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Compliance 360° Part 10: Turn Your CMO Nightmare Into A Dream Come True (1 of 2)

by [Shawn M. Schmitt](#)

This is Compliance 360°, a podcast series from *Medtech Insight* on US FDA compliance and enforcement issues. In this 10th installment – the first of two parts – former FDA investigations branch director Ricki Chase explains how owners of regulated products can learn "tricks" to managing their relationships with contract manufacturing organizations (CMOs) to avoid being "treated" to an FDA-483 inspection observation form.

Owners of regulated products must make sure that contract manufacturing organizations have strong quality systems that are capable of detecting problems early in the production process. That's one of several messages on device companies working with CMOs from former US FDA investigations branch director Ricki Chase, who explains that "high quality builds profitability."

"Early detection and correction of quality problems [at a CMO] allows for less time and money to be spent on cleaning up a mess" in the form of a recalled medical device or some other sort of nonconformance, Chase says in the 10th installment of Compliance 360°, a podcast series from *Medtech Insight* on FDA

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compliance and enforcement issues.

Nevertheless, "the owner is equally responsible, as they need to have a quality system which can look for quality signals, particularly post-market signals, and share that information with the CMO as a means of process improvement," she says. "One should not assume that the other has no need to know when quality metrics indicate that there may be a trend beginning."

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Chase is compliance practice director for Lachman Consultant Services, a firm she joined in 2016 after spending 16 years at FDA, where she was also an investigator, medical device specialist and supervisory investigator.

"A profitable relationship can be built when both the owner and the CMO truly embrace each other as business partners, both of whom want to build capital on their enterprise," she says in the podcast, noting ways to smooth the owner/CMO relationship.

Listen to part one of this two-part podcast via the player below:

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