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QUOTED. Feb. 13, 2018. Ricki Chase.

by

Check out what former US FDA investigations branch director (and current industry consultant) Ricki Chase had to say about the regulations that companies must comply with if they make combination device/drug products.

"The primary function of ... combination products is usually the drug or biological component. In those instances, 21 CFR Part 211 [US FDA's regulation for drugs] would be the primary focus. 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." –Ricki Chase, compliance practice director, Lachman Consultant Services

- Find out more: *Compliance 360° Part 12: Navigating The Quicksand Of Device/Drug Combo Products (1 of 2)*

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