Early communication with the FDA

Guidelines on FDA correspondence for manufacturers developing and marketing medical devices in the US

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Communicating with the US FDA

The FDA is a huge organization, and whether you are a small start-up developing your first device or a large corporation expanding your products, it is common to be at a loss when communicating with the FDA. And let's face it, sometimes it can be intimidating! This paper is intended to provide guidelines, tips and other information to help you feel more confident when corresponding with the FDA to obtain information regarding the development and marketing of your medical device.

When is it appropriate to contact the FDA?

There is no right or wrong answer to this question. Part of the Center for Devices and Radiological Health (CDRH) mission statement is to "...facilitate medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent and efficient regulatory pathways..." Therefore, CDRH is theoretically open to dialogues with device developers and manufacturers to facilitate public access to safe, effective and high-quality medical devices at any time.

So, the simple answer to this question is yes. It is appropriate to contact the FDA when you have a question to which you cannot find an adequate answer. However, the FDA expects you to do your research first — utilize the **FDA device databases**, **CDRH Learn**, **guidance documents**, and other sources on the **CDRH website** — prior to reaching for the phone. If you still cannot find an adequate answer, that is the time to reach out to someone at the agency.

Why should you contact the FDA?

Manufacturers often proceed with development without seeking FDA's input, only to find that their 510(k) or other submission is woefully inadequate, or even that their product is not classified as a device at all. To avoid that unfortunate situation, it is advisable to ensure that you understand the regulatory pathway and device requirements. Even when you may think you have all the answers, there are times when it makes sense to obtain FDA guidance. Some examples of scenarios that should prompt contact with the FDA include:

- Early in the development of a novel device or combination product to ensure the correct classification and align on expectations
- Prior to conducting animal studies
- To clarify standards, guidance documents or test methodologies that may apply to your device
- When aligning on real-world evidence to support a marketing submission
- Before proceeding too far in the development of a clinical investigation plan
- When your device offers significant advantages related to safety and/or effectiveness over other marketed devices to obtain a breakthrough device or safer technologies program designation

Who should you contact and how do you contact them?

The FDA has established the **Division of Industry and Consumer Education (DICE)** within the CDRH. DICE consists of former FDA investigators, reviewers and other specialists who aim to provide technical and regulatory assistance to the medical device industry. This assistance includes a wide range of topics and concerns — from design controls to post-market studies, from establishment inspections to standards, and import requirements to Quality System Regulations (QSR). Therefore, DICE is an excellent point of first contact for general questions and if you haven't yet established a relationship with an applicable reviewer or other relevant FDA staff.

Additional FDA contacts are available on the FDA website:

- **Contact FDA**
- **Small Business Contacts**
- **CDRH Management Directory by Organization**

In addition, the introduction (top) of each FDA guidance document contains the name, phone number, and often email address of the primary FDA contact person responsible for that guidance document. Therefore, questions specific to the content of a guidance document (e.g., testing, labeling, conformance standards) may be addressed to the specified contact person. Of course, if you have initiated communication with someone in the device branch or division with jurisdiction over your device, you may call or email that person directly.

Follow FDA guidance documents

The above information and informal modes to contact the FDA are primarily recommended for general questions. However, for many devices, at some point in the development and premarket lifecycle, the manufacturer will need to obtain more comprehensive input and advice from the FDA to move forward with more assurance. To facilitate those types of communication, the FDA has provided these four guidance documents about how to contact the FDA for feedback:

1. Guidance for Industry and FDA Staff – **FDA and Industry Procedures for Section 513(g) Requests for Information under the FD&C Act** (December 2019).
2. Guidance for Industry and FDA Staff – **Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program** (June 2023).
3. Guidance for Industry and FDA Staff – **Breakthrough Devices Program** (December 2018).
4. Guidance for Industry and FDA Staff – **Safer Technologies Program for Medical Devices** (January 2021).

513(g) Requests for Information

Section 513(g) Requests for Information ("513(g)") requires the FDA to provide feedback about device classification of the requirements applicable to a device under the Federal Food, Drug, and Cosmetic Act. This document establishes procedures for manufacturers to submit this information to the FDA, and for the FDA to review and respond in writing. The FDA will generally provide the following in response to a "513(g) Request":

- Assessment of the generic type of device
- The class of device
- What type of premarket submission is required
- Whether a guidance document is available for the device type
- Additional FDA requirements for the device type

Q-Submissions

The most common type of Q-Submission is a Pre-Submission or Pre-Sub, sent prior to Investigational Device Exemption (IDE) applications or premarket submissions, such as Premarket Notification (510(k)) submissions, Premarket Approval (PMA) applications and Evaluation of Automatic Class III Designations (De Novo requests).

The **Q-Submission Program** provides instruction on how to contact the FDA for medical device feedback and meetings. This guidance provides information about the logistics for the submission, receipt, review of and response to these requests.

