MEDTECH INSIGHT
CITELINE COMMERCIAL

19 Feb 2018 | **Analysis**

Compliance 360° Part 13: Navigating The Quicksand Of Device/Drug Combo Products (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 13th installment – the second of two parts – former FDA investigations branch director Ricki Chase brings you the latest insights into the complexity surrounding combination device/drug products. In this podcast, Chase digs deep into design control, design changes, human factors studies and biocompatibility concerns for combo products. She also discusses some pre- and post-market considerations, as well as common pitfalls to avoid.

All too often, companies that set out to make combination device/drug products conduct design control activities "way too late" in the manufacturing process, former US FDA investigations

Other Compliance 360° Podcasts

- Turn Your CMO Nightmare Into A Dream Come True: *Part 1* & *Part 2*
- *Building Trust With US FDA – Can It Be Done?*
- *US FDA Is Looking Closely At Process Validation – Are You Ready?*
- *Medical Device 483s – US FDA's Top 5 Observations*
- *Factors Feeding Your Inspection Cycle – A New Paradigm*
- *Don't Do That! How To Respond To FDA-483s*
- *How To Better Manage Your Quality Data*

branch director Ricki Chase says.

- *Getting The Most Out Of Inspection Close-Out Meetings*

"Design control is going to be required for a combination product. And it's hard to go back and do a retrospective design history file, because you've not captured a lot of the information that you need to do those things, such as design verification and design validation, along the way," Chase explains in this 13th installment of *Compliance 360°*, a podcast series from *Medtech Insight* on FDA compliance and enforcement issues.

"And the fact is, if you're not caught [with inadequate design control] on submission of [your FDA pre-market] application, you will be caught at the [FDA] pre-approval inspection when they ask to review your design control, or in post-market, when they come to do a post-market approval inspection, or a routine inspection, and they ask you about your design control," she says.

The bottom line? "You need to make sure that you're doing the design control and that you're starting it at an appropriate time in your development."

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.

Also in this podcast, Chase digs deep into design changes, human factors studies and biocompatibility concerns for combo products, and discusses some common pitfalls to avoid.

Listen to Episode 2 of this combination product podcast via the player below...

Click here to explore this interactive content online

...And, if you missed it, check out Episode 1 below:

Click here to explore this interactive content online