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Compliance 360° Part 12: Navigating The Quicksand Of Device/Drug Combo Products (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 12th installment – the first of two parts – former FDA investigations branch director Ricki Chase offers the latest insights into the complexity surrounding combination device/drug products. In this first podcast, Chase reviews regulations and guidance documents related to combo products, and highlights the varying types of combo products, definitions unique to device design, and how combo product manufacturers differ from the typical medical device or drug firm.

When it comes to manufacturing combination products, companies may find themselves scratching their heads, wondering whether they should follow US FDA's regulations for medical devices or drugs.

In this 12th installment of *Compliance 360°*, a podcast series from *Medtech Insight* on FDA compliance and enforcement issues, former FDA investigations branch director Ricki Chase says firms should keep a close eye on both, but points out that there are differences.

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"The primary function of ... combination products is usually the drug or biological component. In those instances, 21 CFR Part 211 [the agency's regulation for drugs] would be the primary focus," Chase said. "However, the differences are that in 21 CFR Part 820 [FDA's Quality System Regulation for devices], the management responsibilities are slightly different and need to be addressed. [And] obviously, there are design controls, which are unique to the design component of the device, which you would not normally see in pharma or biologic manufacturing, and clearly are not stated in Part 211."

Companies should also keep in mind that activities related to purchasing controls, as well as corrective and preventive action (CAPA), are different in the device and drug realms.

Further, "organizations traditionally manufacturing drugs or biologics may have a lack of technical knowledge with regards to the medical device components and/or design controls. And there may be challenges in understanding how the devices make the combination product needs very different," Chase said.

In this podcast, she also highlights the varying types of combo products, definitions unique to device design, and how combo product manufacturers differ from the typical medical device or drug firm.

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 first part of this combo product podcast via the player below.

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