**Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program**

The Q submission program, initiated in 2019, is a broader version of the previous pre-IDE program. Q-Sub refers to the system used to track the collection of interactions with FDA, including Pre-Submissions (Pre-Subs), Submission Issue Requests (SIRs), Study Risk Determinations, and other additional requests. Below is a brief overview of the mechanisms available to submitters whereby they can request feedback or a meeting with the Food and Drug Administration (FDA) regarding potential or planned medical device Investigational Device Exemption (IDE) applications. For more information, refer to the FDA Guidance on these topics at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program>.

**Types of Requests**

1. **Pre-Submissions (Pre-Subs) –** A Pre-Sub includes a formal written request from a submitter for feedback from FDA that is provided in the form of a formal written response or, if the submitter chooses, formal written feedback followed by a meeting in which any additional feedback or clarifications are documented in meeting minutes. Such a Pre-Sub meeting can be in-person or by teleconference as the submitter prefers.

The program is entirely voluntary on the part of the submitter. However, early interaction with FDA on planned non-clinical and clinical studies and careful consideration of FDA’s feedback may improve the quality of subsequent submissions, shorten total review times, and facilitate the development process for new devices.

1. **Submission Issue Requests (SIRs) -** A SIR is a request for FDA feedback on a proposed approach to address issues conveyed in an IDE Letter. The SIR is intended to facilitate interaction between FDA and the submitter to quickly resolve or clarify issues identified in these letters so that projects can move forward, and so that submitters are able to fully address outstanding questions and issues in their formal responses.
2. **Study Risk Determinations -** A Study Risk Determination is a request for FDA determination for whether a planned medical device clinical study is significant risk (SR), non-significant risk (NSR), or exempt from IDE regulations as defined by the IDE regulations (21 CFR part 812). For studies that are not exempt, sponsors are responsible for making the initial risk determination (SR or NSR) and presenting it to the Institutional Review Board (IRB). For more information, please see FDA’s guidance <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/significant-risk-and-nonsignificant-risk-medical-device-studies>.
3. **Informational Meetings -** An Informational Meeting is a request to share information with FDA without the expectation of feedback. This information sharing can be helpful in providing an overview of ongoing device development and familiarizing the FDA review team about new device(s) with significant differences in technology from currently available devices.
4. **Other types of Q submissions** **-** In addition to the Q-Sub types listed above, the Q-Sub program provides a mechanism to track interactions described in other FDA program guidance documents.

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| **Q-Sub Type** | **Method of Feedback** | **Timeframe for Sending Feedback or Scheduling Meeting**  **(from receipt of submission)** |
| Pre-Submission | Meeting (face-to-face or teleconference) with written feedback provided in advance | Written Feedback:  70 days or 5 days prior to scheduled meeting, whichever is sooner  Meeting:  Date based on mutual agreement (typically at 60-75 days) |
| Written Feedback Only | 70 days |
| Submission Issue Request (SIR) | Meeting **or** Written Feedback | If SIR is received **within 60 days** of FDA’s marketing submission letter:  21 days as resources permit |
| If SIR is received **more than 60 days** after FDA’s marketing submission letter:  70 days as resources permit |
| Study Risk Determination | Formal Letter | 90 days |
| Informational Meeting\* | Meeting | 90 days |