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QUOTED. Feb. 20, 2018. Ricki Chase.

by

Lachman Consultant Services' Ricki Chase sees too many companies falling down on design control activities when they set out to make combination device/drug products. Check out what she said here.

"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. And the fact is, if you're not caught [with inadequate design control] on submission of [your US 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." –Ricki Chase, compliance practice director, Lachman Consultant Services

- Find out more: Compliance 360° Part 13: Navigating The Quicksand Of Device/Drug Combo Products (2 of 2)