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Compliance 360° Part 2: Getting The Most Out Of Inspection Close-Out Meetings

by Shawn M. Schmitt

This is Compliance 360°, a podcast series from *Medtech Insight* on US FDA compliance and enforcement issues. In this second installment, former FDA investigations branch director Ricki Chase explains steps your firm should take to make sure inspection close-out meetings are fruitful for everyone involved.

Ricki Chase recognizes that US FDA inspection close-out meetings can be tense and fraught with chilly moments.

“The close-out is rarely viewed as a joyous event where you shake hands [with FDA investigators] and go back about your normal business,” Chase says in the second installment of Compliance 360°, a podcast series from *Medtech Insight* on US FDA compliance and enforcement issues.

Rather, “the close-out meeting is an opportunity to gain an understanding of the investigator's observations. This is a time where spoken word is often more valuable than the written one. It gives insight into the investigator's level of concern, which translates into the tone and presentation of the official Establishment Inspection Report.”

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- *Handling Difficult US FDA Investigators*
- *Getting The Most Out Of Inspection Close-Out Meetings*
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- *How To Better Manage Your Quality Data*
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In the podcast, Chase – a former FDA investigations branch director – explains steps your firm should take to make sure inspection close-out meetings are fruitful for everyone involved.

Strategy

- *US FDA Is Looking Closely At Process Validation – Are You Ready?*

"If you are one of the fortunate ones who do not receive an FDA-483 [inspection form], keep listening – there's still value in the close-out," she implores. "And if you're less fortunate and receive a 483, keep listening – there's value in the close-out."

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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