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Compliance 360° Part 9: US FDA Is Looking Closely At Process Validation – Are You Ready?

by Shawn M. Schmitt

This is Compliance 360°, a podcast series from *Medtech Insight* on US FDA compliance and enforcement issues. In this ninth installment, we interview former FDA investigations branch director Ricki Chase, who explains why your device firm needs to be on the ball when it comes to process validation activities and offers tips for best practices.

US FDA is closely scrutinizing medical device manufacturers' process validation activities during facility inspections – especially those dealing with software, former agency investigations branch director Ricki Chase says.

"The review of software validation by FDA investigators has become more robust, as investigators have become more familiar with software, software validation and potential weaknesses that software can present in a quality system," Chase says in the ninth installment of Compliance 360°, a podcast series from *Medtech Insight* on FDA compliance and enforcement issues.

Chase spoke to us in San Jose, Costa Rica, at an industry conference on process validation and risk management hosted

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by the American Society for Quality's (ASQ) Biomedical Division.

"Specifically, data integrity is a hot topic right now with FDA. But data integrity is nothing new. The expectation has always been that demonstrable evidence is required to prove that data are accurate and maintained as part of the device history record," she said. "The difference is that now FDA investigators are savvy and well-trained to know how to challenge your systems and determine if you have adequately validated the software."

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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.

In the podcast, she also explains other process validation items that FDA investigators will look for, and offers a bevy of tips on how firms can ensure gold-star validation activities.

Listen to the podcast via the player below:

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