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QUOTED. 16 August 2019. Melissa Michurski.

by

Over the past few years, the US FDA has been pulling enforcement punches, relying more on holding face-to-face regulatory meetings than firing off warning letters. See what FDA Compliance Branch director Melissa Michurski said about the meetings here.

"If you're getting a regulatory meeting prior to a warning letter, likely we're looking at giving you more chances to correct observations [found by FDA investigators during a facility inspection]. It means we're taking a more incremental approach." – Melissa Michurski, director, Division 2 Compliance Branch, US FDA's Office of Medical Devices and Radiological Health Operations (OMDRHO) within the Office of Regulatory Affairs (ORA)

- Find out more: [Compliance Corner: 2 FDA Compliance Branch Heads Talk Regulatory Meetings – And What You Can Expect](#)

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