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Compliance 360° Part 4: How To Better Manage Your Quality Data

by Shawn M. Schmitt

This is Compliance 360°, a podcast series from *Medtech Insight* on US FDA compliance and enforcement issues. In this fourth installment, former FDA investigations branch director Ricki Chase explains how your firm can better manage its quality data.

When it comes to convincing company management that activities surrounding the collection and use of quality data is of the utmost importance, sometimes it's all about showing top brass the money.

"If the regulatory and [FDA] expectations alone do not convince you or your leadership that quality data are critical to the success and safety of your device, then perhaps the money will," Ricki Chase says in the fourth installment of Compliance 360°, a podcast series from *Medtech Insight* on US FDA compliance and enforcement issues.

"Studies have found that adopting quality practices such as those by the top quality performers in industry can reduce your manufacturing costs by 20% to 30%, and your profits may increase by as much as 3% to 4%," she said. "Additionally, quality improvement leads to greater customer

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satisfaction and a competitive advantage.

"And after all, who wouldn't like more profitability?"

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

In the podcast, Chase – a former FDA investigations branch director – explains how your firm can better manage its quality data.

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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