Early contact with the FDA

Via a Pre-Sub, the manufacturer may request a meeting (face-to-face or by teleconference) with written feedback or written feedback only before a planned premarket submission (e.g., IDE, PMA, De Novo request, 510(k)). The Pre-Sub process allows manufacturers to obtain FDA feedback on specific questions posed to help facilitate product development and submission preparation. A Pre-Sub is highly recommended before conducting clinical, animal, or analytical studies or a premarket application in the following types of situations:

- The device involves a novel technology
- The device is for a “first of a kind” indications for use
- The regulatory strategy is not well established
- To obtain guidance on specific issues involving study protocols (e.g., bench, animal, clinical)
- For a multiplex IVD or one with a new analyte, reference method, or unclear predicate
- To obtain feedback on real-world evidence
- To receive guidance on specific elements of a pending submission

Conversely, there are situations in which the Pre-Sub program is not an appropriate means of communication. For questions about non-specific device requirements, clarification on guidance document information and similar questions of a general nature, it is advisable to contact DICE or a member of the applicable CDRH branch or OPEC reviewer, as discussed previously. It is also not appropriate to submit a Pre-Sub request after a marketing submission has already been sent to the FDA. If the submission results in a finding of Not Substantially Equivalent (NSE) or if you decide to withdraw the 510(k) to avoid an NSE result, you can then request a Pre-Sub meeting prior to submitting a new premarket submission. However, the FDA has implemented an option for Submission Issue Requests (SIRs) to discuss deficiencies with a 510(k) under review.

The Q-Submission guidance document also includes communication and feedback mechanisms for SIRs and Study Risk Determinations with the FDA. Additionally, the Q-Submission program is also used to track PMA Day 100 Meetings, Early Collaboration Meetings (i.e., Agreement and Determination Meetings), Breakthrough Device Program submissions, Safer Technologies Program (STeP) submissions, and Accessory Classification Requests. There are additional, special Q-Submissions available for devices that have been designated as a breakthrough device or safer technologies program device.

Breakthrough Devices Program

Medical devices and device-led combination devices subject to PMA, 510(k) or De Novo request may qualify for the **Breakthrough Devices Program**. Breakthrough Device designation requests are made via the Q-Submission program prior to a marketing submission. To qualify products must meet the first designation criterion and at least one of the second designation criteria:

1. Providing for more effective treatment or diagnosis of life-threatening or irreversible debilitating diseases/ conditions; and
   - 2a. Represents breakthrough technologies
   - 2b. There are no approved/cleared alternatives
   - 2c. Offers significant advantages over approved/ cleared alternatives, or
   - 2d. Device availability is in patients' best interest

The FDA intends to help accelerate the development and review of devices granted Breakthrough Device designation by offering additional, more interactive Q-Submission types and prioritized review.

STeP Program

Products not eligible for Breakthrough Device designation may still qualify for FDA support to expedite device development and submission reviews in the same manner as for Breakthrough Devices under the **Safer Technologies Program (STeP)**. To be considered for STeP, the device premarket pathway should be PMA, De Novo request, or 510(k). Specific eligibility factors for the program include:

1. Not eligible for the Breakthrough Devices Program due to the disease or condition to be treated, diagnosed, or preventing being of a less serious nature; and
2. The device should be reasonably expected to improve the benefit-risk profile of a treatment or diagnostic via substantial safety innovations providing for at least one of the following:
   - a. Reduction in occurrence of known serious adverse event
   - b. Reduction in occurrence of known device failure
   - c. Reduction in occurrence of known use-related hazard or use error, or
   - d. Improvement in safety of another device or intervention

STeP requests are to be submitted via the Q-Submission process and should be made prior to a marketing submission.

Manufacturers developing novel devices should communicate with the FDA early via a Pre-Submission.

Conclusion

There are many ways to contact and establish ongoing communication with CDRH, whether to simply share information or to request feedback on complex concerns. Over the past several decades, the FDA has swung between operating primarily as an enforcement organization and as an agency open to engaging with the medical device industry. Thankfully, although the regulatory environment is constantly evolving, the FDA seems to currently be on the side of openness and collaboration. To help maintain this culture, I leave you with these simple words of advice for communicating with the FDA:

- DO your homework before contacting the FDA (their website has a wealth of information).
- DO provide them with adequate information to facilitate effective and accurate feedback.
- DO be clear and concise about what you need (ask specific, relevant questions).
- Do NOT become a pest / DO be respectful of their time (build a favorable relationship).
- Do NOT expect the FDA to answer every question in the detail you would like (the FDA is not an R&D or regulatory consultant group).
- Do NOT go it alone. If you don't have existing in-house regulatory expertise, engage a knowledgeable third party to assist in your communications and meetings with the agency.

About the author

Heather Crawford is a Quality & Regulatory Affairs Program Manager at Emergo by UL. With more than 20 years of experience in the medical device industry, Heather's areas of expertise include clinical evaluation reports, European CE Marking, US regulatory submissions, and quality systems.

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