Get by with a Little Help from My Friends (Maybe Not): FDA Reiterates Reliance on Others Doesn't Ensure Regulatory Compliance

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Here we go again. The Food and Drug Administration issued a Warning Letter on December 13, 2017, to a Korean pharmaceutical company for non-compliance with current Good Manufacturing Practice requirements.[1] What caught our eye was yet another FDA reference to the use of contract manufacturers and quality agreements. We wrote recently about similar enforcement actions that mentioned quality agreements and delegation of authority.[2] The reliance on contract manufacturers, and FDA's admonition about abdication of regulatory responsibility, seems to be of continued concern to the agency.

In the Warning Letter, FDA wrote:

> All drugs, including OTC drugs, must be manufactured in conformance with CGMP [current Good Manufacturing Practices]. FDA is aware that many drug manufacturers use independent contractors, such as production facilities, testing laboratories, packagers, and labelers. FDA regards contractors as extensions of the manufacturer.
>
> You are responsible for the quality of drugs you produce, regardless of agreements in place with your contract facilities. You are required to ensure that drugs are made in accordance with section 501(a)(2)(B) of the FD&C Act to ensure safety, identity, strength, quality, and purity.
>
> See FDA's guidance document, *Contract Manufacturing Arrangements for Drugs: Quality Agreements*, at https://www.fda.gov/downloads/drugs/guidances/ucm353925.pdf.

We also note that, in this case, FDA recommended the company engage a GMP consultant. However, it reminded the company that the regulatory buck stops with them, not the third party.

> Your use of a consultant does not relieve your firm's obligation to comply with CGMP. Your firm's executive management remains responsible for fully resolving all deficiencies and for ensuring ongoing CGMP compliance.

AGG Observations

We will repeat the observations we have made in the past.

1. Quality agreements are not legally required, but are recommended. However, as we remind clients, and FDA stated clearly in the Warning Letter, a quality agreement does not absolve a company from complying with its regulatory requirements. While we like the Beatles' song, FDA won't let you get by with a little help from your friends, i.e., third parties.

2. Review any quality agreement your company has with a contract manufacturer and make tweaks, based on experience with the party at issue and others. A good product can always

1 See www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm590011.htm

2 https://www.agg.com/You-Cant-Pass-the-Regulatory-Compliance-Buck-with-a-Quality-Agreement-FDA-Reiterates-the-Point-in-a-Recent-Warning-Letter-09-20-2017/

be made better. If your company doesn't have agreements in place, consider having them. We can assist.

3. In addition to having quality agreements in place, companies should audit and monitor contractors and suppliers for compliance. An agreement, without follow up and proper execution, is merely a piece of paper.

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