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Compliance 360° Part 1: Handling Difficult US FDA Investigators

by [Shawn M. Schmitt](#)

This is Compliance 360°, a podcast series from *Medtech Insight* on US FDA compliance and enforcement issues. In this first installment, former FDA investigations branch director Ricki Chase explains how you should handle a difficult agency investigator who shows up at your facility door.

When Ricki Chase worked at US FDA, she witnessed some truly bizarre behavior from agency investigators.

“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,” Chase says in the first installment of Compliance 360°, a podcast series from *Medtech Insight* on US FDA compliance and enforcement issues.

“This has included outright arguing with industry management, failing to explain decisions or references for observations, checking out early from an inspection to take in the local sights, and crying uncontrollably without explanation.”

In the podcast, Chase – a former FDA

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investigations branch director – explains what you should do if you run into an unruly investigator.

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.

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