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

by Shawn M. Schmitt

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 in this Compliance Corner sequel to last year's most-read *Medtech Insight* story.

This Halloween, trick-or-treaters might not be the only ones wearing a disguise. When you're on the manufacturing floor at your medical device company, take a sharp look at the person standing next to you – he or she could be an imposter from US FDA.

That's what happened to a maker of combination products several years ago at a facility in Brooklyn, NY, says Francis Blacha, global quality leader for devices for *Eli Lilly & Co.*, who told *Medtech Insight* that an agency investigator spent days trying to infiltrate the company (which he did not identify) in a bizarre, desperate bid to meet the CEO.

"FDA is required to, when they do a notification of inspection, issue a Form-482. Investigators must give the form to the most senior person at the firm, which is typically the CEO. A lot of investigators take that task extremely seriously," Blacha said in an Oct. 11 interview.

And at the Brooklyn firm, "the investigator took that on as a personal challenge," he said. "I don't know whether he had the firm under surveillance or not, but he suspected that that the company CEO was there because in the parking lot, the CEO had a dedicated spot, and he could see that a

car was parked there."

Despite the circumstantial evidence, company employees told the investigator that the CEO was not in the facility. That's when he took matters into his own hands.

"What the investigator began doing was, he would come to the plant disguised as an employee. He would wear a black leather jacket and sunglasses. He had facial hair. He'd ride up to the facility on a Harley motorcycle instead of in a government car. He would park the Harley in the employee parking lot, surround himself with actual employees, and then try to make it through the facility to the CEO's office to present the 482 to him."

> *"The firm didn't have appropriate security at this facility. If this disguised investigator could get in, what would prevent somebody else with more nefarious intentions from getting in?" Eli Lilly's Francis Blacha says.*

The investigator – who didn't produce credentials or a government-issued badge – wore the disguise on three separate occasions until he was caught. "He never quite made it to the CEO's office, but he got very close," Blacha said. Eventually, the investigator gave up and handed the notice of inspection to the CEO's subordinate.

"The investigator finally came clean and said, 'Hey, you know what? I've got to get on with this inspection, so I'll give [the FDA-482] to whoever you tell me is the senior person at the firm,'" Blacha said. For whatever reason, the manufacturer never reported the rogue investigator to the agency, but it did double security efforts following the unusual incident.

"The firm didn't have appropriate security at this facility. If this disguised investigator could get in, what would prevent somebody else with more nefarious intentions from getting in? Clearly they didn't have appropriate security measures if someone was getting that far into their facility," Blacha said.

"I don't know if the investigator was proving a point that the firm had a lack of security, or he simply knew that the CEO was there," he said. "But it was very strange for him to not use a government car, to drive up on a motorcycle and to try to blend in with the crowd to be able to navigate his way through the facility undetected."

Blacha suggested that having procedures and policies in place to handle unannounced inspections could help diffuse such sticky situations.

"Clearly, when somebody shows up and presents their credentials – and even if they don't – you should ask them, 'Please identify yourself,'" he said. "You have to make sure that you have the appropriate procedures in place and a list of appropriate contacts. And don't make investigators wait forever."

While few and far between, stories of FDA inspections gone horribly awry aren't unique. In fact, last year's most-read *Medtech Insight* article detailed how an investigator followed a device firm's employee into a restroom to stop her from using a cell phone, while another attempted to fix a manufacturer's rooftop HVAC unit. (Also see "*Investigator Horror Stories: Industry Insiders Tell Of FDA Inspectional Nightmares – And How Device Firms Handled Them*" - Medtech Insight, 7 Jun, 2016.)

In this second edition of "Investigator Horror Stories," Blacha and Ricki Chase – a former FDA investigations branch director – tell a trio of real-world stories of other troublesome inspections, and offer solutions on how firms should respond if they encounter an auditor who engages in strange or unexpected behavior.

