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Lawyer Unclear About FDA's Site Visit Policy For COVID-19 Vaccine EUAs

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Allison Fulton, a partner in the life sciences and FDA team, comments on the FDA's possible decision not to conduct pre-approval inspections of sites that are manufacturing COVID-19 vaccines and that are being considered for emergency use authorization and the lack of clarity about the agency's alternative approaches to site inspections.

Fulton notes, "The agency could also rely on prior facility inspections where the manufacturing process was reviewed for a different vaccine. Or, in the case of overseas facilities, FDA could choose to rely on inspections conducted by foreign regulatory authorities with similar standards."

She further added, "In the case of EUAs ... FDA may not be conducting pre-approval inspections (as it would outside of a "pandemic). But, FDA can rely on other indicators of facility safety and its ability to manufacture safe and effective vaccines. "There's some risk in forgoing pre-approval inspections; however, as long as manufacturers have a history of successful inspections, it should provide a good foundation for the agency. I think there is a basis for FDA to rely on prior successful inspections of vaccine manufacturers with some degree of confidence."

Attorneys

Allison Fulton

Industries

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