to be better in the front room than a book-smart guy."

McKay: "And all of this is very important to practice. When you're doing your internal audits, you want to try to do mock inspections if you can. You want to practice these things and have the person who's doing the mock inspection ask the hardest questions.

"You want to practice so when you're in front of an investigator, for one, it adds confidence, it adds calmness, but also, it's a role you've been through before. So you know where specific things are located, and you know how to get them.

"Performing mock inspections is probably one of the most important management tools that a quality organization has at its disposal."

No. 6

BEST PRACTICE: Ensure prompt, effective communication between the front room – where investigators do the majority of their work – and the back room, used by company workers to fulfill investigator requests for documents, records and other information. Monitor communication between the two rooms throughout the inspection.

WORST PRACTICE: Only use a chatroom to facilitate front room and back room communication, with few face-to-face interactions. There is no need for a lot of coordination.

Elder: "Communication between the front room and the back room is important. And please don't think that using a chatroom is sufficient.

"What I've seen the best companies do – or the companies that perform the best in this area do – is at the end of every day when the FDA inspection team leaves the premises, the front room staff goes to the back room and there's a debrief on the day: what worked, what didn't work, what we need to improve tomorrow. So, make sure that communication is effective, and make sure you monitor how the rooms are communicating with each other.

"You want the people in the front room to have the rapport, to have the relationship, to have all the information they need. The role of the scribe is to communicate to the back room. And the role of the liaison in the front room is to be the primary interacting point with the FDA investigator."

McKay: "And then you need to have someone in the back room who is set up with the records, and a runner who goes back and forth between the front room and the back room, or the data storage area, to get any type of records that the investigator needs to have. So, make sure you have these people fully ready and prepared by performing mock audits.

"Make sure everyone in the back room knows where to find the records. But if an investigator asks for a record and you can't find it right away, ask the investigator what other records they want, or information needs they may have.

"Respectfully tell the investigator that you're working on getting them what they've asked for. Let them know if a runner's going to get it: 'Hey, a runner's going to get the record. It's in the back office storage. We'll bring it to you. We'll let you know as soon as it's available in the front room.' So, make sure that records are flowing. Make sure the information is flowing.

"Also, the back room should check the records before the runner brings them to the front room, to make sure they're complete, make sure they're the right things that were asked for, and make sure they have all the information that's needed."

No. 7

BEST PRACTICE: Use subject matter experts appropriately, and make sure SMEs are trained and qualified to participate in the inspection.

WORST PRACTICE: Overuse or underuse your SMEs.

Elder: "You don't want to overuse SMEs. For example, if an investigator has a straightforward question that a person in the front room as the principal liaison can answer, then let that liaison answer. Don't feel like you have to rope in an SME if an answer is already known. On the flip side,

it's important not to underuse your SMEs.

"And remember that it's OK to make adjustments. It's OK to make a change if a particular SME isn't working out. If the wrong SME is engaging with investigators, it's OK to change them out. Be flexible enough to make those changes on the fly, if necessary. After all, if there isn't a productive relationship of trust and credibility with investigators, then you've already lost. And if there's a significant conflict in personalities, make a change. It's fine."

> *"Sometimes your first-choice SME is not your best person to present in front of the FDA." – Susan Schniepp*

Schniepp: "When it comes to SMEs, I agree with David. Have a backup plan. Sometimes your first-choice SME is not your best person to present in front of the FDA. That's when the investigator can walk you straight into [an FDA-483]."

No. 8

BEST PRACTICE: Ask questions of the FDA inspection team as needed to fully understand any issues or investigator concerns.

WORST PRACTICE: Allow misunderstandings to persist. Don't ask clarifying questions of investigators or provide additional, unsolicited information to correct a misunderstanding.

Elder: "It's OK to ask questions of the inspection team. If they're making a point that you don't quite understand, ask them to clarify. If they ask a question and the question is unclear, ask them to rephrase.

"You don't want to let any misunderstandings persist. You want to address them as quickly as you can. If you see that they're reaching the wrong conclusions – if they're going down a path where you can kind of see that they're headed to the wrong place – or if they face some incomplete information, it's important to correct those misunderstandings before they get bigger."

McKay: "Remember that the inspection is a two-way street, not a one-way street. If there's something you don't understand – perhaps the investigator's line of questioning or their concerns about whatever document they may be looking at – then do speak up.

"Keep in mind that you want every opportunity to present your best case to the investigators with all the data you have. So, if you have questions or if you're unsure about their train of thought, you can ask them and then be able to present other objective information."

No. 9

BEST PRACTICE: Maintain an accurate record of the inspection, including questions asked and answers provided, concerns raised, positive observations and documents given to investigators.

WORST PRACTICE: Rely on a chatroom transcript and employee memories for your inspection record.

Elder: "It's important to have an accurate record of the questions asked and the answers provided. It's only going to serve you well in the long term. And it's also in your best interest, if the investigator happens to say anything positive, to jot that down, as well. If they say, 'This validation study was done beautifully,' write it down."

Compliance Corner: How To Survive An FDA 'Desk Audit' During The COVID-19 Crisis

By Shawn M. Schmitt

15 Apr 2020

A former US FDA investigations branch director explains how a paper-based "desk audit" would be performed by the agency in lieu of an on-site quality systems inspection. Last month the FDA hit the pause button on in-person inspections as the coronavirus pandemic rolls on.

Read the full article here

McKay: "And make sure that your scribe or someone else in the front room is keeping a record of all the documents, records and forms that you show to the FDA. A lot of firms stamp their records as a copy so they can keep track of the records they're giving to investigators."

No. 10

BEST PRACTICE: Be honest with investigators, always and without exception.

WORST PRACTICE: Provide untruthful, inaccurate and incomplete information to investigators.

Elder: "It goes without saying: Be honest at all times. Your employees should know that it doesn't do the company any good to give an investigator an incorrect answer if they think it puts the company in a better light.

"Some employees will do this. They give an answer that they think is protecting the company and protecting the products, and it's an unacceptable practice. It does not show integrity. It does not show a culture of quality. It's just going to get worse from there.

“Being honest always and without exception should be the guidance for every employee in your company.”

McKay: “It’s vitally important that all of your people are honest. I recommend having an honesty culture at your company and having an honesty culture as part of your data integrity policy. If you have that type of culture, then the investigators will get the general idea that you’re honest all the time, whether they’re there inspecting or not.”

The comments from Elder, McKay, Schniepp and Niedelman came during FDAnews’ 14th Annual FDA Inspections Summit.