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Medical Device News and Insights

[Medical Device Or Drug? Negotiating With The FDA](#)

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One of the most interesting aspects of being involved in the medical device industry is witnessing the innovative approaches undertaken by medical equipment organizations when either treating disease or responding to changes in standards of care or regulatory concerns. There are times, however, when the sophisticated integration of a medical device into a treatment schedule can sometimes pose a challenge in terms of both marketing and negotiating with the FDA. retweet

There was once a time when the vast majority of drugs fell into the traditional treatment trio: pills, shots and liquids. Technology has time-warped that concept of what constitutes a drug for both the public and federal regulators, and this has presented a number of issues to medical device companies whose products must walk a very fine line to avoid being misclassified by the FDA.

This regulatory gray zone quite often presents itself around drug delivery devices. Medical equipment manufacturers that developed more efficient methods for administering a particular drug to a patient could in some cases find themselves inadvertently falling under the pharma regulatory banner in the eyes of the Food and Drug Administration.

While it may be simple enough to differentiate between an advanced hypodermic device and the drug it delivers, these types of distinctions may become blurred when examining treatments such as wound powders which are intended to speed up the healing process and prevent infection. Is the medical device company that designed and manufactured the non-active chemical ingredients of this powder subject to pharma regulations once the treatment is combined with a drug? If the powder is combined with a bandage, does the introduction of this new 'delivery system' alchemically transform the powder from device to drug in the eyes of the FDA? Is it possible to that this new product will be viewed by FDA as a drug, despite the device company's great care to position it as a 510(k) device?

These are questions that most emerging medical device organizations can't afford to avoid. At MDCI, we have stepped in time and time again to help inventors and innovators negotiate with the FDA and make it clear that the product in question is a device and not the drug that it delivers. The intricacies of this type of FDA dialogue can be intimidating, particularly when dealing with medical device solutions that are riding of the crest of recent technological developments. It is well worth taking advantage of the resources offered by an experienced negotiator prior to seeking pre-market clearance rather than attempting to broker an agreement after the fact.

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