MEDTECH INSIGHT
CITELINE COMMERCIAL

28 Nov 2019 | **Interviews**

# How Your Medtech Company Can Build Trust With FDA Investigators – And The Agency At Large

*A Compliance 360° Q&A*

by Shawn M. Schmitt

Device makers that build bridges with US FDA investigators will have an easier go of things during facility inspections, says Ricki Chase, a former FDA investigations branch director. By doing this, firms can extend that trust to the agency as a whole. Check out our full Q&A with Chase here.

Medical device manufacturers that build bridges with US Food and Drug Administration investigators will have an easier go of things during facility inspections, an ex-agency official says. By doing this, firms can extend that trust to the agency as a whole.

> *"Professionalism is critical." – Ricki Chase*

"Building trust with the investigator, and therefore the agency, is an integral part of successfully navigating inspections, and if necessary, response to an official action," said Ricki Chase, compliance practice director for Lachman Consultant Services and a former FDA investigations branch director.

"The investigator is the person you will most frequently interact with, and as ORA likes to say, the eyes and the ears of the agency. This is one of the most critical relationships you will build," she told *Medtech Insight*.

ORA is the FDA's Office of Regulatory Affairs, which handles all the agency's field activities.

Read our full Q&A with Chase below.

**Q** **Medtech Insight: In your view, why is building trust so important?**

**A** Ricki Chase: Let me tell you a quick story that will help answer that question. Many years ago, I was responsible for training a new investigator. We had complaints and MDRs [Medical Device Reports] indicating that the firm's device was implicated in patient overdose and death. We also had personal documentation from the patient's family, demonstrating that the firm had been notified of the complaint.

We conducted a routine quality system inspection, but we didn't see the complaint in the firm's record, or in their MDR filings. And we asked several times if they were aware of the matter, and they denied knowledge for three straight days. On the fourth day, we were presented with a file containing the details of the complaint and its investigation. We were told that it was found in the desk drawer of a member of senior leadership at the firm.

Needless to say, it was difficult to trust the personnel or the documents moving forward.

**Q** **What are some ways firms can build trust?**

**A** Chase: Planning for your inspections is important. It demonstrates that you take the inspectional process seriously, and that you understand your role, as well as the role of the investigator.

You should read and train on the FDA's Investigations Operations Manual, and understand how inspections are conducted and what to expect. This will help you plan and prepare accordingly. Not knowing who to call when the investigator arrives, demanding they sign confidentiality agreements or no-photo agreements, or stalling them on arrival, all diminish trust and send the message that you do not respect that there is a job to be done.

And professionalism is critical. You would be horrified to refer to a member of your leadership by the wrong name. So, learn the investigator's name and how they would like to be addressed. Most investigators are very comfortable with the use of their first name. However, public health service officers may want you to use their title. I was once referred to by the wrong name every day for a 10-day inspection, and it wasn't until I signed the FDA-483 [inspectional observation form] did they realize they had called me by the wrong name the entire time. It was not good.

Your professionalism goes beyond knowing the investigator's name, however. It also goes to the attitude and posture presented during the inspection. Investigators who are met with aggressive, confrontational, or even weepy management begin not to trust your intent. Aggressive and confrontational individuals are perceived to be hiding something, and weepy individuals are perceived to be creating a distraction from the process.

**Q** **And I would assume that being transparent and honest is helpful, too.**

**A** Chase: That's right. Corporate and personal integrity should be demonstrated with every action. It seems obvious, but do not lie, and do not lie by omission. Being transparent and helpful builds trust. Offer explanation, particularly for unique processes or products. Make sure the most responsible individual on site is prepared to meet the investigator, and at a minimum, receive the notice of inspection and inspectional observations, if presented.

There have been times when the most responsible individual at the facility has refused to present themselves to receive those documents. FDA investigators are trained that it is their responsibility to issue to this individual. Failure of this individual to produce themselves is seen as leadership shirking its responsibility. So, always strive to present the right person for the job.

**Q** **How important is it to let an investigator speak with your workers?**

**A** Chase: Very important. Don't withhold your personnel from the investigator. Provide the person who is most qualified to answer the question, or explain the process, policy or documents. The right person does not necessarily need to be the subject matter expert [SME]. In fact, oftentimes the SME is very knowledgeable, but lacks the ability to communicate in a way that non-SMEs can understand. Provide the person who has the facts and can communicate them clearly.

Making your knowledgeable staff available demonstrates that personnel at all levels of the organization can communicate their understanding of their role. It also demonstrates that management has nothing to fear from a frontline employee relaying their day-to-day activities.

**Q** **Is it a good idea for a company to have a lawyer attend an inspection?**

**A** Chase: No. That won't help you build trust. If you need a lawyer present for an inspection, it automatically makes an investigator expect that there are things you are not going to share. It would be rare that your legal team has a role in your day-to-day manufacturing, design and CAPA [corrective and preventive action] operations. So, what are the lawyers there to speak to? Instead, demonstrate that the individuals responsible for routine operations know the quality system and how to work within it.

**Q** **Does taking a long time to do something – say, retrieving documents from a backroom – cause an investigator to lose trust?**

**A** Chase: It can, yes. Be prepared to present requested personnel, documents and tours in an expeditious manner. When it begins to take an inordinate amount of time to respond to a request, it raises questions about what is going on behind the scenes. Are you changing documents, or creating those that do not exist? Or are you cleaning house before the tour?

**Q** **What other advice do you have about building trust?**

**A** Chase: Ask questions when you are unclear. Nothing erodes trust more in subsequent

inspections than to see a 483 response that contains information that didn't exist during the course of the inspection, or alleges that management did not understand the observations that were presented. This is particularly worrisome if it is noted in the report that you had no questions or comments.

And keep your promises. Whether you say you will do something during the inspection, during the close-out meeting, or in writing, keep your promises. If you promise a timeframe, do everything possible to meet that timeframe. And if you will not, let the agency or investigator know this before the deadline arrives.

It may feel or seem cliché, but the agency really does view the promotion and protection of public health as a team effort between government, industry and academia. Seek to work together, provide explanation, ask questions, keep promises, and speak to each other with respect for the role that each play. A comfortable conversation builds trust in your knowledge, and in your intent.