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Investigator Horror Stories: Industry Insiders Tell Of FDA Inspectional Nightmares – And How Device Firms Handled Them

by Shawn M. Schmitt

In this Compliance Corner feature, two industry experts give real-world examples of US FDA inspectional overreaches, including one investigator who followed a device firm's employee into a restroom to stop her from using a cell phone. Yes, that actually happened – and it's just one of many inspectional nightmares that manufacturers have faced when inspected by the agency.

Picture this outrageous scenario: During a facility inspection, a male FDA investigator follows a woman who works for a device firm into a restroom. He demands that she surrender her cell phone because he does not want her to call a supervisor.

Believe it or not, that actually happened – and it's just one of several inspectional nightmares that manufacturers have faced when being inspected by the agency. So says industry insider Steve Niedelman.

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> *"You don't want to be a chronic complainer to FDA, of course, but when it comes to something as distasteful as following a woman into a restroom, then it is appropriate to contact the agency," King & Spalding's Steve Niedelman says.*

That particular investigator "refused to stay in the conference room for whatever reason," he said. "When he overheard talking taking place in the restroom, he grew suspicious of the employee's actions, opened the door to the ladies restroom, stepped inside and told the employee that she was not permitted to use her cell phone to call anyone."

Niedelman is a familiar face in the medical device arena, working at FDA for 34 years in both its Office of Regulatory Affairs and Center for Devices and Radiological Health. He is currently lead quality systems and compliance consultant at the law firm King & Spalding.

The manufacturer's female employee "tried to speak to the investigator to help him understand that it was inappropriate behavior for a male FDA investigator to walk into the ladies room," he said. Investigators "don't have the authority to tell you not to use your cell phone. You can use your cell phone in front of them. There's nothing that stops you from doing that."

Although the investigator initially took offense to the employee's concerns, he eventually caved. "He said, 'Oh, please, don't complain. I'll get fired,'" Niedelman said. "Nonetheless, he really wouldn't back off on being suspicious of the manufacturer."

The company later filed a formal complaint with its FDA district office, and a copy was sent to the agency's Associate Commissioner for Regulatory Affairs.

"We got a very prompt response from the district director and a follow-up response within a matter of three to four days. The investigator was obviously taken off the assignment, and the firm was assured that they would never see that investigator again," Niedelman said.

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"The agency is extremely sensitive to those kinds of situations. They are embarrassed by them," he added. "But nonetheless, sometimes you do have to escalate. Sometimes you do have to ramp it up. And you may have to do what you have to do.

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Below, Niedelman and Elaine Messa – president of the Medical Device Practice at consulting firm NSF Health Sciences and a former director of FDA's Los Angeles district office – tell a trio of real-world stories of troublesome agency inspections, and offer solutions on how firms should respond. Comments from both experts came during FDAnews' 13th Annual Medical Device Quality Congress in Bethesda, Md.

Investigating The HVAC

An investigator conducting a facility inspection wanted to check the HVAC filters, which were located on the roof of the building. He returned to his car to get tools to disassemble to the unit.

"The firm stopped the investigator on his way back from his car. The firm provided documentation that the filters were changed. The firm also provided documentation that there was a maintenance program in place. But this investigator was a little bit pushy, to the point where the firm basically said, 'We're not permitting you on the roof, and you do not have permission to access the unit,'" Niedelman said.

"And, of course, if the investigator broke that unit, then the agency would be responsible. And what about interrupting manufacturing that was ongoing without the HVAC unit running? Nevertheless, the investigator never did reach that unit, but it did take some careful maneuvering to make the investigator stop."

Investigator Horror Stories 2: More Terrifying Tales Of FDA Inspections Gone Bad – And How They Were Fixed

By Shawn M. Schmitt

24 Oct 2017

Eli Lilly global quality leader Francis Blacha and former FDA investigations branch director Ricki Chase talk about shocking inspectional run-ins, from an agency investigator who hollowed out a notebook to hide a voice recorder, to another who donned a disguise to force a face-to-face meeting with a company CEO – and more. Find out how they handled the nightmare audits...

Read the full article here

The Paranoid Investigator

An FDA investigator gave a firm he was auditing a choice: Full notes could be taken by a scribe in the *front room*, and the investigator would stick to citing regulations when he found problems and would not discuss them with the firm, or the manufacturer could only take notes on

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document requests and have an open discussion with the investigator as the inspection progressed. The investigator claimed he needed to protect himself and didn't want everyone to see what he said.

"The firm decided it was in its best interest to have an open discussion with the investigator, so it opted to maintain a scribe – but only to undertake requests for documents, as the investigator suggested. But I definitely think it's worth negotiating. In this particular instance, the investigator actually walked back and forth in the front room. The scribe was situated so the investigator was able to see the scribe's computer screen at all times," Messa said.

"Firms have a legal right to have a scribe present. Having a scribe improves the efficiency of the inspection, and most investigators wouldn't care if you have one. But in this particular case, the investigator decided: 'I will not be open with you and discuss your problems if everything I say is documented.'"

Investigator Horror Stories 3: Boozing On The Job? Yup, That Happened – As Have These Other Shocking Tales Of Irregular FDA Inspections

By Shawn M. Schmitt

22 Oct 2018
In the final chapter of our Investigator Horror Stories trilogy, former US FDA investigations branch director Ricki Chase tells how one agency investigator blatantly drank alcohol and asked for bathing suit suggestions during an audit in Greece, and longtime industry insiders Steve Niedelman and David Chesney offer up three bone-chilling stories of investigators who stepped over the line. Check out...

Read the full article here

> ***"As FDA's 'program alignment' unfolds, you're going to start seeing a lot of new investigators at your sites," Niedelman says.***

Added Niedelman: "You're entitled to have a scribe in your front room. There's no legal prohibition from having a scribe. You want to make everybody comfortable and get on the same page. You don't want to get off on a bad foot. But you can reassure the investigator that you're not there to be confrontational. You want to make sure you're staying on top of what the findings are so you can address all issues and memorialize them as they pop up.

"This issue has come up from time-to-time. Start thinking about what would happen if this

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occurred at your firm. As FDA's '*program alignment*' unfolds, you're going to start seeing a lot of new investigators at your sites. So you might be confronted with this situation even though you might not have in the past. So just think about these things in advance so you know how to react should this type of situation arise."

The Nightmare After Christmas

An investigator arrived at a US facility on December 26, the day after Christmas, for an unannounced inspection, and was upset because all of the firm's personnel were not available to immediately begin the inspection.

"If you're open for business, FDA has the right to inspect. The investigators issue a notice of inspection to whoever is in charge. It could be the janitor if somebody points to that person. Or if the investigator asks, for example, 'What happens if somebody pulled the fire alarm today? Who would be responsible?' then they might go to that person and issue a notice of inspection," Niedelman said.

"But you want to be accommodating. You're open for business. According to the statute, FDA is entitled to inspect. So what do you do? You better start calling people to come in. And explain to the investigator that it will take a little bit of time for some people to come in, but you're going to try to do your best to accommodate them," he added. "Unless you're closed during that Christmas break – and many firms do that for a variety of different reasons – then FDA can inspect. It's the same thing on the day after Thanksgiving, New Year's Eve – all of the common holidays. Unless the government is closed because there is an extended three-day weekend, or something along those lines, then the agency has the right to inspect."

From the editors of The Gray Sheet

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