

22 Jan 2019 | News

## QUOTED. Jan. 22, 2019. Susan Neadle.

by

Combination products add complexities to many parts of the regulatory process, and that includes US FDA facility inspections. J&J's Susan Neadle highlights here the importance of speaking the language of both drug and device regulations when an investigator shows up at your combo product facility.

"If the investigator is asking questions, and there is an area where there are interactions between the drug and device worlds, you want to make sure that the person who's doing the talking – along with anyone who might be transcribing – understands the language of devices and drugs." – Susan Neadle, senior director for Global Value Chain Quality Design, Johnson & Johnson

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