The Curious Case Of The Crying Investigator

During her 16 years at FDA – she left in 2016 – Chase witnessed peculiar behavior from agency investigators, she said in a February episode of *Compliance 360°*, a podcast series from *Medtech Insight* on US FDA compliance and enforcement issues.

"Throughout my years, I had numerous opportunities to train and to audit the investigators, and noted attitudes and behaviors that could've been perceived by our partners in industry as aggressive, difficult, inappropriate, and even weird. This has included … crying uncontrollably without explanation," said Chase, who was also an investigator, medical device specialist and supervisory investigator at the agency.

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In an Oct. 19 follow-up interview, Chase told the full story of the weeping investigator.

"There was an investigator that I was a colleague with, and I don't know why, but for some reason, any time she was stressed, she cried. And being an FDA investigator can be very stressful," said Chase, now compliance practice director for Lachman Consultant Services.

"I took her out on investigator training, and in the middle of a conversation with the firm regarding some SOP [standard operating procedure] that seemed very insignificant at the time, she just started crying. I'm sitting there thinking, 'Why is this person crying?'"

> *"It's very uncomfortable sitting there watching somebody cry with no explanation while they're reading your SOP," ex-FDAer Ricki Chase says.*

The quality assurance official at the firm that was being inspected – who also served as the lead for the audit – was taken aback as the investigator-in-training continued to cry uncontrollably.

"I mean, it's very uncomfortable sitting there watching somebody cry with no explanation while they're reading your SOP," Chase said.

"The first thing the QA lead did was get up and get a box of Kleenex and slide it across the table in a very kind of precarious, 'OK, here, do you want some Kleenex?' kind of way," Chase added. "And then, after she started dabbing her face, she began crying even more. So, I said to the lead, 'I think we're going to need to call a timeout. If you could just give us a few minutes.'

"The only thing the person at the firm could think to say was, 'I didn't think our SOP was that bad,' to which I immediately started laughing, which did not help the situation at all. She did not come back the next day, for obvious reasons – she was taken off the inspection."

When Chase told her supervisor at FDA what transpired, "he thought I was lying," she said.

The supervisor then accompanied the weeping investigator on an inspection. To his surprise, "the investigator started crying at the close-out meeting," Chase said. "She made it through the entire inspection, but when the FDA-483 [inspection observation form] was being issued to the firm and she had to discuss the 483 issues, she cried." (Also see "*Compliance 360° Part 2: Getting The Most Out Of Inspection Close-Out Meetings*" - Medtech Insight, 13 Feb, 2017.)

The investigator was not terminated from the agency, though. "I think she knew that she was short-lived for being an investigator, so she went back to working in FDA's lab, which I think she was probably better suited for, where she didn't really have to have a whole lot of human interaction," Chase said.

Q How should a similar situation be handled?

A "If an investigator is upset, obviously, the appropriate thing to do would be to be sympathetic and say, 'I'm very sorry, I can see you're upset. Is there something I can do to help you?' And if they say no and they continue to go on, I think that – unless the investigator pulls it together – the firm has the right to question where that person's mind really is," Chase said.
"The last thing you want is an investigator who is emotionally distraught about something else, or, for whatever reason, can't manage what's going on. They're certainly not going to be focused on what you're doing, and they're certainly not in a position, I wouldn't think, to be making a good decision regarding your compliance status," she said.

If the situation continues, Chase recommends that firms ask to end the inspection day.

"The firm could say, 'There's something clearly going on, and I feel uncomfortable that we're not going to make good headway today working together. Perhaps you would like to end the day. Perhaps you'd like to come back tomorrow,'" she suggested.

"If they continue to say no, then I would definitely call their division office," Chase said. "You should call and say, 'I need to speak to whoever's the manager of this individual. They're in my firm right now, and I feel like we have a little bit of a situation that is timely and we need to discuss it.' And the firm doesn't need to be rude about it, but I think they need to say, 'You know, I'm very concerned about this investigator. They're sitting in my conference room weeping, and they can't seem to pull it together and they don't seem to want to come back tomorrow, so how would you like to proceed on this?'"

