Frequently Asked Questions

Webinar: Combination Products: Lessons Learned on Product Development & Regulatory Submissions
Date of Webinar: March 2, 2017
RCA's Panelists: Lisa Michels/Steve Coulter

1. ***What are a couple examples of a product type that requires more than one submission?***

   Lisa Michels: A common example is a drug-device combination product where the constituent components are manufactured by different companies and provided separately, but they are intended to be used together pursuant the combination product's labeling. Another example is one where a constituent part is already cleared/approved/ licensed for a different indication and is currently being marketed for that particular indication, but as a constituent part of a combination product, it has a new indication for use.

2. ***Do you have some recommendations for dealing with submitting across multiple regulatory jurisdictions, such as US, EU, Canada? Any lessons learned to make it easier?***

   Lisa Michels: You should identify all target markets and/or potential target markets where you may want to launch your Combination Product in your Preliminary Regulatory Strategy and determine the likely classification and applicable regulations for each of the constituent parts and the Combination Product itself. Due to global harmonization efforts by various regulatory bodies, it is likely that you will be able to leverage some, if not all, of your data/documentation across certain markets. However, there may be additional regulatory requirements depending on how each constituent part of the Combination Product may be regulated in the different markets across the globe. It is better to plan for this at the inception of your strategic regulatory planning process to avoid excessive delays and costs associated with not taking a proactive approach.

3. ***Why would the strategy need to be a controlled document?***

   Steve Coulter: "Strategy" and "Plan" were used interchangeably in our discussion. Plans from the cross-functional team areas are required under Design Controls (for medical devices) and good practice for all projects. As a "required" document, the Strategy becomes part of the Design History File, and must become a controlled document.

4. ***How do you modify your recommended regulatory path for 505(b)(2) drug-device products?***

   Lisa Michels: The 505(b)(2) pathway is an alternative regulatory route for a new drug application that allows the Sponsor to rely on existing clinical data or literature produced by other companies. Modifying your recommended regulatory pathway for a drug-device product would require you to carefully assess what aspects of the constituent parts have changed, or may change, to identify whether there is other existing data that may be available to leverage to address the modification(s). It will be important to perform a comprehensive review of any new published literature that may be available and/or a review of any new studies that you may rely on to support a finding a safety and effectiveness for your modified product(s).

5. ***For drug companies that have a combination product which part of Part 820 seems to give them the biggest challenge?***

   Steve Coulter: The biggest problem areas seem to be involved in the setting of requirements (getting to Design Inputs) and doing the V&V testing. The testing is usually a problem because the requirements were not set up to be well defined and "test-able". If the requirements are set up with foresight into how they would be tested, many of these problems disappear.