Recent Pre-Submission/Pre-IDE Process Experiences

Sheri Hall
VP Regulatory Affairs & Compliance
BD Biosciences
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Regulatory Goals in Product Development

- A company submitted a pre-IDE for a novel test. The first round of questions was received within 2 months after pre-IDE submission. Because this is a novel marker, the company submitted information to support a de novo review, including a risk assessment/risk management plan, and supporting literature. A pre-IDE meeting was also scheduled. The company was pleased with the discussions although FDA determined that a de novo application was not appropriate and that the product would need to be submitted as a PMA.

Leveraging the FDA Pre-Submission Process

- A company submitted a pre-IDE for a novel test. The first round of questions was received within 2 months after pre-IDE submission. Because this is a novel marker, the company submitted information to support a de novo review, including a risk assessment/risk management plan, and supporting literature. A pre-IDE meeting was scheduled. The company was pleased with the discussions and FDA agreed that a de novo application was appropriate. However, FDA's clinical trial recommendation was very onerous and seemed more "drug like" than an IVD trial. The medical reviewer required additional data gathering and reference testing which the sponsor questioned. The company must now make a decision whether to proceed.

Importance of Timeline Efficiency

- A company submitted a pre-IDE for a 2006 down-classed device. In the pre-IDE, the company indicated, upon the device clearance using a representative instrument, the assay would be qualified for use on other family instruments internally per the FDA Replacement Reagent Policy with no additional submissions. FDA requested the studies to qualify the assay on the family instruments be designed in accordance to the FDA's Assay Migration studies for Class III IVDs and the data are included in the 510(k). The positive aspect is that the company learned of FDA's expectations through the pre-IDE, but is concerned about the manner in which they learned that FDA may be changing the use of the Replacement Reagent Policy Guidance.

Key Success Factors for Regulatory Affairs

- A company submitted a Pre-IDE for migration of several PMA assays to a new family member instrument platform. The informational exchanges facilitated formulation of efficient testing and analysis protocols by the sponsor, and much of the content of these exchanges also became incorporated into the draft CDRH guidance for assay migration studies.

Importance of Timeline Efficiency

- A company submitted a Pre-IDE for a companion diagnostic device. CDRH feedback regarding statistical and clinical study plans proved highly useful for the design of the sponsor's study protocols.

Importance of Timeline Efficiency

- A company submitted a pre-IDE for a "modified" version of the device. The first question from the reviewer was received after 117 days from the date of submission. The complete FDA response was received one week later. Thereafter, the company requested a teleconference call with FDA. It took another 70 days to have the teleconference. During the teleconference, FDA accepted action items and took another 57 days to send the company answers to the action items. The total time from submission to close out was about 232 days.

Importance of Timeline Efficiency

- A company submitted a pre-IDE for a flu test that they would like to be CLIA waived as well. The first round of questions was received within a month after pre-IDE submission. Both the company and Agency agreed to a "series" of pre-IDE meetings as the product development and CLIA waiver study design progressed. The company was pleased with the discussions and eventually received clearance and waiver. They indicated that the "every 2-3 months interaction" was stressful but helped in the positive outcome.