Another option that device-makers have is to call the division director.

"Regardless of what program the division director works in, the director will know exactly how to get to the right person probably faster than anybody else," Chase said.

> "It's always OK to speak to the division director, and even if it's not their program area, they have a responsibility, if that's going on, to do something about it immediately."

The Investigator Who Wanted To Go High

Eli Lilly's Blacha was involved in an FDA inspection several years ago at an unnamed firm, during which time the investigator was laser-focused on looking at nonconforming components that were stored about 20 feet off the ground in a quarantined section of a warehouse.

"The QA people were there to raise the forklift, pick up the pallet and bring it down to the floor so the investigator could see it. But the investigator didn't want to do that. Rather, he wanted to go up onto the pallet himself," Blacha said.

The firm didn't want to do something so dangerous – yet it did anyway, but only to a certain height.

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

By Shawn M. Schmitt

07 Jun 2016

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.

Read the full article here

"There was a bunch of consultation and stuff like that; finally, the firm agreed to raise the investigator up to only about 8 feet so he could look at information on the components' pallet tag," Blacha said.

At that point, "the firm said, 'That's all. We're trying to be cooperative as much as possible, but we're only going to bring you up to this height so you can see the pallet tag. If you want to see any more information on the pallet, then we must bring the pallet down to the floor,'" he said.

> ***"After a while, people should say, 'Hey, you know what? This is kind of weird. We may need to talk to somebody else about this,'"***

Blacha says.

"To this day, I don't know why the investigator would not let them bring the material down to the floor. For some reason, he just wanted to go up and see it for himself," Blacha added. "A lot of times, you might not understand what the reasoning behind something like that is. Maybe he could have been looking at a potential prosecution down the line. But I think after a while, people should say, 'Hey, you know what? This is kind of weird. We may need to talk to somebody else about this.'"

Q **How should a similar situation be handled?**

A Again, it's best for device-makers to have well-defined policies and procedures on how to handle inspections, and to lay out boundaries for investigators, Blacha said. Firms need to let investigators know that some areas and activities are off-limits because the auditors could put themselves in physical danger.

Manufacturers "should have an area specifically for receiving and inspecting components, and if an investigator wants to see those, then the firm should bring that material down to that area," Blacha said.

The Secret Of The Hidden Voice Recorder

When an FDA investigator was caught consulting for industry and falsifying inspection reports, his superiors conducted an investigation that led to a shocking discovery, consultant Chase recounted.

"Not only was this investigator doing consulting work for firms he was personally inspecting, but he was trying to play 'undercover cop' too, trying to catch a company lying after officials there

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

complained that he was too aggressive," she said.

In an effort to secretly record conversations that happened at the firm, the investigator hollowed out a hardback notebook and placed a voice recorder inside.

"He recorded everything that the company was saying, particularly when he wasn't in the room," Chase said. "When he was out doing the inspection on the floor and the quality people were left in a conference room discussing the inspection, he was recording what was going on. He was a real interesting piece of work."

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

"You know, people do really weird things, but there's a difference between being weird and doing something illegal," Chase says.

An FDA administrator who investigated the crooked auditor's work found the carved-out notebook while poring over journals in the man's desk.

"One of the things you have to do to verify if somebody actually inspected a firm is to get their investigative journals. There must be an investigative journal entry for every inspection," Chase said.

When the notebook was discovered, the recorder was found not long after, which included detailed conversations at the company. Soon after, the investigator was fired.

Q **How should a similar situation be handled?**

A Chase admits that this was an extreme case, and that manufacturers likely won't encounter such deception. But if they do, they should immediately contact FDA. "You know, people do really weird things, but there's a difference between being

> weird and doing something illegal, which is what this individual was doing," she said.

From the editors of The Gray Sheet