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Compliance 360° Part 5: Medical Device 483s – US FDA's Top 5 Observations

by Shawn M. Schmitt

This is Compliance 360°, a podcast series from *Medtech Insight* on US FDA compliance and enforcement issues. In this fifth installment, former FDA investigations branch director Ricki Chase highlights the agency's top 5 inspection observations found on FDA-483 inspection forms, including failing to have procedures for corrective and preventive action (CAPA), complaint handling, purchasing controls, process validation, and nonconforming product.

When it comes to the top flubs made by medical device manufacturers, it's all about procedures.

Specifically, firms fail to have procedures for corrective and preventive action (CAPA), complaint handling, purchasing controls, process validation, and nonconforming product, Ricki Chase says in the fifth installment of Compliance 360°, a podcast series from *Medtech Insight* on US FDA compliance and enforcement issues.

In the podcast, Chase – a former FDA investigations branch director – highlights those top 5 inspection observations, which are found on most FDA-483 forms following a facility

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inspection.

"In my opinion, a solid quality system begins with having a skilled quality team, [and] clear, concise and validated procedures prepared by cross-functional teams; strong employee training, and ownership of their very important role in each step of the process. And, a corporate culture which supports identification and correction of quality problems, continuous improvement, and leadership responsibility," she said.

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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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