Anyone Can Enter Into a Quality Agreement, It's the Hold: FDA Issues a Warning Letter Referencing Lack of Quality Oversight

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Many of us remember the classic comedy bit on the Seinfeld television show where Jerry was unable to secure the rental car for which he had made a reservation. He tells the agent:

> See, you know how to 'take' the reservation, you just don't know how to 'hold' the reservation and that's really the most important part of the reservation; the holding. Anybody can just take them.

For reasons to be discussed, this sketch came to mind when reviewing a Warning Letter that the Food and Drug Administration issued to a pharmaceutical contract manufacturer for non compliance with Current Good Manufacturing Practices (CGMPs).[1]

FDA's Warning Letter primarily focused on the CGMP issues. However, of note here was the agency's reference to quality agreements. FDA stated:

> Firms acting as contract manufacturers must comply with CGMP. FDA is aware that many pharmaceutical product manufacturers use independent contractors, such as production facilities, testing laboratories, packagers, and labelers. FDA regards contractors as extensions of the manufacturer.

The agency continued that, while a quality agreement may help maximize compliance, the drug company sponsor is ultimately responsible for ensuring the safe manufacture of the final product released. Specifically, FDA noted:

> You and your customer [drug company] have a quality agreement regarding the manufacture of [product]. Regardless of this agreement, you and [drug company] are both responsible for the quality of drugs released and ultimately administered to patients.…

FDA cited its guidance document, "Contract Manufacturing Arrangements for Drugs: Quality Agreements," about which we have written.[2] In addition, interestingly, the agency copied the drug company's Chief Operating Officer, signaling the agency was holding the non-contract manufacturer accountable as well.

AGG Observations

- FDA essentially said that, while it was good there was a quality agreement, "regardless of this agreement," non-compliance occurred. Or, in Seinfeld terms, anyone can enter into a quality agreement. It's the implementation, execution, and follow-up. The parties failed to execute and, thus, both bore responsibility.

- Related, we have written and advised clients on quality agreements. We have drafted such agreements. They are useful to have and FDA expects them. We continue to recommend

1 See http://www.fda.gov/iceci/enforcementactions/warningletters/2017/ucm538105.htm. (Last accessed February 4, 2017.)
2 See http://www.agg.com/Come-on-People-Now--Everybody-Get-Together-Try-to-Love-One-Another-FDA-Issues-Final-Guidance-on-Quality-Agreements-12-15-2016/ (Last accessed February 4, 2017.)

them, but they do not exonerate either the contract manufacturer or the drug company sponsor if there is non-compliance. They are merely a roadmap to maximize compliance; failure to use them properly or not providing for oversight to ensure the quality-related conditions are followed merely make the agreement a bunch of words. In addition, as the Warning Letter illustrates, FDA will hold both parties accountable.

- Companies may want to re review existing quality agreements to make sure there are provisions for the drug company to audit and monitor its contract manufacturer's facility. Furthermore, if there are quality-related concerns, the drug sponsor must take steps to help achieve compliance. The drug company cannot merely rely on the other side's promise to meet quality standards. There must be verifiable trust and prompt corrective action taken, if needed. It's not only the "take"; it's the "hold," because FDA will "hold" everyone responsible if there is non compliance.

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