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# Compliance 360° Part 3: Building Trust With US FDA – Can It Be Done?

by Shawn M. Schmitt

This is Compliance 360°, a podcast series from *Medtech Insight* on US FDA compliance and enforcement issues. In this third installment, former FDA investigations branch director Ricki Chase explains how your firm can build trust with agency investigators during a facility inspection.

When Ricki Chase inspected a device firm as a US FDA investigator several years ago, she just couldn't trust the manufacturer after it produced questionable documents.

She was in possession of complaints and 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," Chase says in the third installment of Compliance 360°, a podcast series from *Medtech Insight* on US FDA compliance and enforcement issues.

"We conducted a routine quality system inspection, but we didn't see the complaint in the firm's records or in their MDR filings. And we asked several times if they were aware of the matter, and they

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denied knowledge for three straight days," she said.

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"On the fourth day, we were presented with a file containing the details of the complaint and the 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."

In the podcast, Chase – a former FDA investigations branch director – explains how your firm can build trust with FDA investigators during a facility inspection.

"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," she said.

Chase is compliance practice director for Lachman Consultant Services, a firm she joined in June 2016 after spending 16 years at FDA, where she was also an investigator, medical device specialist and supervisory investigator.

Listen to the podcast via the player below:

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