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Client Alert

FDA and Life Sciences

JUNE 04, 2025

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FDA Issues Two Guidances For the Device Q-Sub Process

CDRH and CBER Release Final Guidance for the Q-Submission Program and Draft Guidance for PreSTAR

On May 29, 2025, the U.S. Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER) jointly issued two guidance documents concerning the Q-Submission (Q-Sub) program for medical devices: "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program" (Final Q-Sub Guidance) [i] and "Electronic Submission Template for Medical Device Q-Submissions" (Draft PreSTAR Guidance).[ii]

The Final Q-Sub Guidance provides comprehensive guidance on the Q-Sub process and finalizes the draft guidance regarding the Q-Sub program that was issued on March 15, 2024, with minimal changes from the draft version. The Draft PreSTAR Guidance announces for the first time the details of the use of the PreSTAR electronic template for Pre-Submission Q-Subs (Pre-Subs), similar to the eSTAR electronic submission templates for 510(k), De Novo, and PMA submissions.

The Q-Sub process is a voluntary process through which companies can receive valuable FDA guidance and feedback prior to submitting, or during FDA's review of, applications for device marketing authorization. Use of the Pre-Sub process, in particular, can save time and conserve resources by getting FDA feedback in advance of an application and potentially avoiding review deficiencies.

Improving the efficiency and predictability of the Pre-Sub process was an important focus of commitments that FDA made during both the Medical Device User Fee Amendments of 2017 (MDUFA IV) and the Medical Device User Fee Amendments of 2022 (MDUFA V). Therefore, it seems

notable that, as FDA and industry prepare to begin negotiations for the next user fee agreement, these documents are among the first substantive new guidance documents that FDA has issued since the incoming Trump Administration leadership took office. Notwithstanding many changes at FDA in recent months, issuance of these anticipated, programmatic guidance documents suggests that FDA is continuing to prioritize fundamental user fee commitments and process predictability.

These guidance documents are also notable for being among the first that FDA has issued since Executive Order 14192, "Unleashing Prosperity Through Deregulation" (the so-called 10-for-1 mandate), which requires that agencies identify at least 10 existing regulations to be repealed when promulgating a new regulation. To that end, the *Federal Register* Notices accompanying publication of the guidances include new language about the application of the executive order. The Federal Register notice for the Final Q-Sub Guidance states that FDA considered applicability of the executive order and the Office of Management and Budget's implementing memorandum, M-25-20, and concluded that the guidance is "deregulatory in nature."[iii] Under OMB's guidance, only "regulatory actions" need to be offset by 10 "deregulatory actions." "Deregulatory actions," even when they involve the issuance of a new draft or final guidance, do not need to be offset by further cuts to regulations. Accordingly, it appears that FDA may be able to "bank" this deregulatory guidance, per the OMB memo, to help offset future regulatory actions.

The Notice of the Draft PreSTAR Guidance invites comments on the applicability of the Executive Order—in particular, on any costs or cost savings that result from the guidance; FDA is accepting comments through July 28, 2025 via Docket No. FDA-2025-D-1082 at regulations.gov.[iv] The Agency does not specify the methodology it used to assess the potential costs and benefits of the guidances. However, to the extent that sponsors are able to estimate potential costs or cost-savings that would be incurred from implementing the Draft PreSTAR guidance, it appears that FDA will take that information into consideration when finalizing the guidance.

FINAL GUIDANCE: REQUESTS FOR FEEDBACK AND MEETINGS FOR MEDICAL DEVICE SUBMISSIONS

In March 2024, CDRH and CBER issued a draft guidance document that described the Q-Sub process and that expanded upon and combined two previous guidance documents—the June 2, 2023 final guidance regarding the Q-sub process and a February 1998 final guidance regarding Day-100 meetings for PMA applications. Both of these guidance documents are superseded by the new Final Q-Sub Guidance, which contains only minor changes—and very few of those—from the March 2024 draft version.

Like the 2024 draft guidance, the Final Q-Sub Guidance outlines the mechanisms available for device firms to interact with CDRH or CBER in advance of, or during, medical device submissions, including investigational device exemptions (IDEs), 510(k) premarket notifications, *de novo* requests, premarket approval applications (PMAs), Clinical Laboratory Improvement Amendment (CLIA) waiver applications, Accessory Classification Requests, and certain investigational new drug applications (INDs), and biologics license applications (BLAs) submitted to CBER. It covers the four types of Q-Subs: Pre-Submissions (Pre-Subs), Submission Issue Requests (SIRs), Study Risk Determinations, and Informational Meetings. The Final Q-Sub Guidance emphasizes the importance of early interaction with FDA to improve the quality of submissions and streamline the review process.

As recommended in two of the comments filed to the docket for the 2024 draft guidance, FDA added to Appendix 2 a new set of examples of productive Pre-Sub questions concerning computational modeling and simulation questions. This was the only substantive change from the 2024 draft guidance, which is not surprising, as FDA only received three relevant comments on the draft guidance.

