This information should not be considered to represent advice or guidance on behalf of the U.S. Department of Health and Human Services or any agency or office thereof.

Strategies for Communicating Effectively in Writing with CDRH

Context

Innovators have a wide variety of questions regarding the regulatory requirements for their product development campaigns. How questions are asked when submitted to FDA can significantly impact the response received. Questions should be presented in a way that elicits precise, unambiguous, and meaningful feedback. Sometimes, a slight change to the wording of a question enables a clearer and more complete response.
For example, the following are examples of vague questions:

- What would be a good predicate device? *or*
- Does FDA think an adaptive design is a good approach for our Phase II clinical trial?

More targeted questions could be phrased as:

- Based on our device description and our proposed predicate, does FDA agree that 510(k) is a suitable pathway for our device? *or*
- We have provided an overview of our clinical testing plan; does FDA agree that this protocol is sufficient to verify our specific clinical claim?

The more targeted questions are likely to elicit a more complete response from FDA. When the answer is yes, you will know that the proposed plan is acceptable. When the answer is no, FDA will generally provide details about why it is not acceptable and may also provide recommendations to the proposed plan. Compiling a thorough proposal with sufficient information detailing proposed regulatory pathways and validation/testing plans is critical as you progress through the premarket review and market authorization processes.

When communicating with FDA, the questions you submit (e.g., through a Q-submission) are the focus of FDA's review. The supporting information included with the questions should outline and provide evidence to support the proposed plans, as applicable. Each question should refer directly to the information provided.

Submitting written questions to FDA is a key part of the meeting request when requesting feedback from FDA—regardless of the type of meeting or the FDA office conducting the review.

Recommendations

Understand How FDA Writes

As described in the guidance document on deficiency communication (an FDA request for additional information is known as a "deficiency"), FDA reviewers have a written communication formula they find most effective when working with device manufacturers. The structure has four parts, as follows:

1. What was provided? Acknowledge the information submitted.
2. What is deficient? Explain why that information is not adequate.
3. What is needed? Request specific additional information.
4. Why is it needed? Refer and connect to relevant regulations/policies and scientific evidence.

Together this forms a complete explanation of what is needed by FDA to complete their review of your submission. From this, you can simply respond to the ask in step 3, based on the justification of how/why the ask is being requested from steps 1, 2 and 4.

Understand How You Can Respond

When responding to FDA, it is a best practice to use the same four-step format described above or a slight variation, as follows:

1. Restate the identified issue
2. Provide one of the following:
    a. The information or data requested
    b. An explanation why the issue does not affect or impact the marketing authorization decision
    c. Alternative information and an explanation describing why the information you provided adequately addresses the issue

Providing the specific information requested is the most likely way to enable FDA to make progress in the review of your device. Using well-organized, unambiguous written communication is often the quickest way to clarify the path forward for the product development.

Put Your Best Foot Forward

Asking the right questions and sharing sufficient supporting information is key to obtaining a complete response from FDA. FDA will not plan a study or write an indication for use (IFU) statement for you. In the case of potential 510(k) submissions, FDA will also generally not identify a potentially applicable predicate. However, reviewers will provide feedback on a well-prepared initial study plan, IFU statement, or regulatory pathway proposal.

Regulatory Resources

- Guidance documents
  - Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions (see Sections IV.B and IV.C)
  - Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program (see Appendix 2 with example questions)
- NIH network
  - Work with program officers and obtain regulatory feedback within NIH, certain Institutes and Centers have regulatory offices with staff who are very knowledgeable about requirements in their mission space.
  - NIH awardees can request a meeting with the NIH Small Business Education and Entrepreneurial Development (SEED) Innovator Support Team to ask questions about this process and request they review your draft cover letter and overall approach. However, the SEED office does not review or comment upon the scientific validity or data elements of the submission.
- Public FDA databases and resources
  - 510(k) – access to 510(k) premarket notification database
  - De Novo – access to De Novo classification pathway database
  - Investigational Device Exemption – overview of investigational device exemptions
  - Breakthrough Device Designation – official overview of the program's procedures and policies

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