

Lawyers Say FDA's Q&A Guide Fails To Address Virtual Inspections

InsideHealthPolicy.com

08.31.2020

Partner Allison Fulton, leader of the Life Sciences and FDA team, comments on the FDA's August 19 Inspection Guidance. Allison notes that the Guidance "mostly focuses on tools that could help improve inspections, such as records requests and border inspections." Allison further commented that she had hoped for further information on the use of remote technologies, "It does not address the use of remote technology to conduct inspections." Allison does "think that they will continue to do things like issue document requests [or] ask for documents, and they can do that remotely without having too much kind of imposition timing wise." She also notes that online audits may not work as well as it would be easier to conceal information and more difficult for agency inspectors to conduct spontaneous reviews.

Industries

Life Sciences