DRAFT GUIDANCE: ELECTRONIC SUBMISSION TEMPLATE FOR MEDICAL DEVICE Q-SUBMISSIONS

Last year, FDA released the PreSTAR electronic submission template for companies to use, voluntarily, to prepare and submit Pre-Subs and 513(g) requests. The PreSTAR template is a structured dynamic PDF that guides users through the construction of a complete Pre-Sub. Like the eSTAR templates for marketing applications, PreSTAR includes integrated FDA databases (e.g., FDA's product code database, voluntary consensus standard database) and includes targeted prompts and text fields to collect and organize information from submitters needed to prepare a Pre-Sub. Until now, and unlike the eSTAR templates for 510(k) and De Novo submissions, FDA had not released a guidance document regarding the use of PreSTAR. The Draft PreSTAR Guidance is a companion guidance to the existing 510(k) and De Novo final guidances on "Electronic Submission Template for Medical Device 510(k) Submissions" and "Electronic Submission Template for Medical Device De Novo Requests," which were issued in final form in October 2023 and August 2024, respectively.

Importantly, until the Draft PreSTAR Guidance is finalized, use of PreSTAR for Pre-Subs remains voluntary. FDA intends, upon issuing the final guidance document, to provide a transition period of at least one year before use of PreSTAR for Pre-Subs becomes mandatory. The final 510(k) and De Novo eSTAR guidances were issued 12 months and 11 months after their associated draft guidances, respectively. Based on those precedents and the minimum transition period, it is likely that PreSTAR will remain voluntary for roughly the next two years.

The Draft PreSTAR Guidance follows the same format as the final eSTAR guidances for 510(k)s and De Novos. It sets forth the scope; significant terminology; electronic submission template structure, format, and use; and waivers, exemptions, and timing. Importantly, with respect to scope, the Draft PreSTAR guidance applies only to Pre-Subs. It does not apply to other types of Q-Subs (like Informational Meetings or SIR Q-Subs); those types of Q-Subs are also not eligible for the voluntary PreSTAR template that was released last year. Additionally, although the PreSTAR template can be used, voluntarily, to submit 513(g) requests, such requests are not covered by the Draft PreSTAR Guidance. We note that the PreSTAR template does have "Submission Type" options for informational meetings, SIRs, and other Q-Sub meeting types, but those options are currently greyed-out, so they may be added in the future.

The guidance confirms that, like the other eSTAR templates, when PreSTAR is used, FDA will undertake a technical screening process, in place of a Refuse-to-Accept (RTA) process, to "verify[] that eSTAR responses accurately describe the device(s) . . . and that there is at least one relevant attachment per each applicable attachment-type question."[v] The technical screening is anticipated to occur within the first 15 days after FDA receives the PreSTAR. Any failures will result in a hold on the Pre-Sub, with a 180-day timeframe to update and resubmit the PreSTAR file.

Table 1 in the Draft PreSTAR guidance identifies each of the PreSTAR sections, and provides a description of the content that FDA recommends including in Pre-Subs submitted using PreSTAR. The content is consistent with the Pre-Sub content recommended by FDA in the Final Q-Sub Guidance, and the table helps submitters determine in which sections of the PreSTAR to include the information requested by the Final Q-Sub Guidance. Like the eSTAR templates, the use of PreSTAR results in the creation of a single PDF file that can be uploaded directly to the CDRH Portal or CBER Electronic Submission Gateway for submission.

Currently, device sponsors submit Pre-Subs using a variety of formats, incorporating (or leaving out) information as is relevant to the sponsor's goals for the Pre-Sub meeting. The PreSTAR template limits sponsors to selecting a maximum of four topic categories for the meeting (e.g., regulatory strategy, biocompatibility, wireless technology). In the PreSTAR template, Pre-Sub questions must be limited to these four selected topic categories. This limitation is presumably to conserve agency resources and ensure all topics can be covered in a one-hour meeting, but will be

an adjustment for device sponsors which have become accustomed to covering all desired topics in a single Pre-Sub meeting.

IMPLICATIONS FOR DEVICE FIRMS

These guidance documents provide direction for using the Q-Submission process to streamline submissions and enhance the efficiency of FDA interactions. Device firms preparing medical device submissions should consider the following actions:

- **Engage Early with the FDA:** Utilize Pre-Subs to obtain valuable feedback that can guide product development and submission strategies.
- **Prepare for Electronic Submissions:** Familiarize your team with the PreSTAR template and consider transitioning to electronic submissions to align early with future FDA requirements.
- **Monitor Guidance Updates:** Stay informed about any changes or updates to these guidance documents, as they may impact submission strategies and timelines.

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[i] FDA, Guidance for Industry and FDA Staff: *Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program*, at 1 (May 2025), https://www.fda.gov/media/114034/download.
[ii] FDA, Draft Guidance for Industry and FDA Staff: *Electronic Submission Template for Medical Device Q-Submissions*, at 1 (May 2025), https://www.fda.gov/media/186664/download.
[iii] 90 Fed. Reg. 22,737, 22,738 (May, 29, 2025).
[iv] 90 Fed. Reg. 22,742, 22,744 (May 29, 2025).
[v] Draft PreSTAR Guidance at 6.