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Compliance 360° Part 6: Don’t Do That! How To Respond To FDA-483s

by Shawn M. Schmitt

This is Compliance 360°, a podcast series from *Medtech Insight* on US FDA compliance and enforcement issues. In this sixth installment, former FDA investigations branch director Ricki Chase explains how your firm can best respond to the agency following the issuance of an FDA-483 inspection form, and tells you four things your firm should never do when replying to FDA.

Ricki Chase doesn't mince words when advising medical device manufacturers on four things they should never do when responding to US FDA after receiving an FDA-483 form following an unfavorable inspection.

First, "do not send a response cold without a cover letter. It is generally not polite, and you want to make sure that the agency understands that you understand the importance of the 483 and the response," Chase says in the sixth installment of Compliance 360°, a podcast series from *Medtech Insight* on FDA compliance and enforcement issues.

Second, "do not send a response that does not tie the corrective action to the observation. A single narrative document

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makes it difficult for the officer to identify which observation you are planning to correct and how," she says. Third, "do not send a response indicating that you have made corrective actions without providing evidence of such. No evidence, it didn't happen."

Finally, "do not make promises that you cannot keep."

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In the podcast, Chase – a former FDA investigations branch director – also explains how your firm can best respond to the agency following the issuance of an FDA-483.

"The expense of a warning letter far outweighs the cost of a swift, dedicated, well-thought-out response, and the opportunity to voluntarily correct and improve your quality system," she says.

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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