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Compliance 360° Part 11: Turn Your CMO Nightmare Into A Dream Come True (2 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 11th installment – the second of two parts – former FDA investigations branch director Ricki Chase discusses some of the more complex problems that may arise in the relationship between the owners of regulated products and contract manufacturing organizations (CMOs), and how to solve them.

The relationship between the owners of regulated products and contract manufacturing organizations can be made unnecessarily complex when the owners make changes to medical devices without first notifying their CMOs.

"This can happen with product design changes, material changes and/or supplier changes," former US FDA investigations branch director Ricki Chase says. That's why "design changes should be discussed with the CMO before they are made. A design change may involve the need for new tooling or a need for the process to undergo validation after the design change; it may also involve the need for new or different testing to be performed."

In this 11th installment of *Compliance*

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[360°](), a podcast series from *Medtech Insight* on FDA compliance and enforcement issues, Chase points out that owners also need to alert CMOs if there are changes to components or raw materials.

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"A change in raw materials or the supplier of the raw material can have a direct impact on how the material reacts in the manufacturing process. Further, changes in materials can cause new and unexpected problems with the manufacturer's equipment. The CMO should know about these changes before they take place," she says.

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.

Listen to the second part of this CMO podcast via the player below...

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