Pre-Submission/Pre-IDE Recent Experiences

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Recent Pre-Submission/IDE Experiences

- Case Study 1
  - A company designed a standard pre-IDE format to be used for their products that aligns with the FDA draft guidance; the design was done for a specific Branch
  - The submission content was comprehensive, complete, and well written
  - The FDA reviewer read all sections and clearly articulated questions
  - The company responded in writing and also asked for a meeting to close remaining issues
  - A meeting was granted; all items were closed; the 510(k) proceeded smoothly
  - The pre-IDE process was completed in 60 days
  - The company was satisfied with the entire process
  - The process was used for a second product to the same Branch with similar results

Recent Pre-Submission/IDE Experiences

- Case Study 2
  - A company used their standard format for their pre-IDE that aligned to the FDA draft guidance
  - The submission content was comprehensive and complete
  - The FDA reviewer contacted the company at day 40 indicating the review was in process and FDA was preparing questions
  - At day 60, the company contacted the reviewer and asked if the Agency needed additional information. The reviewer indicated that she was still reviewing the pre-IDE and preparing questions
  - The company is anxiously awaiting the pre-IDE questions and will continue to monitor with FDA until received

Recent Pre-Submission/IDE Experiences

- Case Study 3
  - The company submitted a pre-IDE with complete and comprehensive content, and requested a meeting at the time of submission
  - The FDA and company had a very productive and informative meeting
  - When the formal written pre-IDE questions arrived from FDA, the company was somewhat perplexed as the questions went beyond performance protocol design, and into consent form design, adverse event reporting, clinical trial design, manufacturing data, additional research publications, and additional information outside of the traditional 510(k)

Recent Pre-Submission/IDE Experiences

- Case Study 3 (cont.)
  - The company asked for an additional meeting upon receipt of the questions
  - Between the follow-up meeting and the pre-IDE questions, the company learned FDA had identified this product as a candidate for the de novo classification process
  - The company appreciated the information up front prior to the 510(k) process as well as FDA's guidance through the de novo process
  - Although a longer pre-IDE activity than originally planned, the company was satisfied with this pre-IDE experience

Recent Pre-Submission/IDE Experiences

- Case Study 4
  - A company submitted a pre-IDE that was comprehensive and complete, and addressed a complicated issue including CLIA waiver
  - FDA had a team of reviewers who returned a comprehensive question list
  - The company responded in writing and asked for a meeting to focus specifically on clinical studies and data requirements for the cut-off values
  - The company was also able to demonstrate the prototype device for education and feedback
  - The company was satisfied with the meeting, and believes their submission will proceed more smoothly as a result

Recent Pre-Submission/IDE Experiences

- Case Study 5
  - A company submitted a pre-IDE that was comprehensive and complete, and requested a meeting in advance of the questions
  - The meeting took approximately 80 days to schedule
  - The meeting was limited to 1 hour although the submission was complex and the company asked for 2 hours
  - The FDA reviewers were well prepared for the meeting, gave very specific feedback on analytical and clinical studies, as well as items to be addressed in the package insert
  - FDA sent all questions in writing 30 days after the meeting and responses have been sent back.
  - So far, the company is satisfied with the process

Recent Pre-Submission/IDE Experiences

- Case Study 6
  - A company submitted a pre-IDE that was comprehensive and complete
  - The first round of questions was received at 90 days
  - The company responded and asked for closure
  - 60 days after the response was submitted, the company received additional questions
  - Answers to the additional questions were submitted
  - The company asked for a follow-up meeting and is waiting for a response from FDA

Recent Pre-Submission/IDE Experiences

- Case Study 7
  - A company submitted a pre-IDE for a proposed modification to a PMA product and requested a meeting prior to questions
  - The meeting took 50 days to schedule
  - The meeting resulted in changes to the clinical trial design (sample size) and statistical analysis proposed by the company
  - The company received additional questions from FDA after the meeting, and the company responded within 30 days
  - A number of additional rounds of questions have followed with new items being discussed each time
  - The company shared that they are approximately 11 months into the pre-IDE process and are just now reaching agreement to proceed with clinical studies

Recent Pre-Submission/IDE Experiences

- Case Study 8
  - A company submitted a pre-IDE for a proposed new product. The predicate device selection and types of data required for substantial equivalence were the key questions posed
  - Nearly 90 days have passed and the company has not received either a telephone call or written questions from the Agency; the acknowledgement letter was received from the DMC
  - The company has not yet called the reviewing Branch

Recent Pre-Submission/IDE Experiences

- Case Study 9
  - A company submitted a pre-IDE for a new product; the product went to a Branch new to them
  - The submission content was comprehensive, complete, and well written (and aligned to FDA guidance)
  - The initial list of questions did not address the company questions regarding analytical data and clinical study design (the reason for the pre-IDE). The questions had a strong academic and theoretical focus. The company called and asked for a meeting prior to submitting written responses.
  - The FDA reviewer admitted to being new and this was his first pre-IDE, and was not familiar with the device, it's clinical laboratory use, or how used in the practice of medicine
  - A meeting was granted; responses were submitted and the company is awaiting FDA response

Recent Pre-Submission/IDE Experiences

- Case Study 10
  - A company submitted a pre-IDE for a new product
  - The submission content was comprehensive and complete (aligned to FDA pre-IDE guidance and addressed items in the product guidance document)
  - At approximately 75 days, the initial list of questions was received and asked for testing/data/information beyond the scope of the guidance; it appeared to the company that FDA was “raising the bar” for their product, a new entry into an established market
  - The company called and asked for a meeting prior to submitting written responses
  - A meeting was granted; FDA indicated their new requirements were in response to the need for better science and new concerns with that product type