CAHIR MEDTECH · COMPANION MANUAL

FDA Q-Sub Master Pack: companion guide

A practical, question-by-question workflow for preparing an FDA Q-Submission: choosing the right Q-Sub type, framing questions FDA can answer, building the briefing document, running the meeting and tracking every commitment afterward.

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Workbook + guide · $499 USD one-time · Applicable taxes may apply

Online guide: https://medtech.cahir.ai/qsub-master-guide

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Start here: feedback before you spend the money

The Q-Submission program is FDA's standing invitation to ask questions before you file a marketing submission. A Q-Sub carries no MDUFA user fee, and the most common type — the Pre-Submission, or Pre-Sub — gets you written feedback and, if you want it, a meeting with the review team that will eventually see your 510(k), De Novo or PMA. FDA's Q-Submission guidance is the rulebook this pack operationalizes.

This Cahir MedTech workbook is your company's preparation aid, not an official FDA form. Use it to keep the objective, the questions, the briefing document and the follow-up actions connected — the same way the Design-Control Traceability Matrix keeps requirements connected to evidence.

The economics are simple: a pivotal study designed around an assumption FDA disagrees with can cost more than the entire regulatory budget. A Pre-Sub that resolves the assumption first costs preparation time and nothing else.

Choosing the right Q-Sub type

The program is a family of request types, and picking the wrong one wastes the interaction. The workbook's Q-Sub Type Selector tab walks through each option; the short version:

Q-Sub type	Use it when	What you get
Pre-Submission (Pre-Sub)	You plan a future submission and want feedback on study design, predicates or data expectations	Written feedback; optional meeting
Submission Issue Request (SIR)	A hold or deficiency letter on a pending submission needs clarification	Response on the specific issue
Study Risk Determination	You need FDA to rule whether a planned study is significant risk, non-significant risk or exempt	Written risk determination
Informational Meeting	You want to brief FDA without asking for feedback	A meeting; no written response
PMA Day 100 Meeting	Your PMA is under review	Meeting during the review clock
Agreement / Determination Meeting	You need a binding agreement on study parameters, or a formal appeal	Binding agreement or determination
Sprint Discussion	Your device has Breakthrough designation and you need rapid iteration	Interactive, expedited discussion

For most teams the Pre-Sub is the workhorse. If your device has Breakthrough Device designation, sprint discussions let you iterate faster than the standard Pre-Sub cycle.

Timing: back-plan from protocol lock

Under the MDUFA V commitment, FDA targets written Pre-Sub feedback — or a meeting — roughly 70 to 75 days from receipt, with meeting minutes following about 30 days after the meeting. That means a Pre-Sub is a quarter-long event, and it only pays off if it lands before your pivotal protocol is locked.

The workbook's Timeline Planner back-plans the sequence:

- Weeks 0-5: align internally, draft questions and the briefing document, review and sign off

- Week 6: submit the Q-Sub
- ~Day 70-75 from receipt: written feedback and meeting
- ~30 days after the meeting: FDA minutes
- Before protocol lock: close every action the feedback created

Submit too early and your study plans are not mature enough for FDA to react to. Submit too late and the feedback arrives after the protocol — and the budget — are frozen. The sweet spot is when your study synopses are concrete enough to critique but nothing is contracted yet.

Framing questions FDA can actually answer

The single biggest Pre-Sub failure mode is question sprawl: fifteen vague questions get fifteen vague answers. FDA's guidance and every experienced reviewer's advice converge on the same discipline — three to four focused questions, each paired with your proposed approach and the rationale behind it.

A good question has three parts:

1. **The specific decision** — not 'Is our clinical plan acceptable?' but 'Does FDA agree that FIB-4 with a biopsy subset is an acceptable comparator for the pivotal study?'
2. **Your proposed approach** — FDA reacts far better to a position it can accept or modify than to a blank page.
3. **The supporting rationale** — the data, standards or precedent that make your approach reasonable.

Use the Question Matrix tab to draft broadly, then cut hard. Every question that survives should be one where a 'no' from FDA would change your program — those are the questions worth the 70-day wait. Our article on Q-Submission timing for point-of-care IVDs shows this framing applied to a De Novo and CLIA waiver strategy.

Building the briefing document

The briefing document is what the review team actually reads. FDA's guidance lists the expected content; the Briefing Document Builder tab turns it into a section-by-section checklist with target lengths:

- **Cover and administrative** — Q-Sub type, contacts, proposed meeting dates (1-2 pages)
- **Device description** — technology, principles of operation, key specifications (3-5 pages)
- **Intended use** — the draft statement that frames everything else (half a page)
- **Regulatory history** — prior submissions and interactions, with outcomes (1 page)
- **Pathway rationale** — predicate analysis or De Novo/PMA justification (1-2 pages)
- **Study synopses** — each planned study: design, endpoints, comparator, sample size, analysis (1-2 pages each)
- **Specific questions** — your three to four questions with proposed approaches (half to one page each)
- **Supporting data** — summaries of the evidence behind your proposed approaches
- **Meeting materials** — agenda, attendee list with roles, presentation draft

Two practical rules. First, keep the package focused — reviewers read hundreds of pages across many files, and a tight 40-page briefing beats a sprawling 200-page one. Second, consider the voluntary eSTAR template for the Pre-Sub; its structure forces the completeness FDA's acceptance review looks for.

Running the meeting

If you request a meeting, treat it as a working session, not a presentation. FDA sends written feedback before the meeting; the meeting exists to discuss the points where you and the written feedback diverge.

- **Rehearse against the written feedback.** By meeting day you should know exactly which answers you accept and which you need to discuss.
- **Bring decision-makers, not an audience.** Every attendee should have a role: regulatory lead, clinical or technical lead for each question area, and one designated note-taker.
- **Spend the time on disagreement.** Walking through slides that restate the briefing document burns the hour. Open with the two or three items where you need clarity.
- **Confirm agreements out loud.** Before each topic closes, restate what you heard: 'So our understanding is that the comparator is acceptable provided the adjudication charter is in place.'

The workbook's Universal Baseline includes the logistics items — proposed dates, attendee roles, presentation draft — so none of this is improvised the week before.

After the meeting: minutes, agreements, actions

FDA issues official meeting minutes, typically within about 30 days. Review them immediately against your own notes: if the minutes omit or soften an agreement you heard, you can request a correction — but only promptly.

Then convert everything into tracked work. The FDA Feedback Tracker tab logs each question, the written response, the meeting discussion, whether an agreement was reached, and the action your team committed to. Two disciplines matter:

- **Close actions before protocol lock.** Feedback that arrives as an open action item on the day the protocol freezes is feedback you paid for and didn't use.
- **Carry the record forward.** Your eventual marketing submission should reference the Q-Sub and show how each piece of feedback was addressed. Reviewers check.

If the feedback fundamentally changes your evidence plan, update the linked tools — the Dual-Intent Clinical Evidence Tracker if payer endpoints shift, or the AI/ML PCCP planner if the change-control scope changes.

Special situations

Breakthrough devices. Designated devices can request sprint discussions — shorter, focused interactions on a single topic — in addition to standard Pre-Subs. Use sprints for iteration and the Pre-Sub for the comprehensive protocol review. See our Breakthrough Devices comparison for how the designation changes FDA interaction.

De Novo candidates. If no predicate exists, the Pre-Sub is where you pressure-test the classification rationale and the special controls you expect to live under — before the De Novo request itself. Our point-of-care IVD guide covers the combined De Novo and CLIA waiver strategy.

Combination products and uncertain jurisdiction. If you are not sure which center will review your product, that question itself can be the subject of early interaction — resolving it late is far more expensive.

Second Pre-Subs. A follow-up Pre-Sub after major feedback is normal and often wise. Budget the extra 70-75 days into the program timeline rather than discovering them.

Frequently asked questions

Does a Q-Submission cost anything?

No. Q-Submissions carry no MDUFA user fee. Fees apply to the marketing submissions that follow — 510(k), De Novo or PMA — not to the Q-Sub itself.

How long does FDA take to respond to a Pre-Sub?

Under the MDUFA V commitment, FDA targets written feedback — or a meeting, if you request one — roughly 70 to 75 days from receipt of the Pre-Sub. Meeting minutes follow about 30 days after the meeting. Back-plan from your protocol-lock date so the feedback arrives while it can still change the plan.

How many questions should a Pre-Sub ask?

Three to four focused questions is the widely recommended discipline. Each question should name a specific decision, state your proposed approach, and give the supporting rationale. Broad or numerous questions get broad, unhelpful answers.

Is FDA's Pre-Sub feedback binding?

Written feedback and meeting agreements are not legally binding on FDA, but they carry enormous practical weight: the agency follows its documented positions unless the science or regulations change. Document every agreement in your own tracker and reference the Q-Sub in the eventual marketing submission.

Should we use the eSTAR template for a Pre-Sub?

FDA's voluntary eSTAR program includes a template for non-IVD Pre-Subs, and its structured format helps ensure the package is complete. It is optional, but teams that struggle with briefing-document completeness often find the template pays for itself.

When is a Q-Sub not worth it?

When you have no real question. An Informational Meeting or a Pre-Sub filed for optics consumes FDA time and yours without changing the program. File when a specific FDA answer would change a specific decision — that is the test the Question Matrix tab applies.

Sources and further reading

- Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program — FDA final guidance
- Medical Device User Fee Amendments (MDUFA)
- Voluntary eSTAR Program
- Breakthrough Devices Program
- Point-of-care IVDs: De Novo, CLIA waiver and the Q-Submission — Cahir MedTech
- FDA Breakthrough Devices vs EU priority pathways — Cahir MedTech

This guide is an educational planning aid from Cahir MedTech, current as of November 5, 2026. Confirm Q-Sub strategy, timing and content for your device with qualified regulatory reviewers.