

27 Jan 2020 | **Analysis**

QUOTED. 27 January 2020. John McKay.

by

Consultant John McKay encourages device makers to ask questions of the US FDA's inspection team during a facility audit. Check out his advice here.

“Remember that the inspection is a two-way street, not a one-way street. If there's something you don't understand – perhaps the investigator's line of questioning or their concerns about whatever document they may be looking at – then do speak up. Keep in mind that you want every opportunity to present your best case to the investigators with all the data you have. So, if you have questions or if you're unsure about their train of thought, you can ask them and then be able to present other objective information.” – John McKay, CEO and chief compliance officer, Q1 Associates

- Find out more: [*Compliance Corner: The 10 Best – And 10 Worst – Things You Can Do When FDA Inspects Your Firm \(Part 8\)*](#)

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