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QUOTED. Nov. 21, 2017. Steve Niedelman.

by

Check out what King & Spalding's Steve Niedelman had to say about device-makers being extra careful about what they tell a US FDA investigator.

"[If] the investigator found something bad, don't point them to other things that are bad. Instead, take your lumps on the one thing that's bad and don't open the kimono for everything else that's going on. Because if you do, that inspection will just grow. What may have started as what was intended as a week inspection, well, FDA could now be in there for six months. You want to avoid that." – Steve Niedelman, lead quality systems and compliance consultant, King & Spalding

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