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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

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 how they handled the outlandish inspections in this Compliance Corner threequel.

There was a time, many decades ago, when drinking alcohol on the job was culturally acceptable and even encouraged. But this isn't the bygone era of "Mad Men" anymore – and a US FDA investigator certainly should not imbibe when conducting a facility inspection.

But that's exactly what happened during a recent agency audit at a company in Greece, Ricki Chase, a former FDA investigations branch director, told *Medtech Insight*.

"The investigator was basically there on vacation. She wasn't there to work. It was apparent," said Chase, who was also an investigator, medical device specialist and supervisory investigator during her time at FDA. She left the agency in 2016.

From the moment the investigator arrived at the firm, she began asking company employees about the hottest tourist attractions and where she could buy a flattering bathing suit.

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"If you're going to have a cocktail, have a cocktail, but don't have a cocktail in the firm, and don't have a cocktail with the firm over lunch," consultant Ricki Chase says.

"It was extremely warm a few months ago in Greece. So, the investigator shows up and spends her time having conversations with the firm about where she can go to buy a bathing suit, and the local sites she should see," said Chase, now compliance practice director for Lachman Consultant Services.

"She was asking, 'Can you show me where to eat?' and, "Can you tell me what parts of Greece I should look at?' and, 'What about the local cuisine?' This went on for about the first three days of the inspection, these conversations. And they weren't brief conversations," she said.

That's a problem for foreign-based inspections, where travel time is limited to a set number of consecutive days. OUS FDA inspections typically run over a brisk three- to five-day timeframe.

Chase continued: "That incessant conversation stimulated a department head at the firm to talk to the investigator about the local alcoholic beverage – sort of like an aperitif. That prompted the department head to say, 'I have some. Do you want to taste it?'"

And the investigator did – a lot of it.

"They sat there and had drinks in the firm during the workday," Chase said. "Look, here's the thing: If you're going to have a cocktail, have a cocktail, but don't have a cocktail in the firm, and don't have a cocktail with the firm over lunch. Have a cocktail at dinner by yourself.

"I've known investigators who, after the end of a foreign inspection, have gone out with the firm's employees, with the clear understanding that they would pay their own bill, and they'd have cocktails at that time – but the inspection was over by that point," she added. "But never have I seen drinking onsite at a firm, like in this instance, and never with the firm's personnel."

Aside from the drinking, Chase said it's inappropriate for an investigator to engage a firm's employees in such casual personal conversation while on the job.

"The investigator must be focused on the work that he or she is there to do. But that particular investigator in Greece wasn't focused on the work that needed to be done," she said.

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Chase says foreign firm employees will often put up with unusual behavior by investigators because they believe they don't have any recourse.

And day-drinking wasn't the only infraction this investigator made. She also asked the firm to arrange for a car to pick her up and return her each day to the hotel where she was staying.

"Investigators are supposed to manage that themselves unless there's truly some important reason why they can't. But this particular investigator was essentially telling the firm that she wanted this to be done for her – she wanted the firm to provide her with a driver for every day of the inspection," Chase said.

"I've been to that facility. It's literally a five-minute drive from the hotel to the facility, so she should've been taking a taxi, which is a normal course of action," she said. "Further, she had no intention of even having the US government pay for it."

Chase said employees at foreign firms will often put up with unusual behavior by FDA investigators because they believe they don't have any recourse.

"They don't feel like they have the power to say, 'That's completely inappropriate,' or, 'Could we not talk about this?' or, 'At the end of the day, when the inspection is done, then maybe we can give you some references to local sites to see.' They don't feel empowered to say those things because they're afraid of the FDA. They're worried that investigators could write an observation [on an FDA-483 inspection form] that isn't real, or they could report that the company wasn't cooperative," Chase said.

"But I tell people this all the time: That type of behavior on the part of investigators is completely inappropriate, and particularly when it's been witnessed by more than one person at the firm. It's incredibly important to document those types of things and report them to the FDA."

Chase said there's no doubt that a domestic company wouldn't hesitate to "pick up the phone and call the FDA and say, 'Your investigator is sitting in my conference room drinking.'"

So why do foreign firms feel powerless to report problematic investigators, but their US counterparts don't?

"Because there's a cultural difference. There's a language difference. They automatically feel like FDA doesn't trust foreign manufacturers, and to some extent, they're right. FDA doesn't," Chase said.

"FDA believes that foreign firms are almost always exclusively worse than US firms," she said. "You also have to remember that FDA doesn't have any legal authority in a foreign country. So, if the firms don't invite FDA in, then they're refusing the inspection. If they refuse inspection, then they don't get to keep their product on the market in the US. So, they're fearful that if they don't go along with an investigator's unusual behavior, that it would be very easy – almost too easy – for something to be made up or communicated that could put their business at harm.

"Frequently, foreign firms don't report these types of things. The only time I've ever seen foreign firms report bad investigator behavior has been when that firm is a US company or has a very strong US presence. But when you're dealing with individual firms that aren't large conglomerates and don't have space in the US market locally, they have even more problems."

Nightmarish inspection scenarios happen all too frequently, it seems. Investigator Horror Stories 2 – last year's most-read *Medtech Insight* article – detailed the curious case of a crying investigator and told the story of an investigator who hollowed out a notebook so he could secretly record conversations with company employees. (Also see "*Investigator Horror Stories 2: More Terrifying Tales Of FDA Inspections Gone Bad – And How They Were Fixed*" - Medtech Insight, 24 Oct, 2017.)

And in the first installment of Investigator Horror Stories – the *Medtech Insight* article read most in 2016 – device industry insider Steve Niedelman told how a male investigator followed a firm's employee into a women's restroom to stop her from using a cell phone, while another tried fixing a device-maker'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.)

"A lot of time and effort is put into training investigators to be professional, to treat people with respect, to be courteous and to be a good representative of FDA, and 99.9% of all investigators, their conduct is appropriate, and the inspections are conducted as expected," Niedelman said at FDAnews' 12th Annual FDA Inspections Summit. "But there are a few rogue investigators out there. There are some that sort of push the envelope."

Niedelman – 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 – is back again with three new stories of inspections gone awry. He shares those stories below with the help of David Chesney, another longtime FDA veteran.

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A Nightmare On Title 18 Street

During an inspection, an FDA investigator accused an employee of lying and demanded that all of the device-maker's workers undergo training on *Title 18*, which is the US government's code for Crimes and Criminal Procedures.

"What happened was, the investigator spoke to a line operator who gave the investigator information. But when the investigator talked to management, a different story was given as to what was going on," said Niedelman, who is currently lead quality systems and compliance consultant at the law firm King & Spalding.

"Management at the firm suggested that the line operator was nervous, so they encouraged the investigator to speak to the line operator again," he said.

But that just made matters worse.

"The investigator spoke to the operator two days later, and the operator changed his story to align with what management said. So right away, the first insinuation by the investigator was that now the line operator was lying and was covering up to protect management," Niedelman said.

"The investigator then required that the firm go through Title 18 training, and that nobody could walk into the front room without a signed statement that they had received Title 18 training."

A so-called front room is where investigators traditionally work when onsite at a device firm. (Also see "*From 'Back' To 'Front': FDA, Industry Experts Advise Device Manufacturers On Best Inspection 'War Room' Practices – And Don't Forget The Swedish Fish*" - Medtech Insight, 9 Dec, 2015.)

"Well, that request was really way over the top, but the firm was in the position where they found that if it was going to get them through the inspection, they were willing to do it. It was really an unusual situation," Niedelman said.

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

But Chesney said the manufacturer should not have complied with such a request.

"If you get a really oddball demand or request like that from an FDA investigator, I would urge you to contact your local district office – even though *'program alignment'* is what it is, you still have a local contact point you can get in touch with to see whether they're supportive of what the investigator is demanding," said Chesney, who spent 23 years in FDA's Office of Regulatory Affairs (ORA) as an investigator and supervisory investigator. He also was director of the agency's San Francisco district office from 1991 to 1995.

Launched in May 2017, program alignment was the most sweeping change to FDA's inspectional approach in agency history. Under the scheme, inspections performed by ORA – the office that conducts all of the agency's field activities – are structured along commodity-specific product lines to make audits more predictable and consistent for investigators and manufacturers. (Also see "*'Program Alignment' Turns 1: FDA Wants To Train Investigators On Innovative Tech As Part Of Its Inspection Scheme – But Will It Be A Cakewalk?*" - Medtech Insight, 15 May, 2018.)

"An investigator that makes demands on a firm, asking that employees be trained on Title 18, is unreasonable. Title 18 is the general criminal laws of the United States. Lawyers go to law school and focus entire portions of their education on that. [A manufacturer] can't even accomplish that. It's completely not feasible," said Chesney, who is now principal and general manager of his own Maine-based consulting firm.

"If I was working with a firm that got that kind of request, I'd call the district office to find out what's going on with this investigator, because that kind of demand is outside the remit of an inspection, does not serve the agency's purpose at all, and is something that needs to be elevated to FDA management when it happens," he said.

The Terminated Inspection

At the close of an introductory presentation during a compliance follow-up inspection, a female investigator commented that if there were more women on the company's management team, then the firm would not have had as many problems.

"And, at the end of the same introductory presentation, the investigator was introduced to the firm's new CEO. She commented that, based on problems firms had in the past when they were involved

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

By Shawn M. Schmitt

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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

with that individual, the company should not expect to improve," Niedelman recounted.

In this particular case, the manufacturer filed a complaint with FDA's Office of the Associate Commissioner for Regulatory Affairs (ACRA).

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...

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When that happened, "the inspection was terminated immediately. A full internal investigation was conducted by the FDA Office of Criminal investigations regarding the behavior of the investigator. The investigation was concluded, and that investigator was removed from the inspectional team," Niedelman said.

Chesney said it's of the utmost importance for device-makers to immediately document inappropriate remarks made by an investigator.

"Carefully document the comments and document all those who were present and heard them," he said. "Sign off on whatever record you create, and I would urge you to create that record as soon as possible after the comments are made, because this is indicative of a bias on the part of that investigator, which could skew their objectivity as they assess your company going forward. And you may at some point need to stand behind that.

"The sooner you document it and the more people you can capture that heard it and can agree on what was said, the better," Chesney added.

The Investigator Who Had 'All The Time In The World'

An FDA investigator identified a potential observation during an inspection. That's when he approached management with a "commitment to correct" document that he prepared, promising that if it was signed, the observation would not be included on the FDA-483.

"The investigator, for some reason, thought this was a great idea. And unfortunately, we were contacted after the first one was signed," King & Spalding's Niedelman said.

There is no such thing as a "commitment to correct" document.

"When management was approached the second time to sign another 'commitment to correct,' management declined to sign it. That's when the investigator advised management that he had 'all the time in the world' to sit in the conference room and wait until they signed the document," he said.

"We advised our client to take the FDA-483 observation and to sign nothing, and to keep moving on with the inspection," Niedelman noted. "We advised the firm to handle any observation that was addressed in their response to the 483."

And, he pointed out, there's no such thing as a "commitment to correct" document.

"We could not, because of fear of retribution, convince our client to go to the agency with this information, unfortunately," Niedelman said. "But don't be intimidated by a 'commitment to correct,' or anything like that. Just accept the 483 observation."

Consultant Chesney agreed. "A receipt for samples [an *FDA-484 form*] is the only form you have a real compulsion to sign. Anything else an FDA investigator shoves at you and asks you to sign is optional on your part.

"But before you sign anything like that, you probably ought to seek the advice of counsel as to whether it's appropriate for you to do that."

From the editors of The Gray